OELs 6

Study on collecting the most recent information on substances to analyse 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, mutagens or reprotoxic substances at work

1,4-dioxane

Final report V3

November 2024

Written by Daniel Vencovsky (RPA Prague) & Karin Heine, Anne Bierwisch (FoBiG)
November 2024

EUROPEAN COMMISSION

Directorate-General for Employment Social Affairs and Inclusion
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Contents

LIST OF ABBREVIATIONS AND ACRONYMS

ACSH	Advisory Committee of Safety and Health at Work
AM	Arithmetic mean
BAT	Best Available Technique
BGV	Biological guidance value
BLV	Biological Limit Value
CAREX	Carcinogen Exposure (inventory)
CAS	Chemicals Abstracts Service
CBA	Cost Benefit Analysis
CEN	European Committee of Standardization
CLP	Classification, Labelling and Packaging of substances Regulation
CMRD	Carcinogens, Mutagens and Reproductive substances Directive
CSR	Chemical Safety Report
DALY	Disability Adjusted Life Years
DG	Directorate General
DRR	Dose Response Relationship
ECHA	European Chemicals Agency
EEA	European Economic Area
ERR	Exposure Risk Relationship
ES	Exposure Scenario
FoBiG	Forschungs und Beratungsinstitut Gefahrstoffe
GESTIS	Internationale Grenzwerte für chemische Substanzen (International limits for chemical substances)
GM	Geometric mean
IA	Impact Assessment
IARC	International Agency for Research of Cancer
ISO	The International Organization for Standardization
LEV	Local Exhaust Ventilation
LOAEL	Lowest observed adverse effect level
LOAEC	Lowest Observed Adverse Effect Level (LOAEC)
LOD	Limit of Detection
LOQ	Limit of quantification
NACE	"Nomenclature statistique des activités économiques dans la Communauté européenne" or the Statistical Classification of Economic Activities in the European Community
NAEC	No Adverse Effect Concentration
NOAEC	No Observed Adverse Effects Concentration
NOAEL	No Observed Adverse Effects Level
OEL	Occupational Exposure Limit
OSH	Occupational Safety and Health
PPE	Personal Protection Equipment
PROC	The process categories
QALY	Quality-Adjusted Life Year
R&D	Research & Development
RAC	Committee for Risk Assessment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Management Measure
RPA	Risk & Policy Analysts
RPE	Respiratory Protective Equipment
SME	Small and Medium-sized Enterprise
TWA	Time Weighted Average

ABSTRACT EN-FR-DE

EN: This study supports the European Commission's Impact Assessment of potential new Occupational Exposure Limit (OEL), Short-Term Exposure Limit (STEL), Biological Limit Value (BLV) and skin notation for 1,4-dioxane under the scope of Carcinogens, Mutagens and Reprotoxic substances Directive (CMRD, Directive 2004/37/EC). This report assesses the costs and benefits of a range of policy options for an OEL, STEL, BLV and skin notation for 1,4-dioxane. The monetised impacts relate primarily to the compliance costs of achieving the limit values and the avoided costs of kidney effects, liver effects and local irritation in the nasal cavity. Workers are presently exposed to 1,4-dioxane in the pharmaceutical, chemical, surfactant and cosmetics sectors and laboratories. Data on current exposure concentrations suggests that impacts (cost and benefits) are primarily expected under the lowest OEL policy option of 7.3 mg/m^3. The estimation of the impacts of a BLV is constrained by limited evidence on the dermal uptake in the relevant exposure scenarios. The costs of a BLV would include biomonitoring costs. In its opinion of 22nd September 2023, the ACSH recommends an OEL of 7.3 mg/m^3, STEL of 73 mg/m^3, and BLV of 45 g HEAA in urine/g Creatinine and a skin notation.

FR: Cette étude soutient l'analyse d'impact de la Commission européenne sur les nouvelles limites d'exposition professionnelle (LEP), limites d'exposition à court terme (LECT), valeurs limites biologiques (VLB) et notations cutanées potentielles pour le 1,4-dioxane dans le cadre de la directive sur les substances cancérogènes, mutagènes et toxiques pour la reproduction (CMRD, directive 2004/37/CE). Ce rapport évalue les coûts et les avantages d'une série d'options politiques pour une LEP, une VLE, une VLB et une notation cutanée pour le 1,4-dioxane. Les impacts monétisés concernent principalement les coûts de mise en conformité pour atteindre les valeurs limites et les coûts évités des effets sur les reins, le foie et l'irritation locale de la cavité nasale. Les travailleurs sont actuellement exposés au 1,4-dioxane dans les secteurs pharmaceutique, chimique, des agents tensioactifs et des cosmétiques, ainsi que dans les laboratoires. Les données relatives aux concentrations d'exposition actuelles suggèrent que les incidences (coûts et avantages) sont principalement attendues dans le cadre de l'option politique de la LEP la plus faible, à savoir 7,3 mg/m3. L'estimation des effets d'une VLB est limitée par le peu d'informations disponibles sur l'absorption cutanée dans les scénarios d'exposition pertinents. Les coûts d'une VLB incluraient les coûts de biosurveillance. Dans son avis du 22 septembre 2023, le CCSS recommande une LEP de 7,3 mg/m3, une VLE de 73 mg/m3 et une VLB de 45 g d'HEAA dans l'urine/g de créatinine, ainsi qu'une notation cutanée.

DE: Diese Studie unterstützt die Folgenabschätzung der Europäischen Kommission für einen möglichen neuen Grenzwert für die berufsbedingte Exposition (AGW), einen Grenzwert für die Kurzzeitexposition (STEL), einen biologischen Grenzwert (BGW) und eine Hautkennzeichnung für 1,4-Dioxan im Rahmen der Richtlinie über krebserzeugende, erbgutverändernde und fortpflanzungsgefährdende Stoffe (Richtlinie 2004/37/EG, kurz CMRD). In diesem Bericht werden die Kosten und der Nutzen einer Reihe von politischen Optionen für einen AGW, STEL, BGW und eine Hautkennzeichnung für 1,4-Dioxan bewertet. Die monetarisierten Auswirkungen beziehen sich in erster Linie auf die Kosten für die Einhaltung der Grenzwerte und die vermiedenen Kosten für Nierenschäden, Leberschäden und lokale Reizungen der Nasenhöhle. Arbeitnehmer sind derzeit in der Pharma-, Chemie-, Tensid- und Kosmetikbranche sowie in Labors 1,4-Dioxan ausgesetzt. Die Daten zu den derzeitigen Expositionskonzentrationen deuten darauf hin, dass Auswirkungen (Kosten und Nutzen) vor allem bei der niedrigsten AGW-Option von 7,3 mg/m3 zu erwarten sind. Die Schätzung der Auswirkungen eines BGW wird durch begrenzte Erkenntnisse über die dermale Aufnahme in den relevanten Expositionsszenarien

eingeschränkt. Die Kosten einer BGW würden auch Biomonitoring-Kosten beinhalten. In seiner Stellungnahme vom 22. September 2023 empfiehlt der ACSH einen AGW-Wert von 7,3 mg/m3, einen STEL-Wert von 73 mg/m3 und einen BGW-Wert von 45 g HEAA im Urin/g Kreatinin sowie einen Hautvermerk.

Executive Summary

The Carcinogens, Mutagens and Reprotoxic substances Directive (Directive 2004/37/EC), hereinafter the CMRD, protects workers from exposure to carcinogens, mutagens or reprotoxic substances at work. The aim of this study is to support the European Commission's Impact Assessment (IA) of a potential new Occupational Exposure Limit (OEL), a Short-Term Exposure Limit (STEL), and a Biological Limit Value (BLV) for 1,4-dioxane (EC No. 204-661-8; CAS No. 123-91-1).

Throughout the analysis of benefits and costs, the following levels are used as reference OELs, STELs and BLVs for the assessment.

Table 1 Reference OEL (8-hr Time Weighted Average) levels for 1,4-dioxane

Level	Reason for inclusion
73 mg/m^3 (20 ppm)	Current Indicative OEL under the Chemical Agents Directive[1]
36 mg/m^3 (10 ppm)	Most common value (mode) of OELs between 73 mg/m^3 and 20 mg/m^3 is 35 or 36 mg/m^3
20 mg/m^3 (5.5 ppm)	Lowest national OEL (Latvia & the Netherlands)
7.3 mg/m^3 (2 ppm)	RAC recommendation

Table 2 Reference STEL (15 min) levels for 1,4-dioxane

Level	Reason for inclusion
150 mg/m^3 (40 ppm)	Highest STEL in an EU Member State (Finland), also 146 mg/m^3 in Austria, Germany and Slovenia and 140 mg/m^3 in the Czech Republic and France
120 mg/m^3 (33 ppm)	Intermediate level at the mid point between 90 mg/m^3 and 150 mg/m^3
90 mg/m^3 (25 ppm)	Intermediate value, selected due to the fact that two Member States (Lithuania and Sweden) have a STEL of 90 mg/m^3
73 mg/m^3 (20 ppm)	RAC recommendation, also close to the lowest national STEL (72 mg/m^3 in Denmark)

Table 3 Reference BLV levels for 1,4-dioxane

Level (HEAA [2]in urine/g Creatinine, at the end of exposure or shift)	Reason for inclusion
366 mg	Corresponds to an OEL of 73 mg/m^3 (20 ppm) in the equation in RAC (2022)
188 mg	Corresponds an OEL of 36 mg/m^3 (10 ppm) in the equation in RAC (2022), also similar to 200 mg BAT in DE

[1] Table 4-1 suggests that all Member States have in place a value of 73 mg/m^3 or lower. This option is retained for the impact assessment so that the study team can check that all of the national OELs of 73 mg/m^3 or lower are binding.

[2] 2-hydroxyethoxyacetic acid

Level (HEAA [2]in urine/g Creatinine, at the end of exposure or shift)	Reason for inclusion
108 mg	Corresponds to an OEL of 20 mg/m^3 (5.5 ppm) in the equation in RAC (2022)
45 mg	RAC recommendation, corresponding to an OEL of 7.3 mg/m^3 in the equation in RAC (2022)

The sectors considered in detail in this report are summarised in Table 4.

Table 4 Analysed sectors with risk of exposure to 1,4-dioxane

NACE code	Short name for sector	NACE description
N/A	Manufacture of 1,4-dioxane	Part of C20.1 Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms
C21.1 and C21.2	Pharmaceutical production (intentional use)	C21.1 Manufacture of basic pharmaceutical products C21.2 Manufacture of pharmaceutical preparations
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as a by-product in the chemicals sector	C20.1 Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics C20.5 Manufacture of other chemical products
M72.1	Laboratories (intentional use as a solvent)	M72.1 Research and experimental development on natural sciences and engineering
C20.4 excl. C20.42	Surfactants – presence as a minor constituent/impurity in the production of detergents, soaps, etc.	C20.4 Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations, excluding C20.42 Manufacture of perfumes and toilet preparations
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	C20.42 Manufacture of perfumes and toilet preparations

Source: Study team.

The costs and benefits (relative to the baseline) estimated in this report for the different OEL options are summarised in Table 5. The benefits are shown for both Method 1 and Method 2. The costs are for the present value (PV) over 40 years with a static discount rate of 3%.

There are significant differences between the costs and benefits for all OEL policy options, with the most stringent policy option having the most effective cost-benefit ratio and the least stringent having no ratio due to no costs and no benefits.

Table 5 Summary of monetised costs and benefits for the OEL options (static discount rate, additional to the baseline, € million)

Policy option	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Total benefits M1	€ 5.4	€ 0	€ 0	€ 0
Total benefits M2	€ 6.8	€ 0	€ 0	€ 0
Total costs	€ 140	-€ 0.3	-€ 0.1	-€ 1.4
Cost benefit ratio M1	25	n/a	n/a	n/a
Cost benefit ratio M2	20	n/a	n/a	n/a

*Notes:*Values relate to method 1 - method 2. n/a = not applicable, division by zero. Totals may not sum due to rounding. Source: Study team.*

The overall costs and benefits of the combined OEL and BLV policy options are shown in Table 6. Since the additional adjustment costs for companies and benefits from reduced ill health from adding a BLV to an OEL cannot be estimated with a sufficient degree of robustness, they are not included in the quantified impacts in the table below which provides a cost benefit analysis (CBA) for combined OEL and BLV options, only taking into account the costs of biomonitoring in addition to the costs presented above in the CBA for the OEL options.[3]

*Table 6 Summary of monetised costs and benefits of **combined OELs and BLVs** (static discount rate, additional to the baseline)*

Policy option	7.3 mg/m³ and 45 mg HEAA in urine/g Creatinine	20 mg/m³ and 108 mg HEAA in urine/g Creatinine	36 mg/m³ and 188 mg HEAA in urine/g Creatinine	73 mg/m³ and 366 mg HEAA in urine/g Creatinine
Total benefits M1	€ 5.4*	€ 0*	€ 0*	€ 0*
Total benefits M2	€ 6.8*	€ 0*	€ 0*	€ 0*
Total costs	€ 260*	€ 58*	€ 10*	€ 4*
Cost benefit ratio M1	47*	n/a	n/a	n/a
Cost benefit ratio M2	38*	n/a	n/a	n/a

*Notes: Values relate to method 1 - method 2. n/a = not applicable, division by zero. * For the BLV component, only partial costs and benefits have been included in the calculation and the totals do not include the adjustment costs and potential health savings additional to the OEL. Totals may not sum due to rounding. Source: Study team.*

[3] Although compliance costs for achieving the different BLV levels could be estimated on the basis of the corresponding OEL levels, it cannot be excluded that this approach would underestimate the costs required for additional reductions in dermal exposure. It cannot be excluded that the equation used in RAC (2022) to relate air exposure and HEAA in urine does not take sufficiently into account dermal intake. In situations where significant dermal exposure (or ingestion due to poor hygiene) occurs, complying with an OEL of 7.3 mg/m3, for example, does not guarantee that the level of HEAA in urine/g creatinine will be below 45 mg.

The multi-criteria analysis summarising both the monetised and qualitative impacts is shown in Table 7.

Table 7 Multi-criteria analysis for the OEL options (all impacts over 40 years and additional to the baseline) per OEL option (millions)

Impact	Stakeholders affected	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Direct costs – adjustment					
Risk management measures - first year	Companies	€ 53	€ 0	€ 0	€ 0
Risk management measures – re-current	Companies	-€ 34	€ 0	€ 0	€ 0
Risk management measures - dis-continuation	Companies	€ 102	€ 0	€ 0	€ 0
Risk management measures total	Companies	€ 121	€ 0	€ 0	€ 0
Risk management measures total per company	Companies	€ 0.067	€ 0	€ 0	€ 0
Monitoring (sam-pling and analy-sis)	Companies	€ 2.4	€ 0.55	€ 0.49	€ 0
Direct costs - administrative					
Administration burden	Companies	€ 0.74	€ 0.21	€ 0.19	€ 0
Direct costs – total compliance					
Adjustment, monitoring and administration burden costs	Companies	€ 130	€1.4	€ 0	€ 0
Adjustment, monitoring and administration burden costs per company	Companies	€ 0.07	€ 0.0004	€ 0.0004	€ 0
Direct costs - enforcement costs					
Transposition costs	Public sector	€ 0.81	€ 0.78	€ 0.66	€ 0
Enforcement costs except transposition	Public sector	Enforcement costs may arise as a result of ensuring compliance with new OELs however these costs are not estimated as they are specific to Member States individual inspection regime.			

Impact	Stakeholders affected	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Indirect costs – other					
Firms discontinuing at least a part of their business - No. of company closures	Companies	6.3	0	0	0
Firms discontinuing at least a part of their business - %	Companies	0.4%	0%	0%	0%
Total compliance costs as % of turnover over 40 years (including discontinuations)	Companies	0.8%	0.01%	0%	0%
First year compliance costs as % of annual turnover (excluding discontinuations)	Companies	Up to 14.3% (C20.1, C20.3 and C20.5 chemicals - small enterprises)	Up to 0.06% (M72.1 laboratories - small enterprises)	Up to 0.06% (M72.1 laboratories - small enterprises)	0%
Employment – Jobs lost	Workers & families	140	0	0	0
Employment – Social cost	Workers & families	€ 13	€ 0	€ 0	€ 0
International competitiveness	Companies	Some non-EU countries would have less stringent OELs		No impact expected	
Consumers	Consumers	No significant impact	No significant impact	No impact	No impact
Internal market Lowest to highest OEL	Companies	7.3 mg/m³-7.3 mg/m³	20 mg/m³-20 mg/m³	20 mg/m³-36 mg/m³	20 mg/m³-73 mg/m³
Specific MSs/regions - MSs that would have to change OELs	Public sector	27	25	22	0
Regulation	Companies	A REACH restriction on use of 1,4-dioxane in surfactants is currently under consideration			
Direct benefits – improved well-being – health					
Reduced cases of ill health (kidney effects)	Workers & families	500	0	0	0
Reduced cases of ill health (liver effects)	Workers & families	630	0	0	0

Impact	Stakeholders affected	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Reduced cases of ill health (local irritation in the nasal cavity)	Workers & families	4,400	0	0	0
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€ 2 - 3 million	€ 0 - 0 million	€ 0 - 0 million	€ 0 - 0 million
Direct benefits – improved well-being – safety					
Avoided costs	Companies	€ 1.6	€ 0	€ 0	€ 0
Avoided costs	Public sector	€ 2	€ 0	€ 0	€ 0
EU policy agenda	All	Improvements in workers fundamental rights and contribution towards Green Deal: Chemical Strategy towards a toxic-free environment			
Direct benefits – improved well-being – environmental					
Environmental releases	All	Potentially, a reduction in emissions into the air but unclear impact on emissions to water			No impact
Direct benefits – market efficiency					
Level playing field	Companies	The ratio between the maximum and minimum national OEL is currently 3.65. The ratio between the maximum/minimum STEL is 2.08. A reduction in the OEL and STEL is likely to improve the level playing field in the internal market.			No impact
Indirect benefits					
Administrative simplification	Companies	Should all Member States have a harmonised OEL this would reduce the administrative burden for enterprises with operations across multiple Member States. However, the majority of enterprises under review are small and are unlikely to have multinational operations and be unaffected by this simplification.			
Synergy	Companies	Synergies in terms of exposure reduction for other chemical substances used in production sectors may occur. The specific substances will vary between the sectors. The level of synergy to be harnessed will also depend on the RMMs applied in each enterprise.			
Corporate Social Responsibility	Companies	Work with 1,4-dioxane may be less perceived as a risky line of work associated with health issues, in particular given the recent reclassification of 1,4-dioxane as Carcinogenic 1B. As a result of such an improvement in the public image, companies may find it easier to recruit and retain staff, reducing the cost of recruitment and increasing the productivity of workers.			
Avoided cost of setting OEL	Public sector	€ 2.7	€ 1.8	€ 1.5	€ 1.4
Other impacts					

Impact	Stakeholders affected	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Recycling – loss of business	Recycling companies	No impacts expected			
Impacts on fundamental rights	All	Improved occupational health			
Impacts on digitalisation	Companies	No impact expected.			
Contributions to the UN sustainable development goals	All	Potential for reduced emissions into the air but it is unclear whether this would not increase emissions into wastewater.			

Source: Study team. Note: Totals may not sum due to rounding.

Since the additional adjustment costs for companies and benefits from reduced ill health from adding a BLV to an OEL cannot be estimated with a sufficient degree of robustness, they are not included in the quantified impacts in Table 8 which provides an Multi-criteria analysis (MCA) for combined OEL and BLV options, only taking into account the costs of biomonitoring (including the associated administrative costs) in addition to the costs presented above in the MCA for the OEL options.[4]

Table 8 *Multi-criteria analysis (all impacts over 40 years and additional to the baseline) per **combined OEL and BLV option** (€ millions). Note: * For the BLV component, only partial costs and benefits have been included in the calculation and the totals do not include the adjustment costs and potential health savings additional to the OEL.*

Impact	Stakeholders affected	7.3 mg/m³ and 45 mg HEAA in urine/g Creatinine	20 mg/m³ and 108 mg HEAA in urine/g Creatinine	36 mg/m³ and 188 mg HEAA in urine/g Creatinine	73 mg/m³ and 366 mg HEAA in urine/g Creatinine
Direct costs – adjustment					
Risk management measures - first year*	Companies	€ 53	€ 0.0	€ 0.0	€ 0.0
Risk management measures – recurrent*	Companies	-€ 34	€ 0.0	€ 0.0	€ 0.0
Risk management measures –	Companies	€ 102	€ 0.0	€ 0.0	€ 0.0

[4] Although compliance costs for achieving the different BLV levels could be estimated on the basis of the corresponding OEL levels, it cannot be excluded that this approach would underestimate the costs required for additional reductions in dermal exposure. It cannot be excluded that the equation used in RAC (2022) to relate air exposure and HEAA in urine does not take sufficiently into account dermal intake. In situations where significant dermal exposure (or ingestion due to poor hygiene) occurs, complying with an OEL of 7.3 mg/m3, for example, does not guarantee that the level of HEAA in urine/g creatinine will be below 45 mg.

Impact	Stakeholders affected	7.3 mg/m³ and 45 mg HEAA in urine/g Creatinine	20 mg/m³ and 108 mg HEAA in urine/g Creatinine	36 mg/m³ and 188 mg HEAA in urine/g Creatinine	73 mg/m³ and 366 mg HEAA in urine/g Creatinine
discontinuation*					
Risk management measures total*	Companies	€ 120	€ 0.0	€ 0.0	€ 0.0
Risk management measures total per company*	Companies	€ 0.067	€ 0.0	€ 0.0	€ 0.0
Monitoring (sampling and analysis – air and biomonitoring)	Companies	€ 120	€ 57	€ 11	€ 5.7
Direct costs - administrative					
Administration burden	Companies	€ 7.9	€ 4	€ 1.3	€ 1.0
Direct costs – total compliance					
Adjustment, monitoring and administration burden costs	Companies	€ 250	€ 61	€ 13	€ 6.8
Adjustment, monitoring and administration burden costs per company	Companies	€ 0.14	€ 0.034	€ 0.007	€ 0.004
Direct costs - enforcement costs					
Transposition costs – OEL and BLV	Public sector	€ 2.1	€ 2.1	€ 2.0	€ 1.3
Enforcement costs except transposition	Public sector	Enforcement costs may arise as a result of ensuring compliance with new OELs however these costs are not estimated as they are specific to Member States individual inspection regime.			
Indirect costs – other					
Firms discontinuing at least a part of their	Companies	6.3	0	0	0

Impact	Stakeholders affected	7.3 mg/m³ and 45 mg HEAA in urine/g Creatinine	20 mg/m³ and 108 mg HEAA in urine/g Creatinine	36 mg/m³ and 188 mg HEAA in urine/g Creatinine	73 mg/m³ and 366 mg HEAA in urine/g Creatinine
business - No. of company closures					
Firms discontinuing at least a part of their business - %	Companies	0.4%	0%	0%	0%
Total compliance costs as % of turnover over 40 years (including discontinuations)	Companies	0.38%	0.09%	0.02%	0.01%
First year compliance costs as % of annual turnover (excluding discontinuations)	Companies	Average: 0.4% Up to 14.6% (C20.1, C20.3 and C20.5 chemicals - small enterprises)	Average: 0.1% Up to 0.51% (C20.1, C20.3 and C20.5 chemicals - small enterprises)	Average: 0.1% Up to 0.33% (M72.1 laboratories - small enterprises)	Average: 0.04% Up to 0.26% (M72.1 laboratories - small enterprises)
Employment – Jobs lost	Workers & families	140	0	0	0
Employment – Social cost	Workers & families	€ 13	€ 0	€ 0	€ 0
International competitiveness	Companies	Some non-EU countries would have less stringent OELs and BLVs			
Consumers	Consumers	No significant impact	No significant impact	No impact	No impact
Internal market Lowest to highest OEL	Companies	7.3 mg/m³ - 7.3 mg/m³	20 mg/m³ -20 mg/m³	20 mg/m³ -36 mg/m³	20 mg/m³ -73 mg/m³
Internal market Lowest to highest BLV	Companies	45 - 45 mg HEAA/g creatinine	108 - 108 mg HEAA/g creatinine	188 - 188 mg HEAA/g creatinine	200 - 400 mg HEAA/g creatinine
Specific MSs/regions - MSs that would have to change OELs	Public sector	27	25	22	0
Specific MSs/regions	Public sector	27	27	27	26

Impact	Stakeholders affected	7.3 mg/m³ and 45 mg HEAA in urine/g Creatinine	20 mg/m³ and 108 mg HEAA in urine/g Creatinine	36 mg/m³ and 188 mg HEAA in urine/g Creatinine	73 mg/m³ and 366 mg HEAA in urine/g Creatinine
- MSs that would have to change BLVs					
Regulation	Companies	A REACH restriction on use of 1,4-dioxane in surfactants is currently under consideration			
Direct benefits – improved well-being – health					
Reduced cases of ill health (kidney effects)	Workers & families	500	0	0	0
Reduced cases of ill health (liver effects)	Workers & families	630	0	0	0
Reduced cases of ill health (local irritation in the nasal cavity)	Workers & families	4,400	0	0	0
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€ 2 - 3 million	€ 0 - 0 million	€ 0 - 0 million	€ 0 - 0 million
Direct benefits – improved well-being – safety					
Avoided costs	Companies	€ 1.6	€ 0	€ 0	€ 0
Avoided costs	Public sector	€ 2	€ 0	€ 0	€ 0
EU policy agenda	All	Improvements in workers fundamental rights and contribution towards Green Deal: Chemical Strategy towards a toxic-free environment			
Direct benefits – improved well-being – environmental					
Environmental releases	All	Potentially, a reduction in emissions into the air but unclear impact on emissions to water		Limited or no impact	Limited or no impact
Direct benefits – market efficiency					

Impact	Stakeholders affected	7.3 mg/m³ and 45 mg HEAA in urine/g Creatinine	20 mg/m³ and 108 mg HEAA in urine/g Creatinine	36 mg/m³ and 188 mg HEAA in urine/g Creatinine	73 mg/m³ and 366 mg HEAA in urine/g Creatinine
Level playing field	Companies	The ratio between the maximum and minimum national OEL is currently 3.65. The ratio between the maximum/minimum STEL is 2.08. A reduction in the OEL and STEL is likely to improve the level playing field in the internal market. Two Member States currently have a BLV both at levels above the relevant BLV options.			No impact for the OEL. Only two Member States currently have a BLV one of which is at level above and one below this BLV option.
Indirect benefits					
Administrative simplification	Companies	Should all Member States have a harmonised OEL this would reduce the administrative burden for enterprises with operations across multiple Member States. However, the majority of enterprises under review are small and are unlikely to have multinational operations and be un-affected by this simplification.			
Synergy	Companies	Synergies in terms of exposure reduction for other chemical substances used in production sectors may occur. The specific substances will vary between the sectors. The level of synergy to be harnessed will also depend on the RMMs applied in each enterprise.			
Corporate Social Responsibility	Companies	Work with 1,4-dioxane may be less perceived as a risky line of work associated with health issues, in particular given the recent reclassification of 1,4-dioxane as Carcinogenic 1B. As a result of such an improvement in the public image, companies may find it easier to recruit and retain staff, reducing the cost of recruitment and increasing the productivity of workers.			
Avoided cost of setting OEL	Public sector	€ 5.3	€ 4.4	€ 4.1	€ 4
Other impacts					
Recycling – loss of business	Recycling companies	No impacts expected			
Impacts on fundamental rights	All	Improved occupational health			
Impacts on digitalisation	Companies	No impact expected.			
Contributions to the UN sustainable development goals	All	Potential for reduced emissions into the air but it is unclear whether this would not increase emissions into wastewater.			

Source: Study team. Note: Totals may not sum due to rounding.

No data are available for the costs of compliance with the STEL options. In the absence of such data, it can be assumed that compliance with the OEL option would also mean that the relevant companies would comply with a STEL at a higher level. The ratios between the STELs and OELs currently in place in the Member States that have both an OEL and a STEL are summarised below.

Table 9 STEL/OEL factors (rounded)

Member State(s) or source	STEL/OEL ratio
AT, CZ, DE, DK, FR, SI	2
LT, SE	3
FI	4
RAC opinion	10

Source: Calculated from information in Table 3-1

Although peak exposures may be significantly higher than the 8-hour TWA, the fact that several Member States have STELs at 2 to 4 times the value of the OEL lends some support to the contention that compliance with an OEL of 7.3 mg/m^3 is likely to ensure compliance with a STEL at ten times this value, i.e. 73 mg/m^3. This would mean that no additional costs would be expected from complementing an OEL of 7.3 mg/m^3 with one of the STELs considered in this study, with the exception of additional measurement costs in cases where companies are particularly concerned about specific high-exposure activities.

Although compliance costs for achieving the different BLV levels could be estimated on the basis of the corresponding OEL levels, it cannot be excluded that this approach would underestimate the costs required for additional reductions in dermal exposure. It cannot be excluded that the equation used in RAC (2022) to relate air exposure and HEAA in urine[5] does not take sufficiently into account dermal intake and, consequently, in situations where significant dermal exposure (or ingestion due to poor hygiene) occurs, complying with an OEL of 7.3 mg/m^3, for example, does not guarantee that the level of HEAA in urine/g creatinine will be below 45 mg. Should there be no dermal uptake of 1,4-dioxane, the costs of RMMs required to comply with a BLV would be the same as those of the corresponding OEL levels as determined by the equation in RAC (2022).

Any kind of direct contact may lead to dermal exposure: splashes, touching contaminated objects or surfaces. High vapour pressure of 1,4-dioxane leads to reduced potential to come into contact with contaminated surfaces/objects and also leads to reduced potential for skin exposure during removal of gloves. Where a BLV is exceeded, it may be because of inhalation and/or dermal exposure. Gloves plus potentially other protective PPE such as clothing, aprons, has the potential to reduce dermal exposure to negligible levels, if properly used. These additional costs cannot be quantified.

In addition, the costs of biomonitoring are estimated to reach €122.87 million over 40 years for the policy option of 45 mg HEAA in urine /g creatinine (or less for the other policy options).

If a worker complies with a BLV of 45 mg HEAA in urine/g creatinine, then the reduction in ill health will be greater than for an OEL of 7.3 mg/m3. For irritation in the nasal cavity, it is

[5] In one of the three studies underlying this function (Young 1976), workers at a chemical plant were tested. The extent of dermal exposure is not clear. The other two studies involved exposure by inhalation of volunteers.

possible that there would be no additional reduction but an additional reduction can be expected for kidney and liver effects. However, there is insufficient information to quantify these additional reductions.

Résumé Exécutif

La directive sur les substances cancérogènes, mutagènes et toxiques pour la reproduction (directive 2004/37/CE), ci-après dénommée CMRD, protège les travailleurs contre l'exposition à des substances cancérogènes, mutagènes ou toxiques pour la reproduction sur le lieu de travail. L'objectif de cette étude est de soutenir l'analyse d'impact (AI) de la Commission européenne concernant une nouvelle limite d'exposition professionnelle (LEP), une limite d'exposition à court terme (LECT) et une valeur limite biologique (VLB) pour le 1,4-dioxane (n° CE 204-661-8 ; n° CAS 123-91-1).

Tout au long de l'analyse des avantages et des coûts, les niveaux suivants sont utilisés comme LEP, VLE et VLB de référence pour l'évaluation.

Table 1 Niveaux de référence de la VLEP (TWA 8 heures) pour le 1,4-dioxane

Niveau	Raison de l'inclusion
73 mg/m³ (20 ppm)	LEP indicative actuelle en vertu de la directive sur les agents chimiques
36 mg/m³ (10 ppm)	La valeur la plus courante (mode) des LEP entre 73 mg/m³ et 20 mg/m³ est de 35 ou 36 mg/m³.
20 mg/m³ (5.5 ppm)	LEP nationale la plus basse (Lettonie et Pays-Bas)
7.3 mg/m³ (2 ppm)	Recommandation du CER

Table 2 Reference STEL (15 min) levels for 1,4-dioxane

Niveau	Raison de l'inclusion
150 mg/m³ (40 ppm)	VLE la plus élevée dans un État membre de l'UE (Finlande), ainsi que 146 mg/m3 en Autriche, en Allemagne et en Slovénie et 140 mg/m3 en République tchèque et en France.
120 mg/m³ (33 ppm)	Niveau intermédiaire à mi-chemin entre 90 mg/m3 et 150 mg/m3
90 mg/m³ (25 ppm)	Valeur intermédiaire, sélectionnée en raison du fait que deux États membres (Lituanie et Suède) ont une VLE de 90 mg/m3.
73 mg/m³ (20 ppm)	Recommandation du CeR, également proche de la VLE nationale la plus basse (72 mg/m3 au Danemark).

Table 3 Niveaux de référence des VLB pour le 1,4-dioxane

Niveau (HEAA dans l'urine/g de créatinine, à la fin de l'expo-sure ou de la période de travail)	Raison de l'inclusion
366 mg	Correspond à une LEP de 73 mg/m3 (20 ppm) dans l'équation du CER (2022)
188 mg	Correspond à une LEP de 36 mg/m3 (10 ppm) dans l'équation du CER (2022), également similaire à 200 mg BAT en DE
108 mg	Correspond à une LEP de 20 mg/m3 (5,5 ppm) dans l'équation du CER (2022)

Niveau (HEAA dans l'urine/g de créatinine, à la fin de l'expo-sure ou de la période de travail)	Raison de l'inclusion
45 mg	Recommandation du CER, correspondant à une LEP de 7,3 mg/m3 dans l'équation du CER (2022)

Les secteurs examinés en détail dans ce rapport sont résumés dans le tableau 4.

Table 4 Secteurs analysés présentant un risque d'exposition au 1,4-dioxane

Code NACE	Nom abrégé du secteur	Description NACE
N/A	Fabrication de 1,4-dioxane	Partie de C20.1 Fabrication de produits chimiques de base, d'engrais et de composés azotés, de matières plastiques et de caoutchouc synthétique sous formes primaires
C21.1 and C21.2	Production pharmaceutique (utilisation intentionnelle)	C21.1 Fabrication de produits pharmaceutiques de base
C20.1, C20.3 and C20.5	Utilisation industrielle comme solvant et production comme sous-produit dans le secteur chimique	C21.2 Fabrication de préparations pharmaceutiques
M72.1	Laboratoires (utilisation intentionnelle comme solvant)	C20.1 Fabrication de produits chimiques de base, d'engrais et de composés azotés, de matières plastiques et de caoutchouc synthétique sous forme primaire
C20.4 exclu. C20.42	Surfactants - présence en tant que constituant mineur/impureté dans la production de détergents, savons, etc.	C20.3 Fabrication de peintures, vernis et revêtements similaires, d'encres d'imprimerie et de mastics
C20.42	Cosmétiques - production en tant que sous-produit dans la production de cosmétiques	C20.5 Fabrication d'autres produits chimiques

Source : Équipe de l'étude.

Les coûts et les bénéfices (par rapport à la situation de référence) estimés dans le présent rapport pour les différentes LEP cibles sont résumés dans le tableau 5. Les bénéfices sont indiqués pour la méthode 1 et la méthode 2. Les coûts correspondent à la valeur actuelle (VA) sur 40 ans avec un taux d'actualisation statique de 3 %.

Il existe des différences significatives entre les coûts et les avantages de toutes les options politiques en matière de LEP, l'option politique la plus stricte présentant le rapport coûts-avantages le plus efficace et l'option la moins stricte n'ayant aucun rapport en raison de l'absence de coûts et d'avantages.

Table 5 Résumé des coûts et avantages monétaires (taux d'actualisation statique, en plus de la base de référence, € million)

Option politique	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Total des bénéfices M1	€ 5.4	€ 0	€ 0	€ 0
Total des bénéfices M2	€ 6.8	€ 0	€ 0	€ 0
Total des coûts	€ 140	-€ 0.3	-€ 0.1	-€ 1.4
Rapport coût-bénéfice M1	25	n/a	n/a	n/a
Rapport coût-bénéfice M2	20	n/a	n/a	n/a

*Notes: *Les valeurs se rapportent à la méthode 1 - méthode 2. s.o. = sans objet, division par zéro. Les chiffres ayant été arrondis, il est possible que leur somme ne corresponde pas exactement au total indiqué.*

Source : équipe de l'étude

Les coûts et avantages globaux des options combinées de la VLEP et de la VLEP sont présentés dans le tableau 6. Étant donné que les coûts d'ajustement supplémentaires pour les entreprises et les avantages liés à la réduction des problèmes de santé résultant de l'ajout d'une VLEP à une VLEP ne peuvent être estimés avec un degré de robustesse suffisant, ils ne sont pas inclus dans les impacts quantifiés du tableau ci-dessous, qui présente une ACB pour les options combinées VLEP et VLE, en tenant uniquement compte des coûts de la biosurveillance en plus des coûts présentés ci-dessus dans l'ACB pour les options relatives à la VLEP[6].

[6] Bien que les coûts de mise en conformité pour atteindre les différents niveaux de LEP puissent être estimés sur la base des niveaux de VLEP correspondants, il ne peut être exclu que cette approche sous-estime les coûts requis pour des réductions supplémentaires de l'exposition cutanée. Il n'est pas exclu que l'équation utilisée par le CER (2022) pour relier l'exposition à l'air et les HEAA dans l'urine ne tienne pas suffisamment compte de l'ingestion cutanée. En cas d'exposition cutanée importante (ou d'ingestion due à un manque d'hygiène), le respect d'une LEP de 7,3 mg/m3, par exemple, ne garantit pas que le niveau de HEAA dans l'urine/g de créatinine sera inférieur à 45 mg.

Table 6 Résumé des coûts et avantages monétaires des LEPs et VLBs combinés (taux d'actualisation statique, en plus de la base de référence, € million)

Policy option	7.3 mg/m³ et 45 mg HEAA in urine/g créatinine	20 mg/m³ et 108 mg HEAA in urine/g créatinine	36 mg/m³ et 188 mg HEAA in urine/g créatinine	73 mg/m³ et 366 mg HEAA in urine/g créatinine
Total des bénéfices M1	€ 5.4*	€ 0*	€ 0*	€ 0*
Total des bénéfices M2	€ 6.8*	€ 0*	€ 0*	€ 0*
Total des coûts	€ 260*	€ 58*	€ 10*	€ 4*
Rapport coût-bénéfice M1	47*	n/a	n/a	n/a
Rapport coût-bénéfice M2	38*	n/a	n/a	n/a

*Notes: *Les valeurs se rapportent à la méthode 1 - méthode 2. s.o. = sans objet, division par zéro. *Pour la composante VLB, seuls des coûts et bénéfices partiels ont été inclus dans le calcul et les totaux ne comprennent pas les coûts d'ajustement et les économies potentielles en matière de santé qui s'ajoutent à la LEP. Les chiffres ayant été arrondis, il est possible que leur somme ne corresponde pas exactement au total indiqué.*

Source : équipe de l'étude

L'analyse multicritères résumant les impacts monétaires et qualitatifs est présentée dans le tableau 7.

Table 7 Analyse multicritères (tous les impacts sur 40 ans et en plus de la ligne de base) par option OEL (millions)

Impact	Acteurs concernés	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Coûts directs – ajustement					
Mesures de gestion des risques - première année	Entreprises	€ 53	€ 0	€ 0	€ 0
Mesures de gestion des risques - récurrent	Entreprises	-€ 34	€ 0	€ 0	€ 0
Mesures de gestion des risques - cessations d'activité	Entreprises	€ 102	€ 0	€ 0	€ 0
Mesures de gestion des risques – total	Entreprises	€ 12	€ 0	€ 0	€ 0
Mesures de gestion des risques – total par entreprise	Entreprises	€ 0.067	€ 0	€ 0	€ 0

Impact	Acteurs concernés	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Surveillance (échantillonnage et analyse)	Entreprises	€ 2.4	€ 0.55	€ 0.49	€ 0
Coûts directs - administratifs					
Charge administrative	Entreprises	€ 0.74	€ 0.21	€ 0.19	€ 0
Coûts directs - conformité totale					
Coûts des charges d'ajustement, de contrôle et d'administration	Entreprises	€ 130	€0.76	€ 0.68	€ 0
Coûts des charges d'ajustement, de contrôle et d'administration par entreprise	Entreprises	€ 0.07	€ 0.0004	€ 0.0004	€ 0
Coûts directs - coûts d'exécution					
Coûts de transposition	Secteur public	€ 0.81	€ 0.78	€ 0.66	€ 0
Coûts d'application hors transposition	Secteur public	Des coûts de mise en œuvre peuvent résulter de la mise en conformité avec les nouvelles LIEO, mais ces coûts ne sont pas estimés car ils sont spécifiques au régime d'inspection de chaque État membre.			
Coûts indirects - autres					
Entreprises cessant au moins une partie de leurs activités - Nombre de fermetures d'entreprises	Entreprises	6.3	0	0	0
Entreprises cessant au moins une partie de leurs activités - %	Entreprises	0.4%	0%	0%	0%
Coûts totaux de mise en conformité en % du chiffre d'affaires sur 40 ans (y compris les cessations d'activité)	Entreprises	0.8%	0.01%	0%	0%

Impact	Acteurs concernés	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Coûts de mise en conformité pour la première année en % du chiffre d'affaires annuel (à l'exclusion des cessations d'activité)	Entreprises	Jusqu'à 14.3 % (produits chimiques C20.1, C20.3 et C20.5 - petites entreprises)	Jusqu'à 0.06% (laboratoires M72.1 - petites entreprises)	Jusqu'à 0.06% (laboratoires M72.1 - petites entreprises)	0%
Emploi - Emplois perdus	Travailleurs et familles	140	0	0	0
Emploi - Coût social	Travailleurs et familles	€ 13	€ 0	€ 0	€ 0
Compétitivité internationale	Entreprises	Certains pays non membres de l'UE auraient des niveaux de LEP moins stricts		Aucune incidence prévue	
Consommateurs	Consommateurs	Pas d'impact significatif	Pas d'impact significatif	Pas d'impact	Pas d'impact
Marché intérieur De la plus basse à la plus haute VLEP	Entreprises	7.3 mg/m³-7.3 mg/m³	20 mg/m³-20 mg/m³	20 mg/m³-36 mg/m³	20 mg/m³-73 mg/m³
États membres/régions spécifiques - États membres qui devraient modifier les LIEP	Secteur public	27	25	22	0
Regulation	Entreprises	Une restriction REACH sur l'utilisation du 1,4-dioxane dans les agents de surface est actuellement à l'étude.			
Avantages directs - amélioration du bien-être et de la santé					
Réduction des cas de maladie (effets sur les reins)	Travailleurs et familles	500	0	0	0
Réduction des cas de mauvaise santé (effets sur le foie)	Travailleurs et familles	630	0	0	0
Réduction des cas de mauvaise santé (irritation locale des fosses nasales)	Travailleurs et familles	4,400	0	0	0
Maladies évitées, y compris les coûts intangibles (M1 à M2)	Travailleurs et familles	€ 2 - 3 million	€ 0 - 0 million	€ 0 - 0 million	€ 0 - 0 million

Impact	Acteurs concernés	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Avantages directs - amélioration du bien-être - sécurité					
Coûts évités	Entreprises	€ 1.6	€ 0	€ 0	€ 0
Coûts évités	Secteur public	€ 2	€ 0	€ 0	€ 0
Agenda politique de l'UE	Tous les secteurs	Amélioration des droits fondamentaux des travailleurs et contribution au Green Deal : stratégie chimique pour un environnement sans toxicité			
Avantages directs - amélioration du bien-être - environnement					
Rejets dans l'environnement	Tous	Potentiellement, une réduction des émissions dans l'air, mais l'impact sur les émissions dans l'eau n'est pas clair.			Pas d’impact
Avantages directs - efficacité du marché					
Des conditions de concurrence équitables	Entreprises	Le rapport entre la LEP nationale maximale et minimale est actuellement de 3,65. Le rapport entre la VLE maximale et la VLE minimale est de 2,08. Une réduction de la LEP et de la VLE est susceptible d'améliorer l'égalité des conditions de concurrence dans le marché intérieur.			Pas d’impact
Avantages indirects					
Simplification administrative	Entreprises	Si tous les États membres disposaient d'une LEP et VLB harmonisée, cela réduirait la charge administrative pour les entreprises qui exercent leurs activités dans plusieurs États membres. Toutefois, la majorité des entreprises examinées sont petites et il est peu probable qu'elles aient des activités multinationales et qu'elles ne soient pas affectées par cette simplification.			
Synergie	Entreprises	Des synergies en termes de réduction de l'exposition à d'autres substances chimiques utilisées dans les secteurs de production peuvent se produire. Les substances spécifiques varieront d'un secteur à l'autre. Le niveau de synergie à exploiter dépendra également des RMM appliquées dans chaque entreprise.			
Responsabilité sociale des entreprises	Entreprises	Le travail avec le 1,4-dioxane peut être moins perçu comme une activité à risque associée à des problèmes de santé, notamment en raison de la récente reclassification du 1,4-dioxane en tant que substance cancérogène 1B. Grâce à cette amélioration de l'image publique, les entreprises peuvent recruter et conserver plus facilement leur personnel, ce qui réduit les coûts de recrutement et augmente la productivité des travailleurs.			
Coût évité de la mise en place d'une LEP	Secteur public	€ 2.7	€ 1.8	€ 1.5	€ 1.4
Autre impacts					
Recyclage - perte d'activité	Entreprises de recyclage	Aucun impact n'est attendu			

Impact	Acteurs concernés	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Impacts sur les droits fondamentaux	Tous	Amélioration de la santé au travail			
Impacts sur la numérisation	Entreprises	Aucune incidence attendue.			
Contributions aux objectifs de développement durable des Nations unies	Tous les	Possibilité de réduction des émissions dans l'air, mais il n'est pas certain que cela n'entraînerait pas une augmentation des émissions dans les eaux usées.			

Source : Équipe de l'étude. Notes: Les chiffres ayant été arrondis, il est possible que leur somme ne corresponde pas exactement au total indiqué.

Étant donné que les coûts d'ajustement supplémentaires pour les entreprises et les avantages liés à la réduction des problèmes de santé résultant de l'ajout d'une VLEP à une VLEP ne peuvent être estimés avec un degré de robustesse suffisant, ils ne sont pas inclus dans les incidences quantifiées du tableau 8, qui présente une AMC pour les options combinées VLEP et VLEP, en tenant uniquement compte des coûts de la biosurveillance (y compris les coûts administratifs associés) en plus des coûts présentés ci-dessus dans l'AMC pour les options relatives à la VLEP[7].

[7] Bien que les coûts de mise en conformité pour atteindre les différents niveaux de VLEP puissent être estimés sur la base des niveaux de VLEP correspondants, il ne peut être exclu que cette approche sous-estime les coûts requis pour des réductions supplémentaires de l'exposition cutanée. Il n'est pas exclu que l'équation utilisée par le CER (2022) pour relier l'exposition à l'air et les HEAA dans l'urine ne tienne pas suffisamment compte de l'ingestion cutanée. En cas d'exposition cutanée importante (ou d'ingestion due à un manque d'hygiène), le respect d'une VLEP de 7,3 mg/m3, par exemple, ne garantit pas que le niveau de HEAA dans l'urine/g de créatinine sera inférieur à 45 mg.

Table 8 *Analyse multicritères (tous les impacts sur 40 ans et en plus de la ligne de base) par option LEP et VBL combinées (millions). Note : * Pour la composante VBL, seuls les coûts et bénéfices partiels ont été inclus dans le calcul et les totaux ne comprennent pas les coûts d'ajustement et les économies potentielles en matière de santé qui s'ajoutent à la LEP.*

Impact	Acteurs concernés	7.3 mg/m³ et 45 mg HEAA in urine/g créatinine	20 mg/m³ et 108 mg HEAA in urine/g créatinine	36 mg/m³ et 188 mg HEAA in urine/g créatinine	73 mg/m³ et 366 mg HEAA in urine/g créatinine
Coûts directs – ajustement					
Mesures de gestion des risques - première année	Entreprises	€ 53	€ 0	€ 0	€ 0
Mesures de gestion des risques - récurrent	Entreprises	-€ 34	€ 0	€ 0	€ 0
Mesures de gestion des risques - cessations d'activité	Entreprises	€ 102	€ 0	€ 0	€ 0
Mesures de gestion des risques – total	Entreprises	€ 120	€ 0	€ 0	€ 0
Mesures de gestion des risques – total par entreprise	Entreprises	€ 0.067	€ 0	€ 0	€ 0
Surveillance (échantillonnage et analyse)	Entreprises	€ 120	€ 57	€ 11	€ 5.7
Coûts directs – administratifs					
Charge administrative	Entreprises	€ 7.9	€ 4	€ 1.3	€ 1
Coûts directs - conformité totale					
Coûts des charges d'ajustement, de contrôle et d'administration	Entreprises	€ 250	€ 61	€ 13	€ 6.8
Coûts des charges d'ajustement, de contrôle et d'administration par entreprise	Entreprises	€ 0.14	€ 0.034	€ 0.007	€ 0.004
Coûts directs - coûts d'exécution					
Coûts de transposition	Secteur public	€ 2.1	€ 2.1	€ 2	€ 1.3

Impact	Acteurs concernés	7.3 mg/m³ et 45 mg HEAA in urine/g créatinine	20 mg/m³ et 108 mg HEAA in urine/g créatinine	36 mg/m³ et 188 mg HEAA in urine/g créatinine	73 mg/m³ et 366 mg HEAA in urine/g créatinine
Coûts d'application hors transposition	Secteur public	Des coûts de mise en œuvre peuvent résulter de la mise en conformité avec les nouvelles LIEO, mais ces coûts ne sont pas estimés car ils sont spécifiques au régime d'inspection de chaque État membre.			
Coûts indirects – autres					
Entreprises cessant au moins une partie de leurs activités - Nombre de fermetures d'entreprises	Entreprises	6.3	0	0	0
Entreprises cessant au moins une partie de leurs activités - %	Entreprises	0.4%	0%	0%	0%
Coûts totaux de mise en conformité en % du chiffre d'affaires sur 40 ans (y compris les cessations d'activité)	Entreprises	0.38%	0.09%	0.02%	0.01%
Coûts de mise en conformité pour la première année en % du chiffre d'affaires annuel (à l'exclusion des cessations d'activité)	Entreprises	Moyenne: 0.4% Jusqu'à 14.6% (produits chimiques C20.1, C20.3 et C20.5 - petites entreprises)	Moyenne: 0.1% Jusqu'à 0.51% (produits chimiques C20.1, C20.3 et C20.5 - petites entreprises)	Moyenne: 0.1% Jusqu'à 0.33% (laboratoires M72.1 - petites entreprises)	Moyenne: 0.04% Jusqu'à 0.26% (laboratoires M72.1 - petites entreprises)
Emploi - Emplois perdus	Travailleurs et familles	140	0	0	0
Emploi - Coût social	Travailleurs et familles	€ 13	€ 0	€ 0	€ 0
Compétitivité internationale	Entreprises	Certains pays non membres de l'UE auraient des niveaux de LEP moins stricts			
Consommateurs	Consommateurs	No significant impact	No significant impact	Pas d'impact	Pas di'impact
Marché intérieur De la plus basse à la plus haute LEP	Entreprises	7.3 mg/m3-7.3 mg/m3	20 mg/m3-20 mg/m3	20 mg/m3-36 mg/m3	20 mg/m3-73 mg/m3

Impact	Acteurs concernés	7.3 mg/m³ et 45 mg HEAA in urine/g créatinine	20 mg/m³ et 108 mg HEAA in urine/g créatinine	36 mg/m³ et 188 mg HEAA in urine/g créatinine	73 mg/m³ et 366 mg HEAA in urine/g créatinine
Marché intérieur De la plus basse à la plus haute VLB	Entreprises	45 - 45 mg HEAA/g créatinine	108 - 108 mg HEAA/g créatinine	188 - 188 mg HEAA/g créatinine	200 - 400 mg HEAA/g créatinine
États membres/régions spécifiques - États membres qui devraient modifier les LIEPs	Secteur public	27	25	22	0
États membres/régions spécifiques - États membres qui devraient modifier les VLBs	Secteur public	27	27	27	26
Regulation	Entreprises	Une restriction REACH sur l'utilisation du 1,4-dioxane dans les agents de surface est actuellement à l'étude.			
Avantages directs - amélioration du bien-être et de la santé					
Réduction des cas de maladie (effets sur les reins)	Travailleurs et familles	500	0	0	0
Réduction des cas de mauvaise santé (effets sur le foie)	Travailleurs et familles	630	0	0	0
Réduction des cas de mauvaise santé (irritation locale des fosses nasales)	Travailleurs et familles	4,400	0	0	0
Maladies évitées, y compris les coûts intangibles (M1 à M2)	Travailleurs et familles	€ 2 - 3 million	€ 0 - 0 million	€ 0 - 0 million	€ 0 - 0 million
Avantages directs - amélioration du bien-être - sécurité					
Coûts évités	Entreprises	€ 1.6	€ 0	€ 0	€ 0
Coûts évités	Secteur public	€ 2	€ 0	€ 0	€ 0
Agenda politique de l'UE	Tous les secteurs	Amélioration des droits fondamentaux des travailleurs et contribution au Green Deal : stratégie chimique pour un environnement sans toxicité			

Impact	Acteurs concernés	7.3 mg/m³ et 45 mg HEAA in urine/g créatinine	20 mg/m³ et 108 mg HEAA in urine/g créatinine	36 mg/m³ et 188 mg HEAA in urine/g créatinine	73 mg/m³ et 366 mg HEAA in urine/g créatinine
Avantages directs - amélioration du bien-être - environnement					
Rejets dans l'environnement	Tous	Potentiellement, une réduction des émissions dans l'air, mais l'impact sur les émissions dans l'eau n'est pas clair		Impact limité ou nul	Impact limité ou nul
Avantages directs - efficacité du marché					
Des conditions de concurrence équitables	Entreprises	Le rapport entre la LEP nationale maximale et minimale est actuellement de 3,65. Le rapport entre la VLE maximale et la VLE minimale est de 2,08. Une réduction de la LEP et de la VLE est susceptible d'améliorer l'égalité des conditions de concurrence dans le marché intérieur. Deux États membres disposent actuellement d'une VLB, toutes deux à des niveaux supérieurs aux options correspondantes de la VLB			Pas d’impact pour LEP. Seuls deux États membres disposent actuellement d'une VLB, dont l'un se situe à un niveau supérieur et l'autre à un niveau inférieur à cette option VLB.
Avantages indirects					
Simplification administrative	Entreprises	Si tous les États membres disposaient d'une LEP harmonisée, cela réduirait la charge administrative pour les entreprises qui exercent leurs activités dans plusieurs États membres. Toutefois, la majorité des entreprises examinées sont petites et il est peu probable qu'elles aient des activités multinationales et qu'elles ne soient pas affectées par cette simplification.			
Synergie	Entreprises	Des synergies en termes de réduction de l'exposition à d'autres substances chimiques utilisées dans les secteurs de production peuvent se produire. Les substances spécifiques varieront d'un secteur à l'autre. Le niveau de synergie à exploiter dépendra également des RMM appliquées dans chaque entreprise.			
Responsabilité sociale des entreprises	Entreprises	Le travail avec le 1,4-dioxane peut être moins perçu comme une activité à risque associée à des problèmes de santé, notamment en raison de la récente reclassification du 1,4-dioxane en tant que substance cancérogène 1B. Grâce à cette amélioration de l'image publique, les entreprises peuvent recruter et conserver plus facilement leur personnel, ce qui réduit les coûts de recrutement et augmente la productivité des travailleurs.			
Coût évité de la mise en place d'une LEP	Secteur public	€ 5.3	€ 4.4	€ 4.1	€ 4
Autre impacts					
Recyclage - perte d'activité	Entreprises de recyclage	Aucun impact n'est attendu			

Impact	Acteurs concernés	7.3 mg/m³ et 45 mg HEAA in urine/g créatinine	20 mg/m³ et 108 mg HEAA in urine/g créatinine	36 mg/m³ et 188 mg HEAA in urine/g créatinine	73 mg/m³ et 366 mg HEAA in urine/g créatinine
Impacts sur les droits fondamentaux	Tous	Amélioration de la santé au travail			
Impacts sur la numérisation	Entreprises	Aucune incidence attendue.			
Contributions aux objectifs de développement durable des Nations unies	Tous les	Possibilité de réduction des émissions dans l'air, mais il n'est pas certain que cela n'entraînerait pas une augmentation des émissions dans les eaux usées.			

Source : Équipe de l'étude. Notes: Les chiffres ayant été arrondis, il est possible que leur somme ne corresponde pas exactement au total indiqué.

Aucune donnée n'est disponible pour les coûts de mise en conformité avec les options VLE. En l'absence de telles données, on peut supposer que le respect de l'option LEP signifierait également que les entreprises concernées se conformeraient à une VLE à un niveau plus élevé. Les rapports entre les VLE et les LEP actuellement en vigueur dans les États membres qui disposent à la fois d'une LEP et d'une VLE sont résumés ci-dessous.

Table 9 Facteurs VLE/LEP (arrondis)

Member State(s) or source	STEL/OEL ratio
AT, CZ, DE, DK, FR, SI	2
LT, SE	3
FI	4
RAC opinion	10

Source : Calculs effectués à partir des informations contenues dans le tableau 3 : Calculé à partir des informations du tableau 3 1

Bien que les pics d'exposition puissent être sensiblement plus élevés que la TWA de 8 heures, le fait que plusieurs États membres aient des VLE de 2 à 4 fois la valeur de la LEP conforte l'idée que le respect d'une LEP de 7,3 mg/m3 est susceptible d'assurer le respect d'une LEP de dix fois cette valeur, c'est-à-dire 73 mg/m3. Cela signifie qu'aucun coût supplémentaire ne devrait résulter de l'ajout d'une LEP de 7,3 mg/m3 à l'une des LEP examinées dans cette étude, à l'exception des coûts de mesure supplémentaires dans les cas où les entreprises sont particulièrement préoccupées par des activités spécifiques à forte exposition.

Bien que les coûts de mise en conformité pour atteindre les différents niveaux de VLEP puissent être estimés sur la base des niveaux de VLEP correspondants, il ne peut être exclu que cette approche sous-estime les coûts requis pour des réductions supplémentaires de l'exposition cutanée. Il n'est pas exclu que l'équation utilisée dans le CER (2022) pour relier l'exposition atmosphérique et les HEAA dans l'urine[8] ne prenne pas suffisamment en compte l'absorption cutanée et, par conséquent, dans les situations où une exposition cutanée significative (ou une ingestion due à une mauvaise hygiène) se produit, le respect d'une VLEP de 7,3 mg/m3, par exemple, ne garantit pas que le niveau de HEAA dans l'urine/g de créatinine sera inférieur à 45 mg. S'il n'y a pas d'absorption cutanée du 1,4-dioxane, les coûts des RMM nécessaires pour se conformer à une VLE seraient les mêmes que ceux des niveaux de VLEP correspondants, tels que déterminés par l'équation du CER (2022).Tout type de contact direct peut entraîner une exposition cutanée : éclaboussures, contact avec des objets ou des surfaces contaminés. La pression de vapeur élevée du 1,4-dioxane réduit le risque de contact avec des surfaces/objets contaminés et réduit également le risque d'exposition cutanée lors du retrait des gants. Le dépassement d'une VLB peut être dû à une exposition par inhalation et/ou par voie cutanée. Les gants et éventuellement d'autres EPI de protection tels que des vêtements, des tabliers, peuvent réduire l'exposition cutanée à des niveaux négligeables, s'ils sont utilisés correctement. Ces coûts supplémentaires ne peuvent être quantifiés.

En outre, les coûts de la biosurveillance sont estimés à 122,87 millions d'euros sur 40 ans pour l'option politique de 45 mg d’HEAA dans l’urine/g de créatinine (ou moins pour les autres option politiques).

Si un travailleur respecte une VLB de 45 mg de HEAA dans l'urine/g de créatinine, la réduction des problèmes de santé sera plus importante que pour une LEP de 7,3 mg/m3. Pour l'irritation des fosses nasales, il est possible qu'il n'y ait pas de réduction supplémentaire, mais on peut s'attendre à une réduction supplémentaire pour les effets sur les reins et le foie. Toutefois, les informations sont insuffisantes pour quantifier ces réductions supplémentaires

.

[8] Dans l'une des trois études qui sous-tendent cette fonction (Young 1976), des travailleurs d'une usine chimique ont été testés. L'ampleur de l'exposition cutanée n'est pas claire. Les deux autres études portaient sur l'exposition par inhalation de volontaires.

Kurzfassung

Die Richtlinie über krebserzeugende, erbgutverändernde und fortpflanzungsgefährdende Stoffe (Richtlinie 2004/37/EG), im Folgenden CMRD genannt, schützt Arbeitnehmer vor der Exposition gegenüber krebserzeugenden, erbgutverändernden oder fortpflanzungsgefährdenden Stoffen bei der Arbeit. Ziel dieser Studie ist es, die Folgenabschätzung der Europäischen Kommission für einen potenziellen neuen Grenzwert für die berufsbedingte Exposition (AGW), einen Grenzwert für die Kurzzeitexposition (STEL) und einen biologischen Grenzwert (BGW) für 1,4-Dioxan (EG-Nr. 204-661-8; CAS-Nr. 123-91-1) zu unterstützen.

In der Analyse von Nutzen und Kosten werden die folgenden Werte als Referenzwerte für AGW, STEL und BGW für die Bewertung verwendet.

Tabelle 1 AGW-Referenzwerte (8-stündiger zeitlich gewichteter Durchschnitt) für 1,4-Dioxan

Wert	Grund für die Berücksichtigung dieses Wertes
73 mg/m^3 (20 ppm)	Aktueller Richtwert für AGW in der Richtlinie über chemische Arbeitsstoffe (CAD)[9]
36 mg/m^3 (10 ppm)	Der häufigste Wert (Modus) der AGWs zwischen 73 mg/m^3 und 20 mg/m^3 liegt bei 35 oder 36 mg/m3
20 mg/m^3 (5,5 ppm)	Niedrigster nationaler AGW (Lettland & die Niederlande)
7,3 mg/m^3 (2 ppm)	Empfehlung des Ausschusses für Risikobewertung (RAC)

Tabelle 2 STEL-Referenzwerte (15 min) für 1,4-Dioxan

Wert	Grund für die Berücksichtigung dieses Wertes
150 mg/m^3 (40 ppm)	Höchster STEL-Wert in einem EU-Mitgliedstaat (Finnland), außerdem 146 mg/m^3 in Österreich, Deutschland und Slowenien und 140 mg/m^3 in der Tschechischen Republik und Frankreich
120 mg/m^3 (33 ppm)	Zwischenwert in der Mitte zwischen 90 mg/m^3 und 150 mg/m^3
90 mg/m^3 (25 ppm)	Zwischenwert, ausgewählt aufgrund der Tatsache, dass zwei Mitgliedstaaten (Litauen und Schweden) einen STEL-Wert von 90 mg/m^3 haben
73 mg/m^3 (20 ppm)	Empfehlung des RAC, ebenfalls nahe dem niedrigsten nationalen STEL-Wert (72 mg/m^3 in Dänemark)

[9] Tabelle 4-1 legt nahe, dass alle Mitgliedstaaten einen Wert von 73 mg/m3 oder weniger festgelegt haben. Diese Option wird für die Folgenabschätzung beibehalten, damit das Studienteam überprüfen kann, ob alle nationalen AGW von 73 mg/m3 oder weniger verbindlich sind.

Tabelle 3 BGW-Referenzwerte für 1,4-Dioxan

Wert (HEAA[10] im Urin/g Kreatinin, am Ende der Exposition oder Schicht)	Grund für die Berücksichtigung dieses Wertes
366 mg	Entspricht einem AGW von 73 mg/m³ (20 ppm) nach der Formel in RAC (2022)
188 mg	Entspricht einem AGW von 36 mg/m³ (10 ppm) nach der Formel in RAC (2022), ähnlich wie 200 mg BAT in DE
108 mg	Entspricht einem AGW von 20 mg/m3 (5,5 ppm) nach der Formel in RAC (2022)
45 mg	Empfehlung des RAC, entspricht einem AGW von 7,3 mg/m³ nach der Formel in RAC (2022)

Die in diesem Bericht im Einzelnen betrachteten Sektoren sind in Tabelle 4 zusammengefasst.

Tabelle 4 Analysierte Sektoren mit Expositionsrisiko gegenüber 1,4-Dioxan

NACE-Code	Kurzbezeichnung des Sektors	NACE-Beschreibung
N/A	Herstellung von 1,4-Dioxan	Teil von C20.1 Herstellung von chemischen Grundstoffen, Düngemitteln und Stickstoffverbindungen, Kunststoffen und synthetischem Kautschuk in Primärformen
C21.1 und C21.2	Herstellung von Arzneimitteln (bestimmungsgemäße Verwendung)	C21.1 Herstellung von pharmazeutischen Grundstoffen C21.2 Herstellung von pharmazeutischen Zubereitungen
C20.1, C20.3 und C20.5	Industrielle Verwendung als Lösungsmittel und Erzeugung als Nebenprodukt im Chemiesektor	C20.1Herstellung von chemischen Grundstoffen, Düngemitteln und Stickstoffverbindungen, Kunststoffen und synthetischem Kautschuk in Primärformen C20.3 Herstellung von Anstrichmitteln, Druckfarben, Kitten und ähnlichen Erzeugnissen C20.5 Herstellung von sonstigen chemischen Erzeugnissen
M72.1	Laboratorien (absichtliche Verwendung als Lösungsmittel)	M72.1 Forschung und experimentelle Entwicklung im Bereich Natur- und Ingenieurwissenschaften
C20.4 ausgenommen C20.42	Tenside - Vorhandensein als Nebenbestandteil/Verunreinigung bei der Herstellung von Waschmitteln, Seifen usw.	C20.4 Herstellung von Seifen, Wasch-, Reinigungs- und Poliermitteln, Riech- und Körperpflegemitteln, ausgenommen C20.42 Herstellung von Riech- und Körperpflegemitteln
C20.42	Kosmetika - Erzeugung als Nebenprodukt bei der Herstellung von Kosmetika	C20.42 Herstellung von Parfüms und Körperpflegemitteln

Quelle: Studienteam.

Die in diesem Bericht für die verschiedenen AGW-Optionen geschätzten Kosten und Nutzen (im Vergleich zum Ausgangswert) sind in Tabelle 5 zusammengefasst. Der Nutzen wird nach zwei

[10] 2-Hydroxyethoxyessigsäure

Methoden berechnet (1 und 2). Bei den Kosten handelt es sich um den Gegenwartswert (PV) über 40 Jahre mit einem statischen Abzinsungssatz von 3%.

Zwischen den Kosten und dem Nutzen aller AGW-Optionen gibt es erhebliche Unterschiede, wobei die strengste Option das beste Kosten-Nutzen-Verhältnis aufweist und die am wenigsten strenge Option aufgrund fehlender Kosten und Vorteile kein Verhältnis aufweist.

Tabelle 5 Zusammenfassung der monetarisierten Kosten und des Nutzens (statischer Abzinsungssatz, zusätzlich zum Basisszenario) (in Millionen €)

Option	7,3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Gesamtnutzen M1	€ 5,4	€ 0	€ 0	€ 0
Gesamtnutzen M2	€ 6,8	€ 0	€ 0	€ 0
Gesamtkosten (AGW)	€ 140	-€ 0,3	-€ 0,1	-€ 1,4
Kosten-Nutzen-Verhältnis M1 (AGW)	25	n/a	n/a	n/a
Kosten-Nutzen-Verhältnis M2 (AGW)	20	n/a	n/a	n/a

Anmerkungen: Werte beziehen sich auf Methode 1 - Methode 2. Die Summe kann sich aufgrund von Auf- bzw. Abrunden von der Gesamtsumme unterscheiden.
Quelle: Studienteam.

Die Gesamtkosten und der Gesamtnutzen der kombinierten AGW- und BGW-Optionen sind in Tabelle 6 dargestellt. Da die zusätzlichen Anpassungskosten für die Unternehmen und der Nutzen einer geringeren Krankheitsbelastung durch die Hinzufügung eines BGW zu einem AGW nicht hinreichend zuverlässig geschätzt werden können, sind sie nicht in den quantifizierten Auswirkungen in der nachstehenden Tabelle enthalten, die eine KNA für die kombinierten AGW- und BGW-Optionen enthält, wobei nur die Kosten für das Biomonitoring zusätzlich zu den oben in der KNA für die AGW-Optionen dargestellten Kosten berücksichtigt werden.[11]

*Tabelle 6 Zusammenfassung der monetarisierten Kosten und des Nutzens der **kombinierten AGWs und BGWs** (statischer Abzinsungssatz, zusätzlich zum Basisszenario) (in Millionen €)*

Option	7.3 mg/m³ und 45 mg HEAA im Urin/g Kreatinin	20 mg/m³ und 108 mg HEAA im Urin/g Kreatinin	36 mg/m³ und 188 mg HEAA im Urin/g Kreatinin	73 mg/m³ und 366 mg HEAA im Urin/g Kreatinin
Gesamtnutzen M1	€ 5,4*	€ 0*	€ 0*	€ 0*
Gesamtnutzen M2	€ 6,8*	€ 0*	€ 0*	€ 0*
Gesamtkosten	€ 260*	€ 58*	€ 10*	€ 4*
Kosten-Nutzen-Verhältnis M1	47*	n/a	n/a	n/a
Kosten-Nutzen-Verhältnis M2	38*	n/a	n/a	n/a

[11] Obwohl die Kosten für die Einhaltung der verschiedenen BGW-Werte auf der Grundlage der entsprechenden AGW-Werte geschätzt werden könnten, kann nicht ausgeschlossen werden, dass dieser Ansatz die Kosten unterschätzt, die für zusätzliche Reduzierungen der dermalen Exposition erforderlich sind. Es kann nicht ausgeschlossen werden, dass die in RAC (2022) verwendete Gleichung für den Zusammenhang zwischen Luftexposition und HEAA im Urin die dermale Aufnahme nicht ausreichend berücksichtigt. In Situationen, in denen es zu einer signifikanten dermalen Exposition (oder einer Aufnahme aufgrund mangelnder Hygiene) kommt, ist die Einhaltung eines AGW von 7,3 mg/m³ beispielsweise keine Garantie dafür, dass der HEAA-Gehalt im Urin/g Kreatinin unter 45 mg liegen wird.

Anmerkungen: Werte beziehen sich auf Methode 1 - Methode 2. n/a = nicht anwendbar, Teilung durch Null.
** Für die BGW-Komponente wurden nur Teilkosten und -nutzen in die Berechnung einbezogen, und die Gesamtsummen enthalten nicht die Anpassungskosten und die potenziellen Gesundheitseinsparungen, die zusätzlich zum AGW anfallen. Die Summe kann sich aufgrund von Auf- bzw. Abrunden von der Gesamtsumme unterscheiden.*

Quelle: Studienteam

Die Multikriterienanalyse, die sowohl die monetären als auch die qualitativen Auswirkungen zusammenfast, ist in Tabelle 7 dargestellt.

Tabelle 7 Multikriterienanalyse (alle Auswirkungen über 40 Jahre und zusätzlich zum Ausgangswert) per AGW-Option (in Millionen €)

Auswirkungen	Betroffene Stakeholders	7,3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Direkte Kosten – Anpassung					
Risikomanagementmaßnahmen - erstes Jahr	Unternehmen	€ 53	€ 0	€ 0	€ 0
Risikomanagementmaßnahmen – wiederkehrend	Unternehmen	-€ 34	€ 0	€ 0	€ 0
Risikomanagementmaßnahmen - Unterbrechung	Unternehmen	€ 102	€ 0	€ 0	€ 0
Risikomanagementmaßnahmen - gesamt	Unternehmen	€ 120	€ 0	€ 0	€ 0
Risikomanagementmaßnahmen gesamt pro Unternehmen	Unternehmen	€ 0,067	€ 0	€ 0	€ 0
Luftüberwachung (Probenahme und Analyse)	Unternehmen	€ 2,4	€ 0,55	€ 0,49	€ 0
Direkte Kosten – Verwaltung					
Verwaltungsaufwand	Unternehmen	€ 0,74	€ 0,21	€ 0,19	€ 0
Direkte Kosten – Einhaltung der Vorschriften (Compliance) gesamt					
Kosten für Anpassung, Überwachung und Verwaltungsaufwand	Unternehmen	€ 130	€1,4	€ 0	€ 0
Kosten für Anpassung, Überwachung und Verwaltungsaufwand pro Unternehmen	Unternehmen	€ 0,07	€ 0,0004	€ 0,0004	€ 0
Direkte Kosten - Durchsetzungskosten (enforcement)					
Umsetzungskosten	Öffentlicher Sektor	€ 0,81	€ 0,78	€ 0,66	€ 0
Durchsetzungskosten außer Umsetzung	Öffentlicher Sektor	Durchsetzungskosten können durch die Einhaltung der neuen AGW entstehen. Diese kosten werden jedoch nicht geschätzt,			

Auswirkungen	Betroffene Stakeholders	7,3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
		da sie von den individuellen Kontrollsystemen der Mietgliedstaaten abhängen.			
Indirekte Kosten - Sonstige					
Unternehmen, die zumindest einen Teil ihrer Geschäftsfähigkeit aufgeben – Anzahl der Unternehmensschließungen	Unternehmen	6,3	0	0	0
Unternehmen, die zumindest einen Teil ihrer Geschäftsfähigkeit aufgeben - %	Unternehmen	0,4%	0%	0%	0%
Gesamtkosten für die Einhaltung der Vorschriften in % des Umsatzes über 40 Jahre (einschließlich Einstellung des Betriebs)	Unternehmen	0,8%	0,01%	0%	0%
Kosten für die Einhaltung der Vorschriften im ersten Jahr in % des Jahresumsatzes (ohne Einstellung des Betriebs)	Unternehmen	Bis zu 14,3% (C20.1, C20.3 und C20.5 Chemikalien - kleine Unternehmen)	Bis zu 0,06% (M72.1 Laboratorien - kleine Unternehmen)	Bis zu 0,06% (M72.1 Laboratorien - kleine Unternehmen)	0%
Beschäftigung - verlorene Arbeitsplätze	Arbeitnehmer & Familien	140	0	0	0
Beschäftigung - Soziale Kosten	Arbeitnehmer & Familien	€ 13	€ 0	€ 0	€ 0
Internationale Wettbewerbsfähigkeit	Unternehmen	In einigen Nicht-EU-Ländern würden weniger strenge AGWs und BGWs gelten.		Keine Auswirkungen erwartet	
Verbraucher	Verbraucher	Keine wesentlichen Auswirkungen	Keine wesentlichen Auswirkungen	Keine Auswirkungen	Keine Auswirkungen
Binnenmarkt Niedrigster bis höchster AGW	Unternehmen	7,3 mg/m³-7,3 mg/m³	20 mg/m³-20 mg/m³	20 mg/m³-36 mg/m³	20 mg/m³-73 mg/m³
Spezifische Mitgliedstaaten/Regionen – Mitgliedstaaten, die AGWs ändern müssten	Öffentlicher Sektor	27	25	22	0
Verordnung	Unternehmen	Eine REACH-Beschränkung der Verwendung von 1,4-Dioxan in Tensiden wird derzeit geprüft.			
Direkte Nutzen – verbessertes Wohlbefinden - Gesundheit					
Geringere Krankheitsfälle (Auswirkungen auf die Nieren)	Arbeitnehmer & Familien	500	0	0	0

Auswirkungen	Betroffene Stakeholders	7,3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Geringere Krankheitsfälle (Auswirkungen auf die Leber)	Arbeitnehmer & Familien	630	0	0	0
Geringere Krankheitsfälle (lokale Reizung der Nasenhöhle)	Arbeitnehmer & Familien	4400	0	0	0
Krankheitsfälle vermieden, einschließlich immaterieller Kosten (M1 bis M2)	Arbeitnehmer & Familien	€ 2 - 3	€ 0 - 0	€ 0 - 0	€ 0 - 0
Direkte Nutzen – verbessertes Wohlbefinden - Sicherheit					
Vermiedene Kosten	Unternehmen	€ 1,6	€ 0	€ 0	€ 0
Vermiedene Kosten	Öffentlicher Sektor	€ 2	€ 0	€ 0	€ 0
Politische Agenda der EU	Alle	Verbesserung der Grundrechte der Arbeitnehmer und Beitrag zum Green Deal: Chemiestrategie für eine giftfreie Umwelt			
Direkte Vorteile - verbessertes Wohlbefinden - Umwelt					
Freisetzungen in die Umwelt	Alle	Möglicherweise eine Verringerung der Emissionen in die Luft, aber unklare Auswirkungen auf die Emissionen in das Wasser			Keine Auswirkungen
Direkte Vorteile - Markteffizienz					
Gleiche Ausgangsbedingungen	Unternehmen	Das Verhältnis zwischen dem maximalen und minimalen nationalen AGW beträgt derzeit 3,65. Das Verhältnis zwischen höchstem und niedrigstem STEL liegt bei 2,08. Eine Senkung von AGW und STEL dürfte die Wettbewerbsgleichheit im Binnenmarkt verbessern.			Keine Auswirkungen
Indirekte Nutzen					
Vereinfachung der Verwaltung	Unternehmen	Sollten alle Mitgliedstaaten über einen harmonisierten AGW verfügen, würde dies den Verwaltungsaufwand für Unternehmen mit Tätigkeiten in mehreren Mitgliedstaaten verringern. Die Mehrheit der untersuchten Unternehmen ist jedoch klein und wird wahrscheinlich nicht multinational tätig sein und von dieser Vereinfachung nicht betroffen sein.			
Synergie	Unternehmen	Bei anderen chemischen Stoffen, die in den Produktionssektoren verwendet werden, kann es zu Synergieeffekten in Bezug auf die Verringerung der Exposition kommen. Die spezifischen Stoffe werden von Sektor zu Sektor unterschiedlich sein. Das Ausmaß der zu nutzenden Synergie hängt auch von den in den einzelnen Unternehmen angewandten Risikomanagementmaßnahmen ab.			
Soziale Verantwortung der Unternehmen	Unternehmen	Die Arbeit mit 1,4-Dioxan wird möglicherweise weniger als riskanter und gesundheitsgefährdender Arbeitsbereich wahrgenommen, insbesondere angesichts der jüngsten Neueinstufung von 1,4-Dioxan als krebserregend 1B. Infolge			

Auswirkungen	**Betroffene Stakeholders**	**7,3 mg/m³**	**20 mg/m³**	**36 mg/m³**	**73 mg/m³**
		einer solchen Verbesserung des Images in der Öffentlichkeit kann es für die Unternehmen einfacher sein, Personal einzustellen und zu halten, was die Kosten für die Einstellung senkt und die Produktivität der Arbeitnehmer erhöht.			
Vermiedene Kosten der Festlegung eines AGW	Öffentlicher Sektor	€ 2,7	€ 1,8	€ 1,5	€ 1,4
Andere Auswirkungen					
Recycling - Verlust von Geschäftsmöglichkeiten	Recycling-Unternehmen	Es werden keine Auswirkungen erwartet.			
Auswirkungen auf die Grundrechte	Alle	Verbesserte Gesundheit am Arbeitsplatz.			
Auswirkungen auf die Digitalisierung	Unternehmen	Es werden keine Auswirkungen erwartet.			
Beiträge zu den UN-Zielen für nachhaltige Entwicklung	Alle	Mögliche Verringerung der Emissionen in die Luft, aber es ist unklar, ob dies nicht zu einem Anstieg der Emissionen ins Abwasser führen würde.			

Quelle: Studienteam. Anmerkungen: Die Summe kann sich aufgrund von Auf- bzw. Abrunden von der Gesamtsumme unterscheiden.

Da die zusätzlichen Anpassungskosten für die Unternehmen und der Nutzen einer geringeren Krankheitsbelastung durch die Hinzufügung eines BGW zu einem AGW nicht mit ausreichender Zuverlässigkeit geschätzt werden können, sind sie nicht in den quantifizierten Auswirkungen in Tabelle 8 enthalten, die eine MCA für kombinierte AGW- und BGW-Optionen enthält, wobei nur die Kosten des Biomonitorings (einschließlich der damit verbundenen Verwaltungskosten) zusätzlich zu den oben in der MCA für die AGW-Optionen dargestellten Kosten berücksichtigt werden.[12]

Table 8 *Multikriterienanalyse (alle Auswirkungen über 40 Jahre und zusätzlich zur Basislinie) pro kombinierter AGW- und BGW-Option (Millionen). Hinweis: * Für die BGW-Komponente wurden nur Teilkosten und -nutzen in die Berechnung einbezogen, und die Gesamtwerte enthalten nicht die Anpassungskosten und potenziellen Gesundheitseinsparungen zusätzlich zum AGW.*

Auswir-kungen	**Betroffene Stakeholders**	**7.3 mg/m³ und 45 mg HEAA im Urin /g Kreatinin**	**20 mg/m³ und 108 mg HEAA im Urin/g Kreatinin**	**36 mg/m³ und 188 mg HEAA im Urin/g Kreatinin**	**73 mg/m³ und 366 mg HEAA im Urin/g Kreatinin**
Direkte Kosten – Anpassung					

[12] Obwohl die Kosten für die Einhaltung der verschiedenen BLV-Werte auf der Grundlage der entsprechenden AGW-Werte geschätzt werden könnten, kann nicht ausgeschlossen werden, dass dieser Ansatz die Kosten unterschätzt, die für zusätzliche Reduzierungen der dermalen Exposition erforderlich sind. Es kann nicht ausgeschlossen werden, dass die in RAC (2022) verwendete Gleichung zur Relation von Luftexposition und HEAA im Urin die dermale Aufnahme nicht ausreichend berücksichtigt. In Situationen, in denen es zu einer signifikanten dermalen Exposition (oder einer Aufnahme aufgrund mangelnder Hygiene) kommt, ist die Einhaltung eines AGW von 7,3 mg/m³ beispielsweise keine Garantie dafür, dass der HEAA-Gehalt im Urin/g Kreatinin unter 45 mg liegen wird.

Auswir-kungen	**Betroffene Stakeholders**	**7.3 mg/m³ und 45 mg HEAA im Urin /g Kreatinin**	**20 mg/m³ und 108 mg HEAA im Urin/g Kreatinin**	**36 mg/m³ und 188 mg HEAA im Urin/g Kreatinin**	**73 mg/m³ und 366 mg HEAA im Urin/g Kreatinin**
Risikomanagementmaßnahmen - erstes Jahr*	Unternehmen	€ 53	€ 0	€ 0	€ 0
Risikomanagementmaßnahmen – wiederkehrend *	Unternehmen	-€ 34	€ 0	€ 0	€ 0
Risikomanagementmaßnahmen - Unterbrechung *	Unternehmen	€ 102	€ 0	€ 0	€ 0
Risikomanagementmaßnahmen - gesamt*	Unternehmen	€ 120	€ 0	€ 0	€ 0
Risikomanagementmaßnahmen gesamt pro Unternehmen*	Unternehmen	€ 0,067	€ 0	€ 0	€ 0
Luftüberwachung (Probenahme und Analyse)	Unternehmen	€ 120	€ 57	€ 11	€ 5,7
Direkte Kosten – Verwaltung					
Verwaltungsaufwand	Unternehmen	€ 7,9	€ 4	€ 1,3	€ 1
Direkte Kosten – Einhaltung der Vorschriften (Compliance) gesamt					
Kosten für Anpassung, Überwachung und Verwaltungsaufwand	Unternehmen	€ 250	€ 61	€ 13	€ 6,8
Kosten für Anpassung, Überwachung und Verwaltungsaufwand pro Unternehmen	Unternehmen	€ 0,14	€ 0,034	€ 0,007	€ 0,004
Direkte Kosten - Durchsetzungskosten (enforcement)					
Umsetzungskosten – AGW und BGW	Öffentlicher Sektor	€ 2,1	€ 2,1	€ 2	€ 1,3

Auswir-kungen	Betroffene Stakeholders	7.3 mg/m³ und 45 mg HEAA im Urin /g Kreatinin	20 mg/m³ und 108 mg HEAA im Urin/g Kreatinin	36 mg/m³ und 188 mg HEAA im Urin/g Kreatinin	73 mg/m³ und 366 mg HEAA im Urin/g Kreatinin
Durchsetzungs kosten außer Umsetzung	Öffentlicher Sektor	Durchsetzungskosten können durch die Einhaltung der neuen AGW entstehen. Diese kosten werden jedoch nicht geschätzt, da sie von den individuellen Kontrollsystemen der Mietgliedstaaten abhängen.			
Indirekte Kosten - Sonstige					
Unternehmen, die zumindest einen Teil ihrer Geschäftsfähig keit aufgeben – Anzahl der Unternehmens schließungen	Unternehmen	6,3	0	0	0
Unternehmen, die zumindest einen Teil ihrer Geschäftsfähig keit aufgeben - %	Unternehmen	0,4%	0%	0%	0%
Gesamtkosten für die Einhaltung der Vorschriften in % des Umsatzes über 40 Jahre (einschließlich Einstellung des Betriebs)	Unternehmen	0,38%	0,09%	0,02%	0,01%
Kosten für die Einhaltung der Vorschriften im ersten Jahr in % des Jahresumsatze s (ohne Einstellung des Betriebs)	Unternehmen	Durchschnitt: 0,4% Bis zu 14,6% (C20.1, C20.3 und C20.5 Chemikalien - kleine Unternehmen)	Durchschnitt: 0,1% Bis zu 0,51% (C20.1, C20.3 und C20.5 Chemikalien - kleine Unternehmen)	Durchschnitt: 0,1% Bis zu 0,33% (M72.1 Laboratorien - kleine Unternehmen)	Durchschnitt: 0,04% Bis zu 0,26% (M72.1 Laboratorien - kleine Unternehmen)
Beschäftigung - verlorene Arbeitsplätze	Arbeitnehmer & Familien	140	0	0	0
Beschäftigung - Soziale Kosten	Arbeitnehmer & Familien	€ 13	€ 0	€ 0	€ 0
Internationale Wettbewerbsfä higkeit	Unternehmen	In einigen Nicht-EU-Ländern würden weniger strenge AGWs und BGWs gelten.			
Verbraucher	Verbraucher	Keine wesentlichen Auswirkungen	Keine wesentlichen Auswirkungen	Keine Auswirkungen	Keine Auswirkungen

Auswir-kungen	Betroffene Stakeholders	7.3 mg/m³ und 45 mg HEAA im Urin /g Kreatinin	20 mg/m³ und 108 mg HEAA im Urin/g Kreatinin	36 mg/m³ und 188 mg HEAA im Urin/g Kreatinin	73 mg/m³ und 366 mg HEAA im Urin/g Kreatinin
Binnenmarkt Niedrigster bis höchster AGW	Unternehmen	7,3 mg/m³ - 7,3 mg/m³	20 mg/m³ -20 mg/m³	20 mg/m³ -36 mg/m³	20 mg/m³ -73 mg/m³
Binnenmarkt Niedrigster bis höchster BGW	Unternehmen	45 - 45 mg HEAA/g Kreati-nin	108 - 108 mg HEAA/g Kreati-nin	188 - 188 mg HEAA/g Kreati-nin	200 - 400 mg HEAA/g Kreat-inin
Spezifische Mitgliedstaaten /Regionen – Mitgliedstaaten , die AGWs ändern müssten	Öffentlicher Sektor	27	25	22	0
Spezifische Mitgliedstaaten /Regionen – Mitgliedstaaten , die BGWs ändern müssten	Öffentlicher Sektor	27	27	27	26
Verordnung	Unternehmen	Eine REACH-Beschränkung der Verwendung von 1,4-Dioxan in Tensiden wird derzeit geprüft.			
Direkte Nutzen – verbessertes Wohlbefinden - Gesundheit					
Geringere Krankheitsfälle (Auswirkungen auf die Nieren)	Arbeitnehmer & Familien	500	0	0	0
Geringere Krankheitsfälle (Auswirkungen auf die Leber)	Arbeitnehmer & Familien	630	0	0	0
Geringere Krankheitsfälle (lokale Reizung der Nasenhöhle)	Arbeitnehmer & Familien	4 400	0	0	0
Krankheitsfälle vermieden, einschließlich immaterieller Kosten (M1 bis M2)	Arbeitnehmer & Familien	€ 2 - 3 million	€ 0 - 0 million	€ 0 - 0 million	€ 0 - 0 million
Direkte Nutzen – verbessertes Wohlbefinden - Sicherheit					
Vermiedene Kosten	Unternehmen	€ 1,6	€ 0	€ 0	€ 0

Auswir-kungen	Betroffene Stakeholders	7.3 mg/m³ und 45 mg HEAA im Urin /g Kreatinin	20 mg/m³ und 108 mg HEAA im Urin/g Kreatinin	36 mg/m³ und 188 mg HEAA im Urin/g Kreatinin	73 mg/m³ und 366 mg HEAA im Urin/g Kreatinin
Vermiedene Kosten	Öffentlicher Sektor	€ 2	€ 0	€ 0	€ 0
Politische Agenda der EU	Alle	Verbesserung der Grundrechte der Arbeitnehmer und Beitrag zum Green Deal: Chemiestrategie für eine giftfreie Umwelt			
Direkte Vorteile - verbessertes Wohlbefinden - Umwelt					
Freisetzungen in die Umwelt	Alle	Möglicherweise eine Verringerung der Emissionen in die Luft, aber unklare Auswirkungen auf die Emissionen in das Wasser		Eingeschränkte oder keine Auswirkungen	Eingeschränkte oder keine Auswirkungen
Direkte Vorteile - Markteffizienz					
Gleiche Ausgangsbedingungen	Unternehmen	Das Verhältnis zwischen dem maximalen und minimalen nationalen AGW beträgt derzeit 3,65. Das Verhältnis zwischen höchstem und niedrigstem STEL liegt bei 2,08. Eine Senkung von AGW und STEL dürfte die Wettbewerbsgleichheit im Binnenmarkt verbessern. Zwei Mitgliedstaaten haben derzeit eine BGW, die beide oberhalb der entsprechenden BGW-Optionen liegen.			Keine Auswirkungen auf den AGW. Nur zwei Mitgliedstaaten haben derzeit einen BGW, von denen einer über und einer unter dieser BGW-Option angesiedelt ist.
Indirekte Nutzen					
Vereinfachung der Verwaltung	Unternehmen	Sollten alle Mitgliedstaaten über einen harmonisierten AGW und BGW verfügen, würde dies den Verwaltungsaufwand für Unternehmen mit Tätigkeiten in mehreren Mitgliedstaaten verringern. Die Mehrheit der untersuchten Unternehmen ist jedoch klein und wird wahrscheinlich nicht multinational tätig sein und von dieser Vereinfachung nicht betroffen sein.			
Synergie	Unternehmen	Bei anderen chemischen Stoffen, die in den Produktionssektoren verwendet werden, kann es zu Synergieeffekten in Bezug auf die Verringerung der Exposition kommen. Die spezifischen Stoffe werden von Sektor zu Sektor unterschiedlich sein. Das Ausmaß der zu nutzenden Synergie hängt auch von den in den einzelnen Unternehmen angewandten Risikomanagementmaßnahmen ab.			
Soziale Verantwortung der Unternehmen	Unternehmen	Die Arbeit mit 1,4-Dioxan wird möglicherweise weniger als riskanter und gesundheitsgefährdender Arbeitsbereich wahrgenommen, insbesondere angesichts der jüngsten Neueinstufung von 1,4-Dioxan als krebserregend 1B. Infolge einer solchen Verbesserung des Images in der Öffentlichkeit kann es für die Unternehmen einfacher sein, Personal einzustellen und zu halten, was die Kosten für die Einstellung senkt und die Produktivität der Arbeitnehmer erhöht.			
Vermiedene Kosten der	Öffentlicher Sektor	€ 5,3	€ 4,4	€ 4,1	€ 4

Auswir-kungen	Betroffene Stakeholders	7.3 mg/m³ und 45 mg HEAA im Urin /g Kreatinin	20 mg/m³ und 108 mg HEAA im Urin/g Kreatinin	36 mg/m³ und 188 mg HEAA im Urin/g Kreatinin	73 mg/m³ und 366 mg HEAA im Urin/g Kreatinin
Festlegung eines AGW					
Other impacts					
Recycling - Verlust von Geschäftsmöglichkeiten		Recycling-Unternehmen		Es werden keine Auswirkungen erwartet.	
Auswirkungen auf die Grundrechte		Alle		Verbesserte Gesundheit am Arbeitsplatz.	
Auswirkungen auf die Digitalisierung		Unternehmen		Es werden keine Auswirkungen erwartet.	
Beiträge zu den UN-Zielen für nachhaltige Entwicklung		Alle		Mögliche Verringerung der Emissionen in die Luft, aber es ist unklar, ob dies nicht zu einem Anstieg der Emissionen ins Abwasser führen würde.	

Quelle: Studienteam. Anmerkungen: Die Summe kann sich aufgrund von Auf- bzw. Abrunden von der Gesamtsumme unterscheiden.

Zu den Kosten der Einhaltung der STEL-Optionen liegen keine Daten vor. In Ermangelung solcher Daten kann davon ausgegangen werden, dass die Einhaltung der AGW-Option auch bedeuten würde, dass die betreffenden Unternehmen einen höheren STEL-Wert einhalten würden. Die Verhältnisse zwischen den STEL und den AGW, die derzeit in den Mitgliedstaaten gelten, die sowohl einen AGW als auch einen STEL haben, sind im Folgenden zusammengefasst.

Tabelle 9 STEL/AGW-Faktoren (gerundet)

Mitgliedstaat(en) oder Quelle	STEL/AGW-Verhältnis
AT, CZ, DE, DK, FR, SI	2
LT, SE	3
FI	4
Stellungnahme des RAC	10

Quelle: Berechnet anhand der Angaben in Tabelle 3 1

Obwohl die Spitzenexposition deutlich höher sein kann als der 8-Stunden-Mittelwert, stützt die Tatsache, dass in mehreren Mitgliedstaaten STEL-Werte gelten, die zwei- bis viermal so hoch sind wie der AGW, die Behauptung, dass die Einhaltung eines AGW von 7,3 mg/m³ wahrscheinlich die Einhaltung eines STEL-Wertes gewährleistet, der zehnmal so hoch ist, d. h. 73 mg/m³. Dies würde bedeuten, dass keine zusätzlichen Kosten zu erwarten sind, wenn ein AGW von 7,3 mg/m³ durch einen der in dieser Studie betrachteten STEL-Werte ergänzt wird, mit Ausnahme zusätzlicher Messkosten in Fällen, in denen die Unternehmen besonders besorgt über bestimmte hochexponierte Tätigkeiten sind.

Obwohl die Kosten für die Einhaltung der verschiedenen BGW-Werte auf der Grundlage der entsprechenden AGW-Werte geschätzt werden könnten, kann nicht ausgeschlossen werden, dass dieser Ansatz die Kosten unterschätzt, die für zusätzliche Reduzierungen der dermalen Exposition erforderlich sind. Es kann nicht ausgeschlossen werden, dass die Berechnungsformel, die in RAC (2022) verwendet wird, um die Luftexposition und HEAA im Urin in Beziehung zu setzen[13], die dermale Aufnahme nicht ausreichend berücksichtigt, so dass in Situationen, in denen es zu einer signifikanten dermalen Exposition (oder einer Aufnahme aufgrund mangelnder Hygiene) kommt, die Einhaltung eines AGW von beispielsweise 7,3 mg/m^3 nicht garantiert, dass der HEAA-Gehalt im Urin/g Kreatinin unter 45 mg liegt. Sollte es keine dermale Aufnahme von 1,4-Dioxan geben, wären die Kosten für Risikomanagementmaßnahmen (RMMs), die zur Einhaltung eines BLV erforderlich sind, dieselben wie für die entsprechende AGW-Option, die durch die Gleichung in RAC (2022) bestimmt werden kann.

Jede Art von direktem Kontakt kann zu einer dermalen Exposition führen: Spritzer, Berührung kontaminierter Gegenstände oder Oberflächen. Der hohe Dampfdruck von 1,4-Dioxan führt zu einem geringeren Potenzial, mit kontaminierten Oberflächen/Objekten in Kontakt zu kommen, und auch zu einem geringeren Potenzial für eine Hautexposition beim Ausziehen der Handschuhe. Wenn ein BGW überschritten wird, kann dies auf eine inhalative und/oder dermale Exposition zurückzuführen sein. Handschuhe und möglicherweise andere schützende persönliche Schutzausrüstung (PSA) wie Kleidung und Schürzen können die Exposition der Haut auf ein vernachlässigbares Maß reduzieren, wenn sie ordnungsgemäß verwendet werden. Diese zusätzlichen Kosten können nicht beziffert werden.

Darüber hinaus werden die Kosten für das Biomonitoring auf 122,87 Mio. € über 40 Jahre für die BGW-Option von 45 mg HEAA im Urin /g Kreatinin geschätzt (oder weniger für die anderen BGW-Optionen).

Wenn bei einem Arbeitnehmer einen BGW von 45 mg HEAA im Urin/g Kreatinin einhalten wird, ist die Verringerung der Gesundheitsschäden größer als bei einem AGW von 7,3 mg/m^3. Für die Reizung der Nasenhöhle ist es möglich, dass es keine zusätzliche Verringerung gibt, aber für die Auswirkungen auf Nieren und Leber ist eine zusätzliche Verringerung zu erwarten. Es liegen jedoch keine ausreichenden Informationen vor, um diese zusätzlichen Verringerungen zu quantifizieren.

[13] In einer der drei Studien, die dieser Funktion zugrunde liegen (Young 1976), wurden Arbeitende in einem Chemiewerk getestet. Das Ausmaß der dermalen Exposition ist nicht klar. Die beiden anderen Studien betrafen die inhalative Exposition von Freiwilligen.

1 INTRODUCTION

This chapter comprises the following sections:

- Section 1.1: Political and legal context
- Section 1.2: Background
- Section 1.3: The study.

1.1 Political and legal context

1.1.1 The Carcinogens, Mutagens and Reprotoxic substances Directive

The Carcinogens, Mutagens and Reprotoxic substances Directive (Directive 2004/37/EC), hereinafter the CMRD, protects workers from exposure to carcinogens, mutagens or reprotoxic substances at work.

Substances within the scope of the directive are substances that meet the criteria for classification as category 1A or 1B carcinogen, mutagen or reproductive toxicant as set out in set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (CLP). Substances that meet the criteria may either have a harmonised classification and listed in Annex VI to the CLP or they may have been classified by the registrant's self-classification under REACH and listed in the Classification and Labelling Inventory (C&L Inventory) at ECHA's website.

1,4-dioxane is today within the scope of the CMRD due to the fact that it is now classified as a category 1B carcinogen.

As a consequence, employers' have today a number of obligations related to 1,4-dioxane within the scope of the Directive which include:

- The employer shall reduce the use of the substances at the place of work by replacing them, in so far as is technically possible, with substances, mixtures or process(es) which, under their conditions of use, are not dangerous or is less dangerous to workers' health or safety, as the case may be.
- Where it is not technically possible to replace the substance, the employer shall ensure that the substances are, in so far as is technically possible, manufactured and used in a closed system.
- Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers to the substances is reduced to as low a level as is technically possible.
- Where it is not technically possible to use or manufacture a threshold reprotoxic substance in a closed system, the employer shall ensure that the risk related to the exposure of workers to that threshold reprotoxic substance is reduced to a minimum.

The requirements for minimisation of the exposure apply today to 1,4-dioxane within the scope of the directive irrespective of establishing an OEL.

The minimum requirements for protecting workers that are exposed to carcinogens and mutagens are, for some substances, expressed by an Occupational Exposure Limit (OELs). For each OEL, Member States (MS) are required to establish a corresponding national limit value (OEL), from which they can only deviate to a lower but not to a higher value.

An OEL express the concentration of the relevant substance in the air within the breathing zone of a worker in relation to a specified reference period as set out in Annex III to the CMRD.

Of importance for the current assessment, in the case of any activity likely to involve a risk of exposure to 1,4-dioxane within the scope of the Directive, the nature, degree and duration of workers' exposure shall be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken. The assessment shall be renewed regularly and, in any event, when any change occurs in the conditions which may affect workers' exposure to the substances.

To determine the degree of exposure it would typically be necessary to measure the workplace concentrations. It should be noted that measurements of workplace concentrations are not specifically linked to the assessment of compliance with an OEL. The assessment shall be renewed regularly, but the CMRD does not require regular monitoring if changed in the conditions which may affect workers' exposure to the substances does not occur.

1.1.2 REACH

The substances within the scope of the study are subject to the requirements for registrations under the Regulation on the registration, evaluation, authorisation and restriction of chemicals (REACH).[14] For some intermediate uses, the use is further described in section 3.9.

Chemical Safety Reports (CSRs). As part of the registration processes for the substances within the scope of the study, companies have prepared CSRs which among others include an assessment of occupational exposure and environmental exposure.

Classification and Labelling Inventory (C&L Inventory). This database contains classification and labelling information on notified and registered substances received from manufacturers and importers (self-classification) as well as harmonised classifications as listed in the CLP. Companies have provided this information in their C&L notifications or registration dossiers. Where there is a difference in the classification and labelling of the substance between potential registrants, the obligatory Substance Information Exchange Forums (SIEF) shall agree on the classification and labelling. For substances without harmonised classification, the self-classifications are used as basis for the human health hazard assessment undertaken as part of the REACH registration process.

1.1.2.1 Restrictions

There are currently no entries for 1,4-dioxane in Annex XVII of REACH. However, a call for evidence by the German Federal Institute for Occupational Safety and Health (BAuA) was open until 20 July 2023 on a potential Annex XV restriction on the manufacture, placing on the market and use of 1,4-dioxane in surfactants, motivated by the need to prevent environmental emissions of 1,4-dioxane. The expected date of submission of the restriction proposal is 2024.

[14] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

1.1.2.2 Authorisation

In 2021, 1,4-dioxane was included in the Substances of Very High Concern (SVHC) Candidate List for Authorisation according to REACH Art. 57 (a) and 57 (f), with this triggering substitution and information requirements.

1.1.2.3 Possible REACH revisions (optional)

No information identified.

1.1.2.4 Risk management option analysis

A Risk Management Option Analysis (RMOA) was completed by Germany in 2020 to assess regulatory options following the change of harmonised classification from C2 to C1B. It was concluded that a potential identification as SVHC and a potential Annex XV restriction were to be considered. As regards occupational exposure, it was noted that:

> *The currently valid IOELV turned out to be obsolete and should not be used from now on as basis for risk assessment. In light of the upcoming Carc. 1B classification the provisions of CMD become relevant and a BOELV should be derived.*

1.1.3 Other relevant legislation

1,4-dioxane is listed in Annex II of Regulation (EC) No 1223/2009 on cosmetic products. According to the Scientific Committee on Consumer Safety (SCCS), the acceptable trace level in cosmetic products is 10 ppm.

1.2 Background

1.2.1 Initiatives by European Commission

Commission Regulation (EU) 2021/849 changed the classification of 1,4-dioxane from Carc. 2 to Carc. 1B, resulting in the inclusion of 1,4-dioxane into the scope of the CMRD from 17 December 2022. 1,4-dioxane is also classified as an eye irritant 2 and STOT SE3 (Specific target organ toxicity - single exposure 3).
As a result of the recent reclassification, the potential additional limit value(s) would be enacted under the CMRD.

1.2.2 Opinion of the Committee of Risk Assessment (RAC)

On the 18 March 2022, the Committee for Risk Assessment (RAC) adopted its opinion on the scientific evaluation of occupational exposure limits for 1,4-dioxane, which is summarised in Table 1-1.

Table 1-1 The outcome of the RAC evaluation to derive limit values for 1,4-dioxane and the evaluation for dermal exposure and suggested notations (ECHA, 2022)

Derived limit value	Concentration / notation
Occupational exposure limit value (OEL) - 8-hour time weighted average (TWA)	7.3 mg/m³ (2 ppm)
Short term exposure limit (STEL)	73 mg/m³ (20 ppm)
Biological limit value (BLV)	45 mg 2-hydroxyethoxyacetic acid/g creatinine
Biological guidance value (BGV)	-

Derived limit value	Concentration / notation
Notations	
Notations	A skin notation is proposed

The key conclusions of the RAC evaluation are used as starting points for the health assessment and further described in Chapter 2.

Selected key conclusions of the evaluation are (ECHA, 2022):

- Nephro- and hepatotoxicity (considered for TWA);
- Respiratory tract irritation (nasal pre-neoplastic lesions considered for STEL);
- Cancer (clear evidence in animals, most likely indirect DNA damage, clastogenicity);
- Liver tumours by regenerative proliferation ;
- Only above saturation levels (humans 180 mg/m³) and
- No Exposure-Risk Relationship (ERR) provided by RAC

1.2.3 Scientific Committee on Occupational Exposure Limits (SCOEL)

Not relevant. The most recent scientific evaluation is by RAC (ECHA, 2022).

1.2.4 Advisory Committee on Safety and Health at Work (ACSH)

The ACSH has in its opinion on priority chemicals for new or revised occupational exposure limit values under EU OSH legislation from 2021 listed 1,4-dioxane as a priority carcinogen under the CMRD (immediate priorities) (ACSH, 2021). In September 2023, the ACSH adopted an opinion on an OEL, STEL, BLV and skin-notation for 1,4-dioxane (see Section 14.6).

1.3 The study

This report is one of six reports elaborated within the framework of a study undertaken for the European Commission by a consortium comprising RPA Risk & Policy Analysts (United Kingdom), RPA Prague (Czech Republic), RPA Europe (Italy and Lithuania), COWI A/S (Denmark) and FoBiG Forschungs- und Beratungsinstitut Gefahrstoffe (Germany). The six reports are:

- Methodological note;
- Report for 1,4-dioxane;
- Report for isoprene;
- Report for polycyclic aromatic hydrocarbons (PAH);
- Report for welding fumes; and
- Report for cobalt and inorganic cobalt compounds

One of the key aims of the study is to provide the Commission with the most recent, updated and robust information on a number of substances with the view to support the European Commission in the preparation of an Impact Assessment report to accompany a potential proposal to amend Directive 2004/37/EC.

The specific objective of this report is to assess the impacts of introducing an OEL for 1,4-dioxane under the scope of the CMRD.

Details on the methodology used across all substances are included in the Methodological note. The note also includes an initial screening of potential impacts for all impact categories.

1.3.1 Study objectives

One of the key aims of the study is to provide the Commission with the most recent, updated and robust information on a number of carcinogenic substances with the view to support the European Commission in the preparation of an Impact Assessment Report to accompany a potential proposal to amend Directive 2004/37/EC.

The general objectives with regard to these substances (except for welding fume) include a detailed assessment of the baseline scenario (past, current, and future), as well as the assessment of the impacts of introducing a new Occupational Exposure Limit (OELV) and, where appropriate, a Short-Term Exposure Limits (STEL), Biological Limit Value (BLV) and a skin notation and a respiratory notation.

The specific objective of this report is to assess the impacts of a potential OEL, STEL, BLV and skin notation for 1,4-dioxane.

1.3.2 Limit values assessed

Throughout this document the term 'Limit Values' is used to refer to the group of measures being proposed. This includes OELs, STELs, BLVs and notations.

OELs are 8-hour time weighted average (TWA) exposures and define a threshold beyond which workers must not be exposed. OELs are set by the European Commission. For each OEL, Member States are required to establish a corresponding national limit value, from which they can only deviate to a lower but not a higher value.

In addition to setting/reviewing OELs, the European Chemicals Agency (ECHA) has also been mandated to adopt, as appropriate, scientific opinions on the establishment of:

- STELs;
- biological limit values; and
- notations.

A 'biological limit value' (BLV) is 'the limit of the concentration in the appropriate biological medium of the relevant agent, its metabolite, or an indicator of effect'.

A 'notation' is a means of alerting employers that air sampling alone is insufficient to accurately quantitate exposure and that other measures may need to be taken. For example, a 'skin notation' would indicate that measures need to be taken to prevent significant absorption through the skin.

Furthermore, in cases where adverse health effects are not adequately controlled by compliance with an 8-hour TWA OEL, short-term exposure limit (STEL) values, which are usually based on a 15-minute reference period, can also be established.

1.3.3 Existing limit values at EU level

Today, no limit value for 1,4-dioxane is established under the CMRD but Commission Directive 2009/161/EU4 of 17 December 2009 establishing a third list of indicative occupational exposure limit values (IOELVs) in implementation of Council Directive 98/24/EC (CAD) set an indicative IOELV of 73 mg/m3 (20 ppm) for 1,4-dioxane. As noted in RPA (2019), it is common for the majority of EU Member States (78%) to implement IOELVs for reprotoxic substances as binding. Although 1,4-dioxane does not have any classifications for reproductive toxicity, it is expected that the same approach is likely to have been adopted by EU Member States for all IOELVs under the CAD and that the majority of EU Member States thus have a binding OEL for 8-hour TWA exposure to 1,4-dioxane.

1.3.4 Substances within the scope of the study

The scope of the study is 1,4 dioxane (EC No. 204-661-8; CAS No. 123-91-1). A large number of synonyms for 1,4-dioxane is in use, including:

- 1,4-dioxacyclohexane;
- diethylene ether;
- diethylene dioxide;
- [1,4]dioxane;
- Dioxan;
- diethylene oxide;
- dioxane, 1,4-;
- p-dioxane;
- Dioxane;
- dioxyethylene ether; and
- 1,4-diethylene dioxide.

2 BACKGROUND FOR ANALYSING THE HEALTH IMPACTS

This chapter comprises the following sections:

- Section 2.1: Summary of epidemiological and experimental data.
- Section 2.2: Deriving an Exposure Risk Relationship (carcinogenic effects) and a Dose Response Relationship (non-carcinogenic effects).
- Section 2.3: Groups at extra risk
- Section 2.4: Summary of background for analysing health impacts

2.1 Summary of epidemiological and experimental data

The literature on health effects of 1,4-dioxane is reported in detail in the documentation by the Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area of the 'Deutsche Forschungsgemeinschaft' (DFG, German Research Foundation; Hartwig and MAK Commission, 2019) or more recently by the Committees for Risk Assessment RAC (ECHA, 2022a, b). In addition, singular more recent and relevant publications are cited (literature search 1 Dec 2022, limited to the publication years 2021 & 2022). In the current report concise summaries are provided.

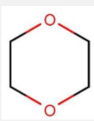
Only limited epidemiological data is available; thus, the assessment and dose-response relationships are based on respective animal data.

2.1.1 Identity and classification

2.1.1.1 Identity

The identification and physico-chemical properties of 1,4-dioxane are described in Table 2-1 below (ECHA, 2022a).

Table 2-1 Identity and physico-chemical properties of 1,4-dioxane (ECHA, 2022a)

Endpoint	Value
IUPAC Name	1,4-dioxane
Synonyms	1,4-dioxacyclohexane; diethylene ether; diethylene dioxide; [1,4]dioxane; dioxan
EC No.	204-661-8
CAS No.	123-91-1
Chemical structure	
Chemical formula	C4H8O2
Appearance	Liquid, colourless

Endpoint	Value
Boiling point	101.2 °C (1013.25 hPa)
Density	1.0336 g/cm³ (20 °C)
Vapour pressure	38.5 hPa (20 °C)
Partition coefficient (log Pow)	-0.42 (20 °C)
Water solubility	completely miscible at 20 °C
Viscosity	1.31 mPa*s (20 °C)
Unit transformation	1 ppm = 3.66 mg/m³ (20 °C) 1 mg/m³ = 0.273 ppm

2.1.1.2 Harmonised classification

Table 2-2 Harmonised classification of 1,4-dioxane according to Annex VI to the CLP Regulation (ECHA, 2022a)

Index No	EC No	Chemical name	CAS No	Hazard class and category	Hazard statement code
603-024-00-5	204-661-8	1,4-dioxane	123-91-1	Flam. Liq.2	H225
				Carc. 1B	H350
				STOT SE 3	H335
				Eye Irrit. 2	H319

Supplementary Hazard Statements Codes: EUH019 (May from explosive peroxides.) and EUH066 (Repeated exposure may cause skin dryness or cracking).
Note: D (i.e. '*Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier must state on the label the name of the substance followed by the words 'non-stabilised'.'*)

2.1.2 General toxicity profile, critical endpoints and mode of action

2.1.2.1 Toxicokinetics

2.1.2.1.1 Absorption

After inhalation administration absorption is rapid. A total of three human volunteer or worker studies are available. For example, 4 male volunteers were exposed to 50 ppm (183 mg/m³) 1,4-dioxane for 6 hours. Within 2 hours blood plasma concentrations increased rapidly, reaching a steady state between 3 and 6 hours after start of exposure. The metabolite reached its peak in blood plasma one hour after end of exposure (ECHA, 2022a, Young et al., 1977).

Experimental studies in rats and mice also indicate rapid and complete absorption after oral exposure (ECHA, 2022a).

Dermal absorption studies on monkeys as well as results from in vitro assays with human skin show a slow and incomplete penetration through the skin. This is mainly attributed to the evaporation of the substances under non-occlusive exposure conditions. Based on the newest data from

Dennerlein et al. (2015) it is however estimated that after non-occlusive exposure of 2,000 cm² skin for 1 hour a maximum amount of 984 mg 1,4-dioxane would be absorbed (penetration rate 0.492 mg/cm²/h), thus indicating significant absorption via the skin (ECHA, 2022a).

2.1.2.1.2 Distribution

From experimental data in animals, it is concluded that the substance is evenly distributed in the body with a slight tendency towards the liver and kidneys, however no experimental data are available for human tissue (ECHA, 2022a).

2.1.2.1.3 Metabolism

The metabolism is rapid and no accumulation occurs. It is mediated through Cytochrome P450-dependent monooxygenases (CYPs, e.g. CYP2E1 or CypB1/2; Dourson et al., 2017). CYP activity in the liver is about the same in rats and in humans, whereas rodents have a higher CYP activity in the lungs than humans, and for kidneys there is no detailed data available (Griem et al., 2002). In the volunteer study mentioned above (4 males, 50 ppm, 6 hours exposure) 99% of 1,4-dioxane was metabolised to 2-hydroxyethoxyacetic acid (HEAA) and was excreted in the urine 6 to 8 hours after beginning of exposure. No saturation was identified in this study (ECHA, 2022a, Young et al., 1977). The transformation to the main metabolite HEAA is linear until saturation (ECHA, 2022a). '*There can also be oxidation of the unbroken ring to produce 1,4-dioxane-2-one, which is in equilibrium with HEAA*' (ECHA, 2022a). Saturation occurs at higher doses (i.e. 30 to 100 mg/kg bw/day in rats and 200 mg/kg bw/day in mice; ECHA, 2022b). Human studies suggest that saturation may also be plausible in humans, as with increasing inhalation concentration urinary HEAA excretion decreases. The saturation level of metabolism in humans is said to be at least 50 ppm (183 mg/m³; ECHA, 2022b).

It is further noted that after repeated exposure 1,4-dioxane can induce its own metabolism, thus the saturation level after single exposure might be lower (ECHA, 2022b).

2.1.2.1.4 Excretion

Excretion of HEAA occurs in large quantities in the urine (main excretion pathway). When given radioactive isotopes to rats, these were measured mostly in urine (mostly HEAA, also minor amount unchanged), but also in exhaled air (unchanged or CO_2). There are no measurements in the faeces for humans, from the animal studies with radioactive isotopes the percentage in feaces is low (~ 1%; ECHA, 2022a).

2.1.2.2 Target organs and key toxicological endpoints

The substance is irritating to the eyes and the respiratory tract and due to its defatting properties causes skin dryness and eventually skin cracking. The main target organs are the respiratory tract (e.g. nasal cavity), liver and kidney, especially after repeated exposure (ECHA, 2022b).

2.1.3 Cancer endpoints – toxicological and epidemiological key studies (existing assessments)

For 1,4-dioxane, there are only a few epidemiological studies available. All of these studies have limitations (i.e. confounding co-exposure to known carcinogens, no or insufficient information on exposure levels) and thus they do '*not allow a conclusion on the carcinogenicity potential of 1,4-dioxane in humans*' (ECHA, 2022b).

An early 2-year carcinogenicity study in rats (exposure on 7 h/d, 5 d/week, to vapours containing 111 ppm, i.e. 400 mg 1,4-dioxane/m³) showed no effects on the target organs (liver and kidney), however the nose as target structure was not examined and clearly the maximum tolerated dose was not achieved (Hartwig and MAK Commission, 2019, Torkelson et al., 1974).

Reliable chronic repeated dose toxicity/carcinogenicity studies in rats with exposure either via inhalation or drinking water identified consistently neoplastic lesions in the liver and the nasal cavity, which were also (if examined) accompanied by pre-and nonneoplastic lesions (for details see section 2.1.5; Kano et al., 2009, Kasai et al., 2009, Kociba et al., 1974, NCI, 1978, ECHA, 2022a, b). Nasal cavity and liver tumours also occurred in mice after drinking water exposure (Kano et al., 2009, NCI, 1978). Other tumour locations identified in the rat studies were '*peritoneum*' (only males)'*, mammary gland and subcutis (both routes) and in the kidney and Zymbal's gland (inhalation only)*' (Kano et al., 2009, Kasai et al., 2009, ECHA, 2022b). Some of these tumour locations are not further considered as relevant for humans: peritoneal mesothelioma found in the mid and high dose group arose from the scrotum, and thus are a species, strain and gender specific finding in F334 male rats. Fibroadenomas of the mammary gland are not considered a premalignant lesion, further to that incidence is slightly elevated, but not statistically significant. This is true also for the kidney and Zymbal gland tumours, incidences of these tumours were elevated in the high dose, yet not statistically significant. The latter being a rat specific organ with no correspondence in humans. Fibroma of the subcutis showed no dose-dependent occurrence in the inhalation study and did not occur at statistically significant incidence in the drinking water study. Further to that this type of tumour in this rat strain has a high spontaneous incidence (6% and more). Usually in such cases with a late onset of a benign tumours in localisations with a high spontaneous incidence rate are most likely due to a growth-promoting effect and thus can be considered as not human relevant (Hartwig and MAK Commission, 2019).

In the drinking water studies, nasal tumours were observed usually only at higher 1,4-dioxane concentrations (0.5%) than liver tumours (0.05%) and also with lower incidence (ECHA, 2022a). RAC outlines, that inhalation exposure while drinking 1,4-dioxane containing water at least contributed to the nasal tumour formation in this type of study (ECHA, 2022a, Sweeney et al., 2008).

The reliable and most relevant study (Kasai et al., 2009) investigated toxicological effects and tumour formation after 2-year inhalation exposure in male F344/duCrj rats. Fifty males per dose group were exposed to concentrations of 0, 50, 250 and 1250 ppm (0, 180, 900, 1800 mg/m³, whole body) 1,4-dioxane for 6 h per day, on 5 days per week for 104 weeks. The details on general systemic effects and pre- and nonneoplastic lesions are provided in section 2.1.5. of this report. The human and thus assessment relevant neoplastic findings in the high dose group were squamous cell carcinoma in the nasal cavity, hepatocellular adenoma, and a slight, statistically yet not significant increase in the incidence of renal cell carcinoma. Renal cell carcinoma was considered relevant despite being not a significant finding, as the kidney is one of the known target organs (ECHA, 2022b).

2.1.3.1 Mode of action (MoA)

With respect to **mode of action** RAC notes:

'*The mode of action (MoA) leading to tumour formation is not fully resolved. There are potentially a variety of ways in which 1,4-dioxane could induce cancer, given the various tissue sites where it was experimentally seen to have induced tumours in animals.*'

and

'*Although 1,4-dioxane may have genotoxic potential, and therefore could be considered a genotoxic carcinogen, there is evidence for indirect DNA damage (from oxidative stress) as the main mechanism in tumour formation*[15]*. Also, cytotoxicity, irritation and inflammation appear to be associated with tumour formation, e.g. in the nasal epithelium and liver. These thresholded mechanisms support a non-linear dose-response relationship*' (ECHA, 2022b).

The latest MAK commission documentation also stated that '*the primary mode of action is non-genotoxic and genotoxic effects play no or at most a minor part at cytotoxic doses*' (when exceeding the DNA repair capacity; Hartwig and MAK Commission, 2019).

The **nasal tumours** identified at high doses are mechanistically attributed to cytotoxicity, inflammation, regenerative cell proliferation and hyperplasia starting already at lower doses (Hartwig and MAK Commission, 2019, ECHA, 2022b).

'*Systemic toxicity (**liver tumours**) is considered to occur only after saturation of metabolism, which is shown in some animal studies (Young et al., 1978a/b; Sweeney et al., 2008; Dietz et al., 1982). For example, Sweeney et al. (2008) observed saturation above 200 mg/kg bw. Dourson et al. (2014; 2017) proposed a regenerative hypoplasia mode of action model with four steps as follows:*

1. metabolic saturation and consequently accumulation of 1,4-dioxane.

2. Liver hypertrophy

3. Hepatocellular cytotoxicity

4. Regenerative cell proliferation leading to liver tumour formation.'

Recently published evidence (Chappell et al., 2021, Lafranconi et al., 2021) further supports this hypothesis identifying a mitogenic response upon 1,4-dioxane exposure (also preceding cytotoxicity and regenerative hyperplasia; ECHA, 2022b).

The underlying mechanism leading to **kidney tumour** formation is less well investigated. One study however identified that CYP2E1 induced after chronic 1,4-dioxane exposure can lead to higher exposure to reactive oxygen species (ROS) in the kidney, this could potentially promote tumour formation (Hartwig and MAK Commission, 2019, Nannelli et al., 2005).

2.1.4 Genotoxicity

As pointed out in the section above, genotoxicity might contribute to tumour formation observed at higher doses, however is most certainly not the lone MoA. Below available data investigating the genotoxic potential of 1,4-dioxane is summarised.

No chromosomal aberration was observed in peripheral lymphocytes of 6 workers exposed to 1,4-dioxane at unspecified levels for 6 to 15 years (Thiess et al., 1976). The increased level of chromosomal aberration observed in a later study with workers exposed for over 20 years to alkylene oxides including 1,4-dioxane cannot be used for the assessment as co-exposure to known mutagens cannot be excluded (Thiess et al., 1981). Overall, these studies are insufficient to address

[15] Comment by the author of this report: for further details on experimental data related to genotoxicity see section 2.1.4

genotoxic potential of 1,4-dioxane due to their size and unknown exposure conditions, including concurrent exposure to known mutagens.

Considering animal testing, no reliable studies using germ cells are available.

When somatic cell mutagenicity was investigated the micronucleus studies showed mixed results. In most of these studies, no data on cytotoxicity were given, which makes a correct interpretation of the results difficult. In addition, dose levels used were above the suggested limit dose. Secondly, the differences in the results of the individual studies could (at least in part) be explained by using a small number of animals, different dosing regimens and test methods. '*Nevertheless, statistically significant dose-related positive findings were observed in micronuclei in bone marrow at doses below the limit dose of 2000 mg/kg bw' (Mirkova, 1994, Roy et al., 2005)', indicating that 1,4-dioxane may have genotoxic potential*' (ECHA, 2022a). No unscheduled DNA synthesis was observed when investigating rat liver and nasal epithelial cells and no induction of DNA alkylation was identified in another study in rats. *'Further, a study on the measurement of DNA alkylation in liver cells, and the measurement of cell proliferation by the replicative DNA synthesis assay in two studies were negative.*' (ECHA, 2022b) Yet a dose-dependent increase in DNA single-strand breaks at high doses in rats was found using the Comet assay. A newer subchronic study using a transgenic rat model (guanine phosphoribosyl transferase (*gpt*) delta) showed increased mutation frequency (dose-dependent mutagenic potency) in the liver without cytotoxicity, and increased mRNA gene expression related to cell proliferation, and DNA repair. GST-P positive foci (pre-neoplastic lesions thus mutagenic response) and increased cell proliferation was observed also in wild-type F344 rats at ≥222 and 560 mg/kg bw/day, respectively (with the high dose being above the DNA repair capacity) (Gi et al., 2018). Frozen liver samples of the wild-type F344 rats were analysed and results reported later showed an increase in DNA adducts, especially 8-oxo-dG (indicative of oxidative stress). In another in vivo micronucleus test, genotoxicity was found in the liver at ≥2,000 mg/kg bw, but not in the bone marrow (i.e. clastogenic effect in liver). Within the same publication, results of a Pig-a gene mutation assay in rat peripheral blood are provided and showed negative results. When gene expression profiles (11 marker genes in liver cells) of known genotoxic and non-genotoxic hepatocarcinogens were compared to the profile of 1,4-dioxane, this was distinct from both (intermediate profile). In another study, using wild-type or glutamate cysteine ligase modifier subunit (*Gclm*) knock-out mice models (more sensitive to oxidative stress, due to lower levels of glutathione (GSH)) significant differences were observed after 1,4-dioxane exposure, e.g. upregulation of genes involved in anti-oxidative response. It was concluded that genotoxicity in the liver is mediated through oxidative stress (by redox dysregulation) and thus '*could be a candidate mechanism of 1,4-dioxane liver carcinogenicity*' (ECHA, 2022a).

The ECHA scientific report, which is the basis for RACs opinion on 1,4-dioxane, was published in September 2021. In a literature search for the current project covering the years 2021 and 2022 two relevant studies were identified and thus are reported in more detail here.

In one study female BDF-1 mice were exposed to 1,4-dioxane at 0, 50, 500 or 5,000 mg/l in drinking water for either one or four weeks. Using various techniques like histopathology, transcriptomics, and metabolomics the investigators found signs for DNA damage and repair (e.g. H2AXγ high indicating DNA double strand breaks; expansion of precholangiocytes). Liver transcriptomics results indicated that cell signalling of oxidative stress response, detoxification actions and DNA damage were affected, whereas no effects were seen on metabolomic profiles of liver, kidney, faeces and urine. For the authors this indicates that there was a counterbalance between DNA damage and repair response after 1,4-dioxane exposure (Charkoftaki et al., 2021).

In another study, *Drosophila melanogaster* was used as test subject to determine mutagenicity and genotoxicity. The test subjects were exposed to either 0.1, 0.25, 0.5, or 1% of 1,4-dioxane (no further details), distilled water (solvent control) or ethyl methanesulfonate (EMS, as positive control). At nontoxic concentrations a mutagenic (1%) and recombinogenic (0.1, 0.25, or 0.5%) response was observed in wing spot test (somatic mutation and recombination test (SMART)) and genotoxicity in haemocytes using comet assay. Further to that reactive oxygen species (ROS, indicative of oxidative stress) were significantly increased at all concentrations. In additional there was concentration-dependent abnormal climbing behaviour, thermal sensitivity and some phenotypic alterations observed in all concentration groups (Turna Demir, 2022).

In vitro genotoxicity assays gave negative test results (i.e. six reverse mutation tests on bacterial cells, three gene mutation tests, one micronucleus test and two chromosome aberration tests on mammalian cells, two unscheduled DNA synthesis assays, two sister chromatid exchange assays (one positive without cytotoxicity information), one DNA damage assay and one aneuploidy assay with yeast). At cytotoxic concentrations 1,4-dioxane gave a positive response in an assay indicative of DNA damage (i.e. single strand breaks, Comet assay; Hartwig and MAK Commission, 2012, ECHA, 2022b).

CONCLUSION

'*The positive results above the limit dose may be due to cytotoxicity, leading to the induction of cell proliferation. The positive results found in the tests measuring replicative DNA synthesis as a marker for cell proliferation would confirm a* ***non-genotoxic mode of action****. However, since*' statistically significant dose-dependent '*positive results in the micronucleus tests are found at doses below the limit dose of 2000 mg/kg bw a genotoxic mechanism as a secondary mode of action cannot be excluded*' (ECHA, 2022a, b)[16]. In one study for example it was shown that '*mutagenic effects were observed only after the DNA repair capacity was exceeded*' (Gi et al., 2018).

With that in mind the most '*recent studies confirm the possibility that 1,4-dioxane might have some genotoxic potential, involving DNA damage, cytotoxicity and oxidative stress. However, this is reported at doses higher than tumours are reported. In general, substances that cause tumours at multiple tissue sites most commonly have a DNA-reactive MoA. The question in the case of 1,4-dioxane would be whether DNA adduct formation is a consequence of oxidative stress or occurs via direct DNA binding.* ***Overall, there might be more clues to indirect genotoxicity via cytotoxicity and oxidative stress***' (ECHA, 2022b).

In conclusion for carcinogenicity and genotoxicity RAC states '*Although some uncertainty on the mode of action remains, the carcinogenicity of 1,4-dioxane is considered to be related to a non-genotoxic mechanism, involving saturation of metabolic capacity, irritation at high exposure levels and formation of liver tumours by regenerative proliferation. Even though a mode of action-based threshold is assumed for the carcinogenic effects of 1,4-dioxane, some uncertainties with regard to residual cancer risk remain. However, the level of uncertainty is considered to be low, in view of the evidence that only above saturation levels of metabolism (which in humans is above 180 mg/m^3; EU, 2002) are tumours formed.*' (ECHA, 2022b).

[16] referenced publications are Mirkova, 1994 and Roy et al., 2005

2.1.5 *Non-cancer endpoints – toxicological and epidemiological key studies (existing assessments)*

'*At least three human studies, including a total of seven fatalities, reported cases following occupational inhalation exposure to 1,4-dioxane. No or limited information were available about levels and duration of exposure*' (in one case e.g. between 761-2380 mg/m³) '*, and potential co-exposures to other workplace chemicals. The main reported target organ effects were liver and kidney necrosis, haemorrhagic nephritis and epigastric pain. The available information on acute dermal toxicity is limited to one case report where potential confounding factors where not addressed.*' Acute animal studies revealed only low acute systemic toxicity (all exposure routes; ECHA, 2022a).

'*1,4-dioxane did not show sensitisation properties on a Guinea-Pig Maximization Test. The human data are too limited to draw conclusions*' (ECHA, 2022a).

'*No reproductive toxicity effects were observed in rats and mice after administration of 1,4-dioxane. However, 1,4-dioxane was studied on generation studies only as stabiliser for 1,1,1-trichloroethane. The human studies do not allow to conclude on potential effects on reproductive toxicity*' (ECHA, 2022a).

Assessment relevant endpoints, e.g. local respiratory irritation and systemic effects observed after repeated exposure with 1,4-dioxane are presented in more detail below.

2.1.5.1 Local effects – Irritation (short term exposure)

In a volunteer study three healthy males and three healthy females were exposed to '*step-wise increasing exposure levels of dioxane vapours, starting with 1 followed by 2, 5, 10, and 20 ppm (3.6, 7.2, 18, 36, 72 mg/m³). Each step level lasted for 10 min. At each level, the subjects performed symptom ratings*' according to a standardised assessment method, i.e. the visual analogue scale (VAS). No effects were noted by the participants of this study. Based on these results concentration levels for the main study were chosen. Here six healthy males and six healthy females were exposed for 2 hours twice at an interval of at least 2 weeks at rest to vapours containing either 0 or 20 ppm 1,4-dioxane. Before, during and after exposure the volunteers again rated 10 symptoms according to the VAS. Further effect measurements included blink frequency, pulmonary function and nasal swelling (before exposure, at 0 and 3 hours after exposure), and inflammatory markers in plasma (before and 3 hours after exposure). As none of these measurements significantly changed due to the 1,4-dioxane exposure, the No Observed Adverse Effects Concentration (NOAEC) of this study is 20 ppm (73 mg/m³; Ernstgård et al., 2006).

In the toxicokinetic study with 8-hour exposure (with a 45 minute break) either at rest or under slight physical activity no irritative effects were noted a the exposure concentration of 20 ppm (Göen et al., 2016, Hartwig and MAK Commission, 2019).

In the toxicokinetic study with 6-hour exposure of 4 volunteers at rest to 50 ppm (183 mg/m³) 1,4-dioxane, eye irritation was complained about throughout the exposure (Young et al., 1977).

Older human volunteer studies support these findings; however, they do not meet today's standards (e.g. exposure concentration not verified). These studies mostly with higher exposure concentrations (up to 2,000 ppm, 7,320 mg/m³) for shorter exposure durations (starting from 1 minute to 15 minutes) showed **that 20 ppm is generally acceptable to humans**, but higher concentrations e.g. ~ 300 ppm even at short term exposure typically result in irritation in eyes, nose and throat (ECHA, 2022a).

There is one reliable animal study supporting the human data mentioned above that 1,4-dioxane has irritating effects. An acute inhalation study in rats also supported the findings in humans, indicating respiratory irritation elicited by 1,4-dioxane. Older investigations with inhalation exposure of various species also support these substance characteristics of being irritating to mucous membranes of the nose and the eye but used higher exposure concentrations.

Concerning the skin, 1,4-dioxane elicits only a slight skin irritating effect, however as a fat removing solvent it is able of damaging the skin due to a defatting effect.

2.1.5.2 Systemic effects after repeated exposure

In an occupation mortality study (Texas, USA), a cohort study (Germany) and a retrospective epidemiological study (textile workers) no clear toxicity emerged, mostly due to the limited quality of these studies.

Assessment thus is based on the most suitable animal studies. In general, the main target organs in these studies were the kidneys, the liver (inhalation and drinking water exposure) as well as the respiratory tract (inhalation and some drinking water studies). In some drinking water studies, the skin or the stomach were also affected. For an overview of the plethora of these studies please see the RAC supporting document (2022a) or the German MAK commission documentations (Hartwig and MAK Commission, 2012, 2019).

The relevant data of the study used as basis for the OEL proposal by RAC and also for the derivation of DRRs in the current report is described in more details as well as accompanying studies that will further help the discussion. These studies include some 13-week toxicity studies in rats and mice (Kano et al., 2008, Kasai et al., 2008) as well as the 2-year carcinogenicity studies in rats and mice (Kano et al., 2009, Kasai et al., 2009).

In the 13-week inhalation study male and female F344/DuCrj rats were exposed to vapours containing 0, 100, 200, 400, 800, 1600, 3200, or 6400 ppm 1,4-dioxane for 6 h/d and 5 d/week. High dose animals died during the first week of exposure (marked necrosis in renal tubules and consequently deaths primarily caused by renal failure). The remaining animals showed no clinical signs. Terminal body weight was decreased in some groups not dose-dependently (males: 200 and 800 ppm; females: 200, 800 ppm and above), and the relative organ weights of liver, kidney and lungs were increased (for details see original publication). Other relevant findings identified in the remaining groups were: in the 3200 ppm group some erythrocyte parameters were slightly increased as well as elevated levels of transaminases in liver (males: ALT at 3200 ppm; females: ALT at 3200 ppm, AST at 200 and 320 ppm; for further effects please see original publication). Histopathological findings in this study are in the kidneys in female animals at 3200 ppm in the upper and lower respiratory tract as well as the liver (single-cell necrosis and centrilobular swelling of hepatocytes[17]) in both males and females. '*Glutathione S-transferase placental form (GST-P) positive liver foci (a preneoplastic lesion in rat hepatocarcinogenesis) were observed in the 1600 ppm exposed females and 3200 ppm exposed males and females*' (ECHA, 2022a). The most sensitive lesion, i.e. nuclear enlargement of nasal respiratory epithelial cells and the other lesions that occurred in the nasal cavity are described in more detail in Table 2-3 (Kasai et al., 2008).

For the 2-year carcinogenicity study only male F344/duCrj rats were exposed to 0, 50, 250, or 1250 ppm 1,4-dioxane for 6 h/d and 5 d/week. '*Survival was statistically decreased from week 91*

[17] Metabolising/activating cytochrome P450 localised predominantly perivenous, thus centrilobular liver cell necrosis mechanistically plausible.

*at the high dose and was attributed to tumours formation. In the high dose group, decrease in body weight, statistically significant increase in relative liver and lung weights were observed, as well as changes in clinical chemistry and haematology[18]. In all treated groups, changes on the olfactory epithelium in the form of significant increase in nuclear enlargement, atrophy and respiratory metaplasia were observed. In the high dose group, significant increases of **liver lesions** and changes in the proximal tubule of the kidney were recorded, while significant **nuclear enlargement of the proximal kidney tubule** were observed in the mid and high dose groups*' (ECHA, 2022a). Please note that the changes in the nasal cavity are detailed in Table 2-3 and the dose response data for DRR relevant effects in liver and kidney of the Kasai et al. (2009) study are described in more detail in the respective sections 2.2.3.1 and 2.2.3.2 of this report.

'*Kano et al. (2008) administered 1,4-dioxane to both Crj:BDF1 mice and F344/DuCrj rats for 13 weeks at doses of 0, 640, 1600, 4000, 10,000 and 250,00 ppm in drinking water. Dose dependent decrease of food, water consumption and consequently of body weight was reported in all rodents. As in the previous studies the affected organs were respiratory tract, liver and kidneys, which was established as change in relative weight (kidney and lung in rats and mice and liver in rats) and further investigated histopathologically*' (Kano et al., 2008, ECHA, 2022a).

Kano et al. (2009) reports the results of 2-year continuous administration of 1,4-dioxane in the drinking water to Crj:BDF1 mice and F344/DuCrj rats (50 male and female animals of each species). Rats were exposed to 0, 200, 1,000, and 5,000 ppm this corresponds to 0, 11, 55, 274 mg/kg bw/d for males and 0, 18, 83, and 429 mg/kg bw/d for females. Starting from the mid dose group 1,4-dioxane dose-dependently induced nuclear enlargements of the olfactory epithelium as most sensitive endpoint (statistical significance was reached for females only). In the high dose group effects on the respiratory epithelium were observed as well (for details please see Table 2-3). The No Observed Adverse Effects Level (NOAEL) is 11 and 18 mg/kg bw/d for male and female rats, respectively. The systemic NOAEL is 83 mg/kg bw/d as in the high dose group body weight and body weight gain was decreased, and relative liver weights were increased, and survival was significantly decreased (due to increasing death rates induced by nasal tumours and peritoneal mesothelioma in males and nasal and hepatic tumours in females). Mice were exposed to 0, 500, 2,000 and 8,000 ppm, which correspond to 0, 49, 191, 677 mg/kg bw/d for males and 0, 66, 278, and 964 mg/kg bw/d in females. Starting from the mid dose group body weight and body weight gain decreased, relative liver weights increased in males, and survival decreased in females (due to increased number of deaths attributed to hepatic tumours). In the high dose feed and water intake were reduced and relative liver weights were also increased in females. The drinking water application results in a statistically significant increase in the incidence of hepatocellular adenomas and carcinomas in both sexes, starting in females at the lowest dose of 49 mg/kg bw/d (see section 2.1.3). Therefore, no NOAEL for mice can be derived.

[18] High dose group: significant decreases in haemoglobin, mean corpuscular volume (MCV), and mean corpuscular haemoglobin (MCH). Aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), and γ-glutamyltranspeptidase (γ-GTP) were significantly increased. Urinary pH was significantly decreased.

Table 2-3 Dose-response data for lesions in the nasal cavity of rats from various studies

Kasai et al. 2008, 13-week inhalation study (ppm); male and female F344 rats, n = 10.							
Lesions in the nasal cavity	**0**	**100**	**200**	**400**	**800**	**1600**	**3200**
Male							
Nuclear enlargement: resp. epithelium	0	7* (1+)	9* (1+)	7* (1+)	10* (1+)	10* (2+)	10* (2+)
Nuclear enlargement: ol. epithelium	0	0	5* (1+)	10* (1+)	10* (1+)	10* (2+)	10* (2+)
Vacuolic change: ol. epithelium	0	1 (1+)	3 (1+)	6* (1+)	10* (1+)	10* (1+)	9* (1+)
Females							
Nuclear enlargement: resp. epithelium	0	5* (1+)	9* (1+)	10* (1+)	10* (1+)	10* (2+)	10* (2+)
Nuclear enlargement: ol. epithelium	0	2 (1+)	6* (1+)	10* (9:1+; 1:2+)	10* (1+)	10* (7:2+; 3:3+)	10* (2+)
Vacuolic change: ol. epithelium	0	1 (1+)	2 (1+)	3 (1+)	7* (1+)	9* (1+)	10* (1+)

Kasai et al. 2009, 2-year inhalation study (ppm); male F344 rats, n = 50				
Lesions in the nasal cavity [19]	0	50	250	500
Respiratory epithelium				
- Nuclear enlargement	0	50*	48*	38*
- Squamous cell metaplasia	0	0	7*	44*
- Squamous cell hyperplasia	0	0	1	10*
- Inflammation	13	9	7	39*
Olfactory epithelium				
- Nuclear enlargement	0	48*	48*	38*
- Atrophy	0	40*	47*	48*
- Respiratory metaplasia	11	34*	49*	48*
- Inflammation	0	2	32*	34*

Kano et al. 2008, 13-week drinking water study (ppm); male and female F344 rats, n = 10						
Lesions in the nasal cavity	0	640	1600	4,000	10,000	25,000[a]
Male						
Nuclear enlargement: resp. epithelium	0	0	9* (1)	10* (2)	9* (2)	10* (2)
Nuclear enlargement: ol. Epithelium	0	0	0	10* (1)	9* (1)	10* (2)
Female						
Nuclear enlargement: resp. epithelium	0	0	5* (1)	10* (1)	10* (1)	8 *(1)
Nuclear enlargement: ol. Epithelium	0	0	0	9* (1)	10* (1)	8* (1)

Kano et al. 2009, 2-year drinking water study (ppm); male and female F344 rats, n = 50				
Lesions in the nasal cavity	0	200	1,000	5,000
Doses in mg/kg bw/d for m/f as calculated by RAC	0	11/18	55/83	274/429
Male				

[19] Please note that in this study even more effects on the nose are reported, but they only reach significance at the mid dose and high dose. Thus, in this table for this study the most severe effects reaching significance already at the lowest exposure concentration and such effects that also reached significance in the 2-year drinking water study are reported. For further effects please see the original publication of the study.

Kasai et al. 2008, 13-week inhalation study (ppm); male and female F344 rats, n = 10.							
Lesions in the nasal cavity	**0**	**100**	**200**	**400**	**800**	**1600**	**3200**
Respiratory epithelium							
- Nuclear enlargement	0	0		0		26*	
- Squamous cell metaplasia	0	0		0		31*	
- Squamous cell hyperplasia	0	0		0		2	
Olfactory epithelium							
- Nuclear enlargement	0	0		5		38*	
Female							
Respiratory epithelium							
- Nuclear enlargement	0	0		0		13*	
- Squamous cell metaplasia	0	0		0		35*	
- Squamous cell hyperplasia	0	0		0		5	
Olfactory epithelium							
- Nuclear enlargement	0	0		28*		39*	

Notes: resp. = respiratory, ol. = olfactory, * significantly different from control at $p \leq 0.01$ by χ^2 test; [a] only 9 females; for Kasai et al., 2008: The parenthesized values indicate the number of the animals bearing the lesion with each of the 4 different grades of severity, i.e., 1+: slight, 2+: moderate, 3+: marked, 4+: severe. For Kano et al. 2008: The values in parentheses indicate the average of severity grade index of the lesion. Grade: 1= slight, 2 = moderate, 3 = severe. The average of severity grade was calculated with the following equation: Σ(grade * number of animals with grade)/number of affected animals.

Based on the mentioned data above, the Annex 1 in support of the RAC opinion summarises the following as most relevant toxic effects in the respective target organs: '*Hepatic effects including hepatocellular degeneration, single cell necrosis, centrilobular swelling, vacuolisations in rats and mice and some studies reported significant changes of liver enzyme activity. In the kidneys in both mice and rats the effects recorded included histopathological alterations in some experiments accompanied by increase in kidney weight, cellular swelling, vacuolar changes, nuclear enlargement of the proximal tubule and lesion to the cortex such as degeneration, necrosis haemorrhages and vascular congestions*' (ECHA, 2022a).

2.1.6 Biological monitoring – toxicological and epidemiological key studies (existing assessments)

Based on the three available studies with human volunteers (Göen et al., 2016, Young et al., 1977) or workers (Young et al., 1976) in Germany a BAT value of 200 mg HEAA/g creatinine in correlation to the German MAK value of 10 ml 1,4-dioxane/m^3 was derived. Sampling time is immediately after exposure or at end of shift (Eckert et al., 2020). Based on the same data and using the same function the BLV proposed is 45 mg 2-hydroxyethoxyacetic acid/g creatinine corresponding to the proposed OEL by RAC (ECHA, 2022b). An example for an analytical method is given in the RAC Annex: determination of HEAA in urine with a detection limit 0.6 mg HEAA per litre urine can be achieved via a method based on gas chromatography with mass selective detection (GC–MS; ECHA, 2022a).

2.2 Deriving an Exposure Risk Relationship (carcinogenic effects) and a Dose Response Relationship (non-carcinogenic effects)

2.2.1 Starting point

As pointed out in the sections above epidemiological studies about 1,4-dioxane mediated effects are unreliable, yet there are various reliable sub chronic and chronic animal studies available.

The most reliable study identifying neoplastic lesions, as well as the preceding pre- and nonneoplastic lesions is the 2-year inhalation study with male F344 rats (Kasai et al., 2009; described in detail in section 2.1.5). This study also serves as the starting point for the OEL derivation of RAC (ECHA, 2022b).

For **systemic effects** RAC converted the NOAEC of 50 ppm study from rat to human, considering differences in respiratory volume and adjustment for exposure conditions (i.e. 6.7m³ / 10m³, and 6/8 h). Further to that respective default assessment factors (AF) were applied (total AF = 12.5; i.e. 2.5 for interspecies differences, 5 for intraspecies differences, none for exposure duration), leading to an OEL of 7.3 mg/m³ (2 ppm).

For **local effects** RAC identified a Lowest Observed Adverse Effect Level (LOAEC) at 50 ppm from the Kasai et al. (2009) study. For the respective OEL derivation this LOAEC was converted to a No Adverse Effect Concentration (NAEC) using the default AF of 3. As local irritation is thought to be mostly concentration dependent, no adjustment for exposure conditions (setup in animal experiment versus workplace) was performed and no allometric scaling from rat to human is applied for this local effect. The default AF (2.5) for remaining uncertainties with regard to dynamic differences was applied, as well as the AF of 3 for intraspecies differences. In summary this is yielding a total AF of 22.5, resulting in an OEL of 8.1 mg/m³ (2.2 ppm).

Finally, RAC proposes the more conservative value of '*7.3 mg/m³ (2 ppm) based on the systemic effects in kidney, which is also protective of the nasal irritation effects leading to carcinogenicity and the effects found in liver*' as the new OEL (8-h TWA).

2.2.2 ERR for carcinogenic effects

As summarised in section 2.1.4 in vitro genotoxicity studies show mostly negative results. However, recent publications pointed to the possibility that 1,4-dioxane induces clastogenic effects. It is still unclear whether these are due to direct or indirect DNA damage. Most of the studies indicate that cytotoxicity and oxidative stress are driving factors for positive results in genotoxicity testing. Therefore, RAC states '*Although some uncertainty on the mode of action remains, the carcinogenicity of 1,4-dioxane is considered to be related to a non-genotoxic mechanism, involving saturation of metabolic capacity, irritation at high exposure levels and formation of liver tumours by regenerative proliferation. Even though a mode of action-based threshold is assumed for the carcinogenic effects of 1,4-dioxane, some uncertainties with regard to residual cancer risk remain. However, the level of uncertainty is considered to be low, in view of the evidence that only above saturation levels of metabolism (which in humans is above 180 mg/m³; EU, 2002) are tumours formed. Therefore, in this case, no additional dose-response for carcinogenicity (i.e. cancer risk estimates) is provided for the purpose of this report*.' (ECHA, 2022b).The study team agrees with this approach and as the metabolic saturation concentration is also well above the least stringent policy option considered in this project, thus no ERR is derived with in this report.

2.2.3 DRR for non-carcinogenic effects

2.2.3.1 Kidney

2.2.3.1.1 Approach

The proposed OEL for systemic effects by RAC is based on systemic effects in kidney (nuclear enlargement of the proximal tubule in 20 of 50 animals affected at the mid dose group) from the Kasai et al. (2009) inhalation carcinogenicity study in rats (ECHA, 2022b).

This effect represents repeated nuclei acid replication without nuclear division or cytokinesis. It can occur sporadically but is associated also more frequently with certain chemicals specifically with renal carcinogens (Frazier et al., 2012). Human relevancy is given as renal effects like haemorrhage around the glomeruli and/or focal necrosis mostly in the area of the cortex was identified post mortem in some older studies where exposure to 1,4-dioxane was associated with fatal outcomes (ATSDR, 2012, Barber, 1934, Johnstone, 1959).

RAC used the identified NOAEC of 50 ppm (corresponding to 183 mg/m³) as starting point for their OEL derivation. For the purpose of deriving a DRR for this specific effect it was preferred to perform benchmark dose modelling (EFSA Scientific Committee et al., 2022) using the PROASTweb tool (version 70.1) and the data reported in Table 2-4.

Table 2-4 Dose-response data from Kasai et al. (2009), used for dose-response modelling

Conc (ppm)	Number of animals exposed per group (n)	Incidence (n) for nuclear enlargement in the proximal tubule of the kidney
0	50	0
50	50	1
250	50	20*
500	50	47*

* significantly different from control at $p \leq 0.01$ by χ^2 test

Dose-response modelling with PROAST results in a BMCL10 of 101 ppm (BMCU 195 ppm) in rats. The details and the protocol of the benchmark dose modelling are documented in the 'Annex: 1,4-dioxane – kidney effects'. This value requires adjustment from animal experimental conditions to workplace relevant conditions which is done following ECHA guidance Chapter R.8 (ECHA, 2012), i.e.:

- daily exposure duration - from 6 h in animal experiment to 8 h shift exposure
- annual working time - from 52 weeks in animal experiment to 48 weeks at the workplace
- respiratory volume - from 6.7 m³ at rest to 10 m³ anticipating light physical activity.

No further assessment factors are applied, to intentionally match an actual excess risk of 10% for this effect. Thus, the adjusted human (h)$BMCL_{10}$ is 55 ppm (corresponding to 201 mg/m³).

2.2.3.1.2 Conclusion – DRR for kidney effects

The DRR for nuclear enlargement of the proximal tubules is created from the points in Table 2-5.

Table 2-5 DRR for kidney effects, derived from Kasai et al. (2009)

	Concentration (mg/m³)	Kidney effects (%)
RAC OEL for systemic effects	7.3	0
Adjusted $hBMCL_{10}$	201	10

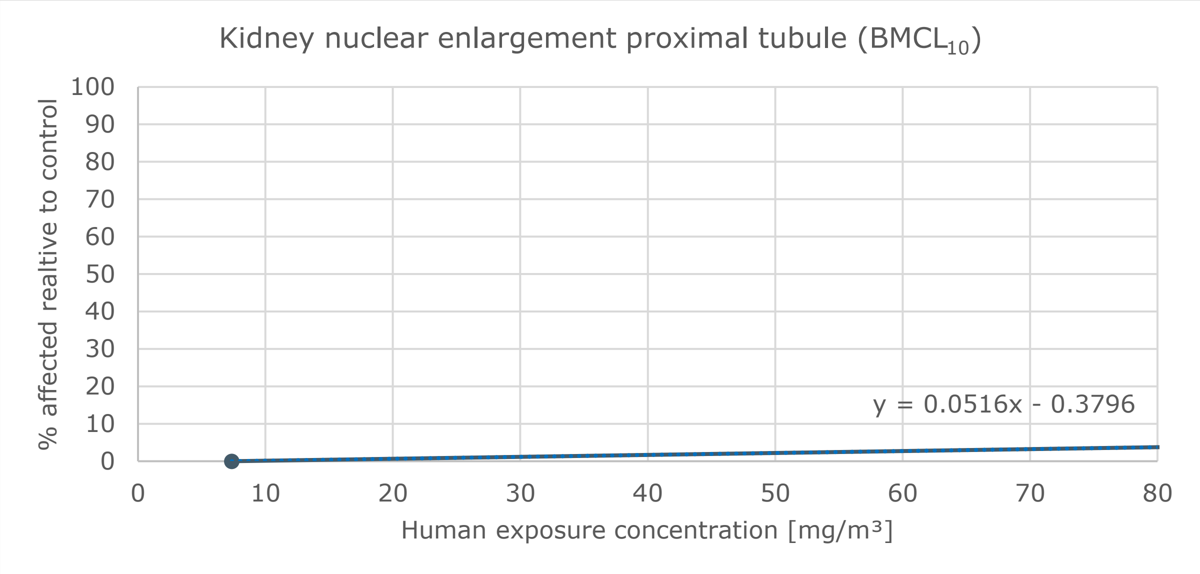


Figure 2-1: DRR for the endpoint work-related kidney effects after 1,4-dioxane exposure.

Equation 1:

$\text{Incidence}_{conc} = 0.0516 * \text{conc} - 0.3796$

where

- Incidence_{conc} refers to the incidence for kidney nuclear enlargement (%)

and

- conc is the human exposure concentration given as mg/m^3 (workplace scenario: 8 h/d, 5 d/w, 48 weeks/year).

For this equation the starting point is the proposed OEL of 7.3 mg/m^3 (2 ppm; no effects are expected below that concentration), thus at the highest exposure concentration of 1,4-dioxane used for the policy options in this study which is 73 mg/m^3 (20 ppm) additional 3.4% of the workers would be affected. As part of the project, it was neccessary to transform such histopathological finding in experimental animals to a clinically relevant finding in humans. As indicated above nuclear enlargement of proximal tubular cells points to the occurrence of acute tubular necrosis, in fact tubular necrosis was identified in older case studies with fatal outcome. Acute tubular necrosis is a so called intrinsic renal cause (in contrast to prerenal or postrenal causes) for the clinical manifestation of acute kidney injury (AKI, formerly also known as acute kidney failure). AKI is a sudden decrease in function that lasts only for a short term period and is usually reversible, but could also become chronic. The clinical diagnosis of AKI and the respective staging is made based on a person's signs and symptoms, along with lab tests for serum creatinine (increase) and measurement of urine output (oliguria or anuria) (KDIGO, 2012, 2021). AKI patients have an increased risk of developing chronic kidney disease in the future and can also result in cardiovascular morbidity in the long term (Dietel et al., 2008, KDIGO, 2021, Medizinische Fachredaktion Pschyrembel, 2018). It is obvious that the readings from animal experiments are not suited to perform the respective staging as parameters and especially quantification of these parameters is not comparable between species and whereas serum creatinine levels are assessed usually in a 90-day toxicity study, this might not be the case in a 2-year carcinogenicity study. In the respective experimental key study from Kasai it is indicated that urinary parameters and blood chemistry analysis were performed. No impairment of creatinine serum levels of urinary volume was reported. In addition, as there are no indications of loss of function, for the further assessment it is assumed that only stage 1 of the AKI is induced, which still could be reversible.

As the DRR is based on animal data no information on the onset of such effects in workers is available. In the 90-day inhalation toxicity study in rats) such effects are not yet reported indicating that prolonged repeated inhalation exposure is required. Yet in the 90-day drinking water study histopathological kidney lesions were reported, yet at higher doses (i.e. 10,000 ppm and above corresponding to approx. 550 and 830 mg/kg bw/d for male and females, respectively). Thus, indicating that already shorter than chronic exposure can lead to the same effects. In the absence of reliable information and in order to ensure a conservative approach MinEx of 1 day (0 years) and MaxEx of 1 year is assumed.

2.2.3.1.3 Discussion

It should be noted that the approach used for the DRR is conservative and the DRR could potentially overestimate the risks as it is based on experimental data from animal studies assuming similar incidences in rats and humans. Moreover, the fact that only male rats were assessed in the key study might seem as another uncertainty, however based on the results from the 90-day inhalation study in which females proved to be less sensitive this concern seems negligible. In addition, no sex related differences in sensitivity were noted in the drinking water studies. The uncertainty associated with transforming this pathological observation from the animal experiment to a human relevant clinical syndrome is discussed well already above. And the stage 1 AKI is a clinically mild picture that may also remain undetected and untreated. These uncertainties are somewhat mitigated as the effect is observed in the available data with high consistency in the type and severity of effects.

2.2.3.2 Liver

2.2.3.2.1 Approach

The proposed OEL for systemic effects by RAC is based on systemic effects in kidney from the Kasai et al. (2009) inhalation carcinogenicity study in rats, however centrilobular liver necrosis is noted in the rationale as relevant endpoint (ECHA, 2022b). This is the liver effect most sensitive, showing no elevated incidence in the control group, being dose-dependent with statistical significance achieved in the high dose group (Kasai et al., 2009).

Centrilobular zonal necrosis is specific and often seen for chemical induced liver effects (Krishna, 2017, Thoolen et al., 2010) especially if metabolization takes place. Even though the 1,4-dioxane metabolizing P450 CYPs are located throughout the body, yet their concentration is the highest and conditions for metabolizing function are the best at the liver centrilobular region (Dietel et al., 2008, Thoolen et al., 2010), thus it is there where the effects are starting to show first.

Using centrilobular liver necrosis as endpoint for benchmark dose modelling is protective, as it is a clear apical effect in the MoA to liver tumour formation and which is seen in a dose-dependent manner reaching statistically significance in the high dose group (Dourson et al., 2014, Dourson et al., 2017, ECHA, 2022a). It is also human relevant, as enlarged livers and centrilobular liver necrosis was identified post mortem in some older studies were exposure to 1,4-dioxane was associated with fatal outcomes (ATSDR, 2012, Barber, 1934, Johnstone, 1959).

For the purpose of deriving a DRR for this specific effect it was preferred to perform benchmark dose modelling (EFSA Scientific Committee et al., 2022) using the PROAST-web tool (version 70.) and the data reported in Table 2-6.

Table 2-6 Dose-response data from Kasai et al. (2009), used for dose-response modelling

Conc (ppm)	Number of animals exposed per group (n)	Incidence (n) for centrilobular liver necrosis
0	50	1
50	50	3
250	50	6
500	50	12*

* significantly different from control at $p \leq 0.01$ by χ^2 test

Dose-response modelling with PROAST results in a $BMCL_{10}$ of 80 ppm (BMCU 441 ppm) in rats. The details and the protocol of the benchmark dose modelling are documented in the 'Annex: 1,4-dioxane – liver effects'. This value requires adjustment from animal experimental conditions to workplace relevant conditions which is done following ECHA guidance Chapter R.8 (ECHA, 2012), i.e.:

- daily exposure duration - from 6 h in animal experiment to 8 h shift exposure
- annual working time - from 52 weeks in animal experiment to 48 weeks at the workplace
- respiratory volume - from 6.7 m³ at rest to 10 m³ anticipating light physical activity.

No further assessment factors are applied, to intentionally match an actual excess risk of 10% for this effect. Thus, the adjusted $hBMCL_{10}$ is 43.6 ppm (corresponding to 159.4 mg/m³).

2.2.3.2.2 Conclusion – DRR for liver effects

The DRR for centrilobular liver effects is created from the points in Table 2-7. Even though the starting point is the proposed OEL, which is associated to effects in kidney it can also be used to derive the DRR for effects in the liver. As in the key study the dose-dependent liver effects were also seen in the mid dose group, reaching statistical significance only in the high dose group the same NOAEC as for kidney effects is applicable (i.e. 50 ppm). Both kidney and liver effects are of the same order of magnitude.

Table 2-7 DRR for liver effects, derived from Kasai et al. (2009)

	Concentration (mg/m³)	Liver effects (%)
RAC OEL for systemic effects	7.3	0
Adjusted $hBMCL_{10}$	159.4	10

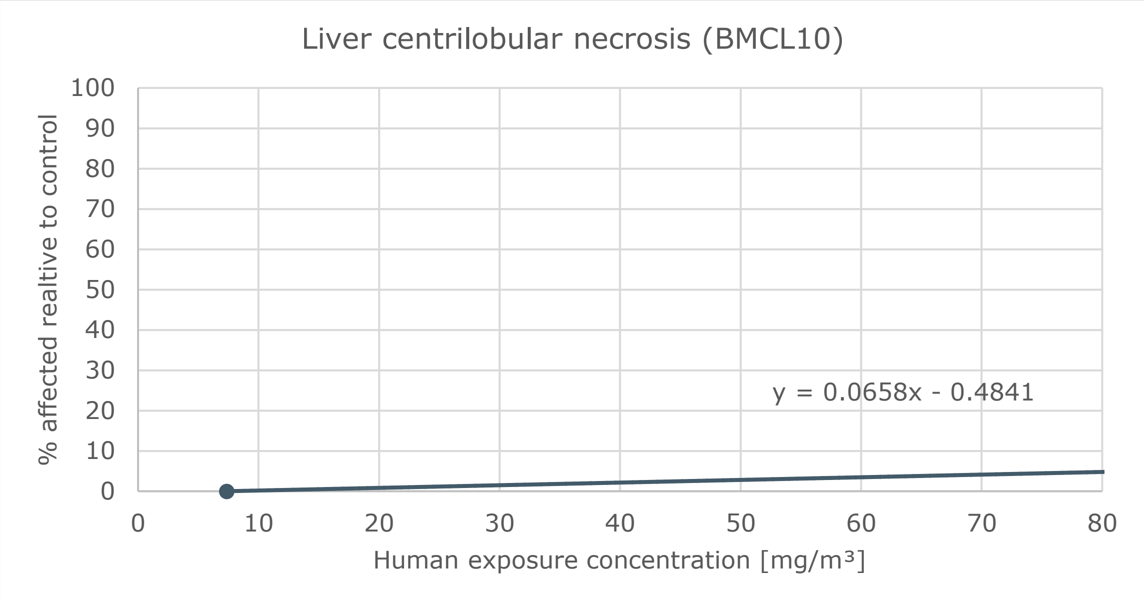


Figure 2-2: DRR for the endpoint work-related liver centrilobular necrosis after 1,4-dioxane exposure.

Equation 2:

$Incidence_{conc}$ = 0.0658 * conc – 0.4841

where

- $Incidence_{conc}$ refers to the incidence for liver centrilobular necrosis (%)

and

- conc is the human exposure concentration given as mg/m^3 (workplace scenario: 8 h/d, 5 d/w, 48 weeks/year).

For this equation the starting point is the proposed OEL of 7.3 mg/m³ (2 ppm; no effects are expected below that concentration), thus at the highest exposure concentration of 1,4-dioxane used for the policy options in this study which is 73 mg/m³ (20 ppm) additional 4.32% of the workers would show effects in the liver.

As centrilobular necrosis in the liver can be a starting point for various severe liver diseases that have other than chemical induced ethiology and no further functional parameters are reported consistently in the animal studies, this effect will not be transformed into a certain disease, but rather seen as an apical event of a plethora of liver diseases, and thus is a conservative approach.

Centrilobular liver necrosis is the pathological finding, that one can find only when looking at the liver tissue (i.e. through biopsy or in post-mortem investigations). Under normal clinical conditions liver disease in humans is mostly not treated on basis of pathological investigation, but rather functional parameters (i.e. levels of transaminase (ALT, AST), γ-GT, bilirubin, INR/QUICK value (measure for blood coagulation)). The pattern of the respective levels and timely occurrence thereby is essential for clinical diagnosis (Dietel et al., 2008). At termination of the key study the transaminase (ALT and AST) as well as the γ-GTP levels are statistically increased in the high dose group. These markers without elevated levels of glutamate dehydrogenase (not mentioned in the publication, thus it is uncertainty if it is not measured or not mentioned due to no/low effect) usually indicate weak liver damage. As this is qualitatively indicative of a liver damage in humans too, no quantitative transfer can be done. Overall transformation of the most sensitive pathological effect, which served as basis for the DRR into a definite clinical condition for humans seems not possible.

As the DRR is based on animal data no information on the onset of such effects in workers is available. In the 90-day inhalation toxicity study in rats effects on hepatic enzymes (ALT, AST) and histopathological findings (single-cell necrosis and centrilobular hepatic swelling) are reported, thus indicating that already shorter than chronic exposure can lead to the start of the effects. However, it shows that severity of effects progress with time. In the absence of reliable information and in order to ensure a conservative approach MinEx of 1 day (0 years) and MaxEx of 1 year is assumed.

2.2.3.2.3 Discussion

It should be noted that the approach used for the DRR is conservative and the DRR could potentially overestimate the risks as it is based on experimental data from animal studies assuming similar incidences in rats and humans. Moreover, the fact that only male rats were assessed in the key study might seem as another uncertainty, however based on the results from the 90-day inhalation study in which females proved to be less sensitive this concern seems negligible. In addition, no sex related differences in sensitivity were noted in the drinking water studies. These uncertainties are somewhat mitigated as the effect is observed in the available data with high consistency in the type and severity of effects.

2.2.3.3 Local respiratory effects

2.2.3.3.1 Approach

The pre- and nonneoplastic lesion identified in the respiratory and olfactory epithelium identified by RAC as critical for local respiratory effects are nuclear enlargement of the respiratory epithelium, and nuclear enlargement, atrophy, and respiratory metaplasia of the olfactory epithelium. For example, nuclear enlargement is a sign of regeneration after previous damage due to repeated injury and respiratory metaplasia is seen as transformation due to repeated loss of respective epithelia (Renne et al., 2009), and thus can serve as markers for the local irritating effects of 1,4-dioxane.

There are only short-term studies with workers or human volunteers available indicating also that local irritating effects are caused by 1,4-dioxane exposure. Older studies report that 20 ppm is generally acceptable to humans for short exposure times, but higher concentrations e.g. ~ 300 ppm (~ 1,000 mg/m³) even at short term exposure (starting from 1 to 15 minutes) typically result in irritation in eyes, nose and throat. Newer studies under controlled exposure conditions indicated that 20 ppm either for 2 or 8 hours under rest or slight activity do not yield irritation in the subjects, but after 4-hour exposure to 50 ppm the volunteers reported eye irritation. These observations in humans are the basis for the STEL proposed by RAC, i.e. 20 ppm; however they are not sufficient to derive a 8-hour TWA that is protective for workers throughout their working life. To achieve this level of protection the LOAEC from the 2-year rat study is used by RAC to derive a respective OEL for local irritating effects and in this report for DRR derivation.

The data of pre-/non-neoplastic lesions in the nasal cavity are not suitable for benchmark-dose modelling as already the lowest concentration (i.e. LOAEC = 50 ppm, corresponding to 183 mg/m³) yields high incidences of the effects marking damage to the upper respiratory tract (EFSA Scientific Committee et al., 2022, Hartwig and MAK Commission, 2019). For example, 100% of affected animals for nuclear enlargement of the respiratory epithelial cells in the nasal cavity. For dose response data of the other critical lesions in the nasal cavity of the key study mentioned above, see the details in Table 2-3 in section 2.1.5. Thus, the DRR is based on a linear equation starting from the OEL derived by RAC for local irritating effects to the lesion with the highest incidence at 50 ppm, i.e. nuclear enlargement of the respiratory epithelial cells in the nose (see Table 2-8). There is no further adjustment of this LOAEC from the animal study as RAC states that adjusting '*the LOAEC for nasal effects with respect to differences in human and experimental exposure conditions is deemed not necessary, as the toxic effects (local irritation) is driven by the concentration*' (ECHA, 2022b).

2.2.3.3.2 Conclusion – DRR for local respiratory irritating effects

The DRR for nuclear enlargement of the respiratory epithelium is created from the points in Table 2-8.

Table 2-8 DRR for respiratory irritating effects, derived from Kasai et al. (2009)

	Concentration (mg/m³)	Respiratory irritating effects (%)
RAC OEL for local effects	8.13	0
LOAEC (no adjustment)	183	100

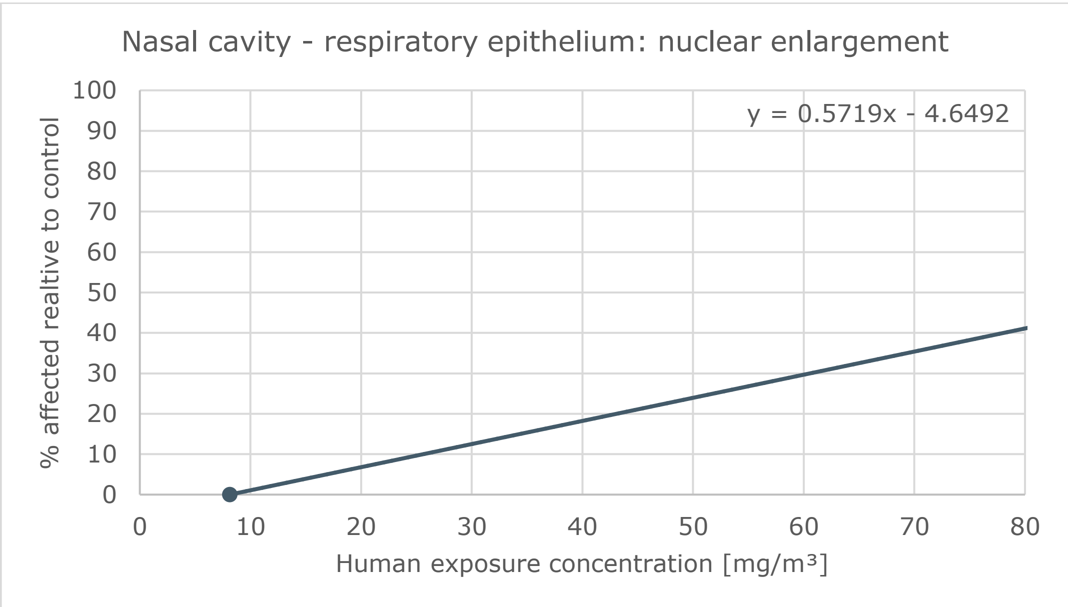


Figure 2-3: DRR for the endpoint work-related upper airway irritation after 1,4-dioxane exposure.

Equation 3:

$Incidence_{conc} = 0.5719 * conc - 4.6492$

where

- $Incidence_{conc}$ refers to the incidence for nuclear enlargement of respiratory epithelial cells (%)

and

- conc is the human exposure concentration given as mg/m³ (workplace scenario: 8 h/d, 5 d/w, 48 weeks/year).

For this equation the starting point is the derived OEL for local respiratory effects of 8.13 mg/m³ (2.2 ppm; no local irritating effects are expected below that concentration), thus at the highest exposure concentration of 1,4-dioxane used for the policy options in this study which is 73 mg/m³ (20 ppm) additional 37.10% of the workers would show some effects that would result of direct local irritation in the upper respiratory tract.

No transformation from the animal experiment to the human condition has to be performed as irritation of the upper respiratory tract is a suitable readout in humans. Such irritative effects often leading to inflammation can be revealed in humans e.g. as rhinitis (Renne et al., 2009).

Since the effects can occur after short-term exposure, a MinEx of 1 day (0 years) is assumed. In the absence of reliable information the standard value of 1 year is assumed for MaxEx.

2.2.3.3.3 Discussion

Alternatively to the DRR for nuclear enlargement in respiratory epithelium the linear DRR of the other effects, i.e. atrophy and respiratory metaplasia in olfactory epithelium was considered. Looking at the resulting equations (not provided in this report) the least stringent option of 73 mg/m³ would lead to additional of 29.7% or 17.1% affected workers, respectively. Nuclear enlargement in olfactory epithelium was not considered as it also showed 96% affected animals in the lowest concentration and thus would yield practically the same results as the DRR provided for the same effect in the respiratory epithelium. The lower DRRs are not used for the final DRR as based on the RAC recommendation the critical effect yielding the most conservative equation is considered relevant. One could also argue that proliferative lesions in laboratory rodents may arise from the aging process, but as pointed out by Renne et al. (2009) '*the most toxicologically important proliferative respiratory tract lesions result from exposure (usually repeated inhalation exposure) to potentially toxic test materials.*' Aging is excluded as being the sole reason for the observed effects as for the critical effects none of the age-coherent animals showed these effects. The only exception is respiratory metaplasia in olfactory epithelium, here control animals were affected as well, which in turn as the DRR considered the percentage affected in the 50-ppm group relative to the control group leads to the least slope and thus the lower percentage of workers affected.

The fact that only male rats were assessed in the key study might seem associated with uncertainty, however based on the results from the 90-day inhalation study in which females proved to be less sensitive this concern seems negligible. In addition, no sex related differences in sensitivity were noted in the drinking water studies (only general argument as drinking water studies cannot be used to assess the local irritating effects in the upper airway). These uncertainties are somewhat mitigated as the effect is observed in the available data with high consistency in the type and severity of the effect.

As rodents are obligate nose breathers and humans can switch between mouth and nose when breathing (Brüning et al., 2014), using animal data for DRR derivation of this specific effect can be considered conservative as in a human voluntary study with short term exposure at 20 ppm (which is 10 times higher than the current RAC OEL recommendation and is the highest exposure concentration used for the policy options in this study) no irritating effects could be noted (see section 2.1.5). As reliable worker long term exposure information is missing this is nevertheless the best approach to be applied. Even tough local irritation is thought to be mostly concentration dependent (at least at low concentrations without pathological effects), there is increasing experimental evidence that exposure duration contributes to the occurrence and severity of the effect (Nielsen and Wolkoff, 2017). From the 90-day and 2-year inhalation toxicological studies e.g. for the modelled effect (nuclear enlargement) it can be seen that severity increases with exposure concentration, but also the incidence increases with exposure duration. Thus, validating the approach taken here in order to be protective.

Yet in turn reveals a slight inconsistency, as for the OEL derivation by RAC adjustment of *'the LOAEC for nasal effects with respect to differences in human and experimental exposure conditions is deemed not necessary, as the toxic effects (local irritation) is driven by the concentration'* (ECHA, 2022b). In line with the RAC opinion for the purpose of DRR derivation in this report no adjustment to human exposure conditions was performed, this is yet considered inconsequential, as previous assumptions have always followed the more conservative/protective approach (see discussion points above).

2.3 Groups at extra risk

No groups at extra risk were identified (ECHA, 2022a).

2.4 Summary of background for analysing health impacts

2.4.1 Summary of exposure, uptake and health effects

2.4.1.1.1 Routes of exposure and toxicokinetics

As reported in the REACH dossiers the occupational exposure is expected to occur via inhalation during production, processing and use of the substance[20]. The dermal route also contributes to the body burden (no quantification available; ECHA, 2022b). Adsorption after inhalation and oral exposure is rapid. Newer data (Dennerlein et al. 2015; RAC 2022a) also point to considerable adsorption after dermal exposure. Once absorbed 1,4-dioxane is evenly distributed and rapidly metabolised (CYP mediated) to HEAA (and 1,4-dioxane-2-one, which is in pH-dependent equilibrium with HEAA). Excretion takes place mostly in urine as HEAA (minor amount unchanged), but also to some degree in exhaled air (unchanged or CO_2).

2.4.1.1.2 Adverse health effects

The substance is irritating to the eyes and respiratory tract and due to its defatting properties causes skin dryness and eventually skin cracking. The substance is not known to be a skin sensitiser from animal experiments and does not show reproductive and/or developmental toxic effects in available studies on rats and mice. The main target organs are the respiratory tract (e.g. nasal cavity), liver and kidney, especially after repeated exposure (ECHA, 2022b). With regard to carcinogenicity, there is only limited evidence from human epidemiological studies. However, based on results from experimental animal data 1,4-dioxane is considered carcinogenic in rodents, thus leading to harmonised classification as Carc. 1B (ECHA, 2022a).

In the following table the carcinogenic and non-carcinogenic endpoints are listed.

[20] Estimates range from 0.03 mg/m³ up to around 26 mg/m³

Table 2-9 Relevant carcinogenic and non-carcinogenic endpoints and their use for deriving ERRs and DRRs

Endpoint	Assessment
Cancer	Not considered (not relevant in the range of the policy options)
Liver effects	Considered quantitatively for DRR
Kidney effects	Considered quantitatively for DRR
Local respiratory effects	Considered quantitatively for DRR

2.4.2 Summary of ERR and DRR

No cancer risk assessment and thus no ERR is provided, which is in line with the following RAC conclusions:

- There is some uncertainty about the MoA, but tumour formation is thought to be mostly non-genotoxic (threshold mechanism).
- Nevertheless 1,4-dioxane might have some genotoxic potential at higher doses than tumour formation is observed.
- The potential residual cancer risk at the OEL level proposed is considered low, due to that tumour formation is only observed above saturation levels of metabolism.
- Saturation of metabolism in humans is said to be above 50 ppm (183 mg/m^3) (ECHA, 2022b),

which is even well above any of the discussed policy options in this report.

The following DRRs for 1,4-dioxane were derived:

Equation 1 – for kidney effects:

$\text{Incidence}_{conc} = 0.0516 * \text{conc} - 0.3796$

where

- Incidence_{conc} refers to the incidence for kidney nuclear enlargement (%)

and

- conc is the human exposure concentration given as mg/m^3 (workplace scenario: 8 h/d, 5 d/w, 48 weeks/year).

Equation 2 – for liver effects:

$\text{Incidence}_{conc} = 0.0658 * \text{conc} - 0.4841$

where

- Incidence_{conc} refers to the incidence for liver centrilobular necrosis (%)

and

- conc is the human exposure concentration given as mg/m^3 (workplace scenario: 8 h/d, 5 d/w, 48 weeks/year).

Equation 3 – for local respiratory effects:

$Incidence_{conc}$ = 0.5719 * conc – 4.6492

where

- $Incidence_{conc}$ refers to the incidence for nuclear enlargement of respiratory epithelial cells (%)

and

- conc is the human exposure concentration given as mg/m^3 (workplace scenario: 8 h/d, 5 d/w, 48 weeks/year).

3 CURRENT SITUATION

This chapter comprises the following sections:

- Section 3.1: Existing national limits
- Section 3.2: Relevant sectors, processes and uses
- Section 3.3: Exposure concentrations
- Section 3.4: Exposed workforce
- Section 3.5: Current risk management measures
- Section 3.6: Voluntary industry initiatives
- Section 3.7: Examples of good/best practice
- Section 3.8: Standard monitoring methods/tools
- Section 3.9: Intermediate uses not covered by certain REACH procedures
- Section 3.10: Market analysis
- Section 3.11: Alternatives
- Section 3.12: Current disease burden (CDB)
- Section 3.13: Summary of the current situation

3.1 Existing national limits

3.1.1 OELs and STELs in Member States and other countries

The existing limit values for 1,4-dioxane are shown in the table below.

Table 3-1 OELs and STELs in EU Member States and selected non-EU countries for 1,4-dioxane

Country	OEL (mg/m^3)	Specification of OEL	STEL (mg/m^3)	Specification of STEL
Austria [1,2,3]	73 *	- Carc, Sk	146 *	- Momentary value, Carc, Sk
Belgium [1,2,4]	73 **	- Sk	-	
Bulgaria [5]	73 **		20 **	
Croatia [6]	73 **		-	
Cyprus [7]	73 **		-	
Czechia [8]	70 *	- Sk	140 *	- Sk

Country	OEL (mg/m³)	Specification of OEL	STEL (mg/m³)	Specification of STEL
Denmark [1,2,9]	36 (T) & **	- Carc, Sk	72 (T) & **	- 15 min average value, Carc, Sk
Estonia [10]	73 *		-	
Finland [1,2,11]	36 (I) & ^^	- Sk	150 (I) & ^^	- 15 min average value, Sk
France [1,2,12]	73 *	- Restrictive statutory limit values, Carc	140 ^	- Carc
Germany [1,2,13]	73 *	- Sk	146 *	- 15 min average value, Sk
Greece [14]	73 *		-	
Hungary [1,15]	73 *	- Sk	-	
Ireland [1,2,16]	73 ^^	- Sk	-	
Italy [1,17]	73 **	- Sk	-	
Latvia [1,2,18]	20 **		-	
Lithuania [19]	35 **	- Carc	90 **	- Carc
Luxembourg [20]	73 ***		-	
Malta [21]	73 %		-	
Netherlands [1,22]	20 (T) & **		-	
Poland [1,2,23]	50 (V) & **		-	
Portugal [24]	73 ^		-	
Romania [1,2,25]	73 *	- Carc, Sk	-	
Slovakia [27]	73 **		-	
Slovenia [27]	73 **	- Sk	146 **	- Sk
Spain [1,2,28]	73 **	- Carc, Sk	-	
Sweden [1,2,29]	35 **	- Carc	90 ^^	- 15 min average value, Carc

Country	OEL (mg/m³)	Specification of OEL	STEL (mg/m³)	Specification of STEL
European Union [1,2,30]	73	- IOELV	-	
RAC [2]	7.3	- Sk	73	- Sk
EU candidate counties				
Albania [46]	73 ^	- Sk	20 ^	- Sk
Bosnia and Herzegovina [47]	-		-	
Georgia [48]	-		-	
Moldova [49]	73 *		10 *	
Montenegro [50]	-		-	
North Macedonia [51]	73 *	- Carc, Sk	-	
Serbia [52]	73 *		-	
Turkey [1,41]	73 %		-	
Ukraine [53]	-		-	
Other countries				
Australia [1,31]	36 ***	- Carc, Sk	-	
Brazil [32]	-		-	
Canada, Ontario [1,33]	20 ***	- value only given in ppm	-	
Canada, Québec [1,34]	72 ***	- Carc, Sk	-	
China	-		-	
India [35]	-		-	
Japan, MHLW [1,36]	10 ***	- value only given in ppm	-	
Japan, JOSH [1,37]	3.6 ^^^	- Carc, Sk	-	

Country	OEL (mg/m³)	Specification of OEL	STEL (mg/m³)	Specification of STEL
Norway [1,2,38]	18 (T) & ^^	- Carc, Sk	36 (T) & ^^	- 15 min average value, Sk
Russia [39]	10 (V) %		-	
South Korea [1]	20 %	- value only given in ppm, Sk	-	
Switzerland [1,2,40]	72 *	- Carc, Sk	144 *	- Carc, Sk
United Kingdom [1,2,42]	73 *	- Sk	-	
USA, ACGIH [43]	20 ^	- value only given in ppm, Carc, Sk	-	
USA, NIOSH [1,2,44]	-		3.6	- ceiling limit value (30 min), Carc
USA, OSHA [1,2,45]	360 *	- Sk	-	

Notes:
RAC = Committee for Risk Assessment
MHLW = Ministry of Health, Labour and Welfare
JSOH = Japan Society for Occupational Health
ACGIH = American Conference of Governmental Industrial Hygienists
NIOSH = National Institute for Occupational Safety and Health
OSHA = Occupational Safety and Health Administration
(V) = vapour
** Binding value according to country-specific source*
*** Binding value according to reply of member state authority on questionnaire*
**** Binding value according to the Final report for OEL/STEL deriving systems from 2018 (Available at: https://bit.ly/3PKDhbS, accessed on 05.07.2023). Status was not checked since 2018.*
^ Indicative value according to country-specific source
^^ Indicative value according to reply of member state authority on questionnaire
^^^ Indicative value according to the Final report for OEL/STEL deriving systems from 2018 (Available at: https://bit.ly/3PKDhbS, accessed on 05.07.2023). Status was not checked since 2018.
% According to (country-specific source) unclear if value is binding or indicative
& Information according to reply of member state authority on questionnaire
Carc = notation for carcinogenicity
Sk = skin notation assigned or danger of skin absorption
- no value available

Country	OEL (mg/m³)	Specification of OEL	STEL (mg/m³)	Specification of STEL

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Country	OEL (mg/m³)	Specification of OEL	STEL (mg/m³)	Specification of STEL

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Country	OEL (mg/m³)	Specification of OEL	STEL (mg/m³)	Specification of STEL

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3.1.2 BLVs in Member States

The existing biological limit values (BLVs) or reference values for 1,4-dioxane are shown in the table below.

Table 3-2 BLVs in EU Member States and selected non-EU countries for 1,4-dioxane

Country	1,4-Dioxane in urine	Specification
Germany [1,2]	200 µg/g creatinine	"Biologischer Grenzwert" biological limit value at workplace; Parameter analysed 2-Hydroxyethoxyacetic acid; Sampling time for long-term exposure: at the end of the shift after several shifts
Slovenia [3]	400 mg 2-Hydroxyethoxyacetic acid/g creatinine	Parameter analysed 2-Hydroxyethoxyacetic acid; Sampling time: at the end of the work shift
RAC [1]	45 mg 2-hydroxyethoxyacetic acid/g creatinine	Parameter analysed 2-Hydroxyethoxyacetic acid; Sampling time: at the end of exposure or end of shift
Non-EU countries		
Switzerland [4]	400 mg 2-Hydroxyethoxyacetic acid/g creatinine	Parameter analysed 2-Hydroxyethoxyacetic acid; Sampling time: at the end of the work shift or end of exposure

RAC = Committee for Risk Assessment
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3.1.3 Minimum, maximum and average national OELs

The table below shows the maximum, minimum, median, mode and mean OELs and STELs in EU Member States. Due to the fact that only Germany and Slovenia have a BLV in place, the maximum, minimum, median, mode and mean for national BLVs is not presented in the table below.

Table 3-3 Maximum, minimum and average of OELs (mg/m³) and STELs (mg/m³) for 1,4-dioxane in those EU Member States where an OEL or STEL exists

Maximum, minimum and averages	OEL (mg/m³)	STEL (mg/m³)
Maximum	73	150
Minimum	20	72
Median	50	140
Mode	73	146
Mean	63	124

Note: In the determination of the median OEL, values of 35 and 36 mg/m³ were treated as the same value.

Source: Study team on basis of information presented in this section.

3.2 Relevant sectors, processes and uses

3.2.1 Summary of REACH registration data

1,4-dioxane has a full registration under REACH in the ≥ 1,000 to < 10,000 tonnage ban and the EU registered tonnage in 2021 was approximately 3,000 tonnes (ECHA, 2022). The manufacturers/importers or their representatives include eight companies, amongst them BASF (Germany), Labcorp Development (Spain), Merck (Germany), OLON (Italy), Synthesia Technology (Spain), etc. Although 1,4-dioxane has a full registration, the information in the registration dossier shows that some of its uses are considered intermediate use.

The main production site in the EU relies on acid-catalysed conversion of diethylene glycol by ring closure in a closed system (ECHA, 2022).

Table 3-4 Summary of REACH registrations for 1,4-dioxane

Substance	EC No	Registered tonnage, t/year	Registration type	Status	Consortium
1,4-dioxane	204-661-8	3,000 tonnes	Full	Active	N/A

Source: ECHA (2022) and the 1,4-dioxane registration dossier available at https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15842

Table 3-5 REACH registrations for registered 1,4-dioxane . Registered tonnage and number of registrants (reg).

Substance (REACH registration name)	EC No	Registered tonnage, t/year		Status	Consortium
		Intermediate	Full registration		
1,4-dioxane	204-661-8	-	3,000 tonnes	Active	N/A

Source: ECHA (2022) and the 1,4-dioxane registration dossier available at https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15842

3.2.2 Manufacture of 1,4-dioxane

Of the total registered tonnage of approximately 3,000 tonnes, two thirds of which were manufactured at a single site in the EU, a small amount made at a second site in the EU and approximately one-third being imported (ECHA, 2022).

The main production site in the EU relies on acid-catalysed conversion of diethylene glycol by ring closure in a closed system (ECHA, 2022).

3.2.3 Overview of key intentional uses

The information in the REACH registration dossier suggests that the main uses are:

- Use as solvent (use in industrial settings)
- Use in laboratories (use in industrial settings)
- Use in laboratories (use in professional settings)
- Use at industrial sites in polymerisation processes

The information in ECHA (2022 and 2022b indicates that the main use of 1,4-dioxane is as a solvent in industrial settings, with the use in laboratories being less common.

However, with regard to use in polymerisation processes, there is additional potential for exposure (possibly including occupational exposure) during article service life due the presence of 1,4-dioxane in articles. ECHA (2022) notes that 1,4 dioxane can be found in rubber used for articles with intense direct dermal (skin) contact during normal use (e.g. gloves, boots, clothing, rubber handles, gear lever, steering wheels). No information has been identified with regard to the potential for 1,4 dioxane to remain in mixtures or articles due to its use as solvent. Due to the fact that, in general, solvents can have a wide range of applications, e.g. in paints, adhesives, sealants, which are often distributed to a large number of sectors.

In addition, as a by-product of the ethoxylation process, 1,4-dioxane can contaminate cosmetics and personal care products such as deodorants, perfumes, shampoos, toothpastes and mouthwashes (ECHA, 2022) but it is unclear what the associated levels of downstream occupational exposure are.

In addition to the uses listed in RAC (2022 and 2022b), BAuA (2020) notes that 1,4-dioxane is an impurity or constituent of substances of high economic impact produced in large annual quantities, e.g. surfactants.

In summary, the main downstream uses/potential sources of exposure include:

- Use as solvent in industrial settings (main use)
- Use in laboratories in industrial settings
- Use in laboratories in professional settings
- Use at industrial sites in polymerisation processes

In Uses 1-3, the Technical Function (TF) is as a solvent. At least for the fourth use stated above, 1,4-dioxane can be present in articles and there is the potential for occupational exposure further downstream, including during article service life (e.g. people who repair shoes).

According to SER (2011),1,4-dioxane was used as a solvent in the production of lacquers, varnishes, cleaning and detergent preparations, adhesives, cosmetics, deodorant fumigants, emulsions and polishing compositions, pulping of wood, extraction medium for animal and vegetable oils, laboratory chemical (eluent in chromatography), cassettes, plastic and rubber, and insecticides and herbicides.

The information on ECHA's substance portal suggests a wider range of uses; these are summarised below.

Table 3-6 Use information on ECHA's substance portal

Lifecycle stage	Uses
Manufacture	Manufacturing of the substance
Uses at industrial sites	This substance is used in the following products: polymers, pH regulators and water treatment products, laboratory chemicals, lubricants and greases and pharmaceuticals. This substance has an industrial use resulting in manufacture of another substance (use of intermediates). This substance is used for the manufacture of: chemicals and plastic products.
Formulation or re-packing	Formulation of mixtures
Widespread uses by professional workers	This substance is used in the following products: laboratory chemicals and pH regulators and water treatment products. This substance is used in the following areas: scientific research and development and health services. Other release of this substance is likely to occur from: indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners) and indoor use in close systems with minimal release (e.g. cooling liquids in refrigerators, oil-based electric heaters).
Article service life	Other release of this substance is likely to occur from: outdoor use in long-life materials with low release rate (e.g. metal, wooden and plastic construction and building materials) and indoor use in long-life materials with low release rate (e.g. flooring, furniture, toys, construction materials, curtains, foot-wear, leather products, paper and cardboard products, electronic equipment). This substance can be found in products with material based on: rubber used for articles with intense direct dermal (skin) contact during normal use (e.g. gloves, boots, clothing, rubber handles, gear lever, steering wheels).
Sources: ECHA substance portal, https://echa.europa.eu/de/substance-information/-/substanceinfo/100.004.239	

REACH registration data reproduced on the ECHA substance information portal suggest that 1,4-dioxane may have a large number of uses in articles, by professional workers (widespread uses), in formulation or re-packing, and at industrial sites. However, the experience of the consultants with REACH registration data suggests that registrants may sometimes have included more uses than those that were in use to ensure that these uses were covered under REACH. In addition, over time, many uses in REACH registration dossiers cease to be relevant. For this reason, REACH registration data often include uses that are no longer relevant.

3.2.4 Processes unintentionally generating 1,4-dioxane

1,4-dioxane is generated as a by-product of the ethoxylation process. This is a source of occupational exposure in a number of sectors, including in the production of some chemical products, detergents and soaps and cosmetics.

3.2.5 Presence of 1,4-dioxane as impurity

1,4-dioxane can be present as an impurity in a number of products, including surfactants, rubber used for articles with intense direct dermal (skin) contact during normal use (e.g. gloves, boots, clothing, rubber handles, gear lever, steering wheels). For more information, see Table 3-6.

3.2.6 Overview of sectors

3.2.6.1 Sources of information about sectors using 1,4-dioxane

The key sources of information about sectors using 1,4-dioxane include the REACH registration dossier, consultation for this study, and published literature from the EU and other countries (Australia, Canada, and the Unites States).

3.2.6.2 Sectors of use (SU) in REACH registration dossiers

The information from the REACH registration dossier is reproduced above in Section 3.2.1.

3.2.6.3 Summary of sector data sources

There is a general agreement on the main sectors with occupational exposure to 1,4 dioxane but some sources mention sectors for which it is not clear whether occupational exposure is still relevant and whether it is significant.

Table 3-7 Summary of sectors using 1,4-dioxane according to data sources.

NACE	Name	Consultation	REACH Registration	ECHA website	RAC	EU RAR	CAREX Canada
N/A	Manufacture of 1,4-dioxane	E,W	M	M	M		
C21.1 and C21.2	Pharmaceutical production (intentional use)	E, W	M	M			W
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as a by-product in the chemicals sector	E, W	M	M	M		W
M72.1	Laboratories		M	M	M		W
C20.4 excl. C20.42	Surfactants - presence as a minor constituent/impurity in the	E, W	M	M			W

NACE	Name	Consul-tation	REACH Regis-tration	ECHA website	RAC	EU RAR	CAREX Canada
	production of deter-gents, soaps, etc.						
C20.42	Cosmetics – generation as a by-product in the production of cosmet-ics			M			
	Others			M			W

Consultation responses include responses received from survey and meetings with industry associations
W = workers, E = exposure, M = mention

3.2.7 Criteria for selection of sectors for further analysis

The criteria for exclusion are as follows:

- The sector is mentioned only by one (or two) sources without further data on the extent of exposure being available.
- Due to lack of information, downstream sectors where 1,4-dioxane may be present as an im-purity are excluded.
- The available data indicates that the application may not take place today or the application area is small as compared to other areas.
- The available data (e.g. Mohr et al 2020) indicate that exposure is low.
- For cross-sectoral applications, some sectors with limited use may be excluded and the esti-mated number of workers exposed are allocated to the main sectors for the application.

Additional information may be available from a background note for a consultation on a potential restriction on 1,4-dioxane in surfactants published by ECHA on 20 April 2023 (the background note is referred to in this report as BaUA, 2023). This document will require further analysis and addi-tional sectors may be included in the second interim report.

3.2.8 Identified sectors with risk of exposure to 1,4-dioxane

The sectors where exposure from intentional uses and unintentional generation are summarised below.

Table 3-8 Gross list of identified sectors with potential risk of exposure to 1,4-dioxane

Sector (NACE Code)	NACE description	Specific activity
N/A	Part of C20.1 Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms	Manufacture of 1,4-dioxane

Sector (NACE Code)	NACE description	Specific activity
C21.1 and C21.2	C21.1 Manufacture of basic pharmaceutical products C21.2 Manufacture of pharmaceutical preparations	Pharmaceutical production (intentional use)
C20.1, C20.3 and C20.5	C20.1 Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics C20.5 Manufacture of other chemical products	Industrial use as a solvent and generation as a by-product in the chemicals sector
M72.1	M72.1 Research and experimental development on natural sciences and engineering	Laboratories
C20.4 excl. C20.42	C20.4 Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations, excluding C20.42 Manufacture of perfumes and toilet preparations	Surfactants – presence as a minor constituent/impurity
C20.42	C20.42 Manufacture of perfumes and toilet preparations	Cosmetics – generation as a by-product in the production of cosmetics
N/A	N/A	Others

Source: Study team on the basis of sources listed in Table 3-7

3.2.9 Uses or sectors excluded from analysis

All sectors in Table 3-8 with the exception of the 'Other' category are retained for analysis in this study.

3.2.10 Sectors taken forward for analysis

The sectors taken forward for the analysis are summarised below.

Table 3-9 Analysed sectors with risk of exposure to 1,4-dioxane

NACE code	Short name for sector	NACE full name
N/A	Manufacture of 1,4-dioxane	Part of C20.1 Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms
C21.1 and C21.2	Pharmaceutical production (intentional use)	C21.1 Manufacture of basic pharmaceutical products C21.2 Manufacture of pharmaceutical preparations
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as a by-product in the chemicals sector	C20.1 Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics C20.5 Manufacture of other chemical products
M72.1	Laboratories (intentional use as a solvent)	M72.1 Research and experimental development on natural sciences and engineering

NACE code	Short name for sector	NACE full name
C20.4 excl. C20.42	Surfactants – presence as a minor constituent/impurity in the production of detergents, soaps, etc.	C20.4 Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations, excluding C20.42 Manufacture of perfumes and toilet preparations
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	C20.42 Manufacture of perfumes and toilet preparations

Source: Study team.

Several sectors have not been included in the assessment but they will be further investigated during the remainder of the study and could potentially be included in the assessment. These sectors are painting conservators (exposure data reported in EPA 2020), film (celluloid) processing, optical lens manufacture (data reported in NICNAS, 1998).

3.3 Exposure concentrations

3.3.1 Data sources

ECHA (2022) notes that occupational exposure is expected to occur during the production, processing, and use of 1,4-dioxane, via inhalation or dermal uptake. The three key sources of data on exposure concentrations are:

- Publicly available data from the REACH registration dossier (reproduced in other documents such as ECHA, 2022).
- Responses from individual companies received within the framework of consultation for this study.
- REACH Chemical Safety Reports (CSRs).
- Other published studies, including the EU RAR (2002), the German MEGA database and sources from non-EU countries like Australia, Canada and the US.

The key shortcomings of the available data include the fact that a) data for some of the sectors can be relatively old or collected in jurisdictions outside the EU and b) some companies are currently not measuring 1,4-dioxane concentrations in the workplace and, consequently, there is a data gap. In addition, some of the measured or estimated data (e.g. the modelled data in EU RAR 2002) do not take into account the use of PPE, meaning that the actual exposure of workers is overestimated.

3.3.2 Inhalable vs. respirable fraction

Not relevant to 1,4-dioxane

3.3.3 Exposure data from national databases

The only measured data for 1,4-dioxane exposure concentrations from a national database in the EU has been identified in Germany, where the MEGA database contains the results of 40 measurements taken in nine companies between 1991-95, predominantly in the processing of plastics. The results are reproduced below.

Table 3-10 MEGA database results for 1,4-dioxane

Sector	P50 (mg/m³)	P90 (mg/m³)	P95 (mg/m³)
All sectors, 40 measurements in 9 companies	< LoQ	35	41

Source: BGAA (1999)

3.3.4 Exposure data by sector

In the REACH registration data, for all the uses with occupational exposure, estimated exposure levels range from 0.03 mg/m^3 to around 26 mg/m^3.

3.3.4.1 Manufacture of 1,4-dioxane

Exposure data for the manufacture of 1,4 dioxane are taken from consultation for this study. These data suggest that exposures are typically below the Limit of Detection (LoD) and maximum exposures are thus significantly below the threshold for the effects modelled in this study (7.3 mg/m^3 8-hour TWA).

Short-term exposure data provided through consultation are also at a similar level, typically below LoD, same as 8-hour TWA[21], and the maximum is also significantly below the threshold for effects (7.3 mg/m^3).

Table 3-11 Exposure concentrations in the production of 1,4-dioxane

Sector	8-hour TWA	Peak exposure	Biomonitoring
Manufacture of 1,4-dioxane	Significantly below 7.3 mg/m^3	Significantly below 7.3 mg/m^3	No data

Additional published exposure data for the production of 1,4-dioxane are presented in EU RAR (2002) based on measurements carried out between the 1970s and 1990s. The two most recent datasets summarised in the EU RAR (2002) suggest arithmetic averages below 2.6 mg/m^3 for all activities but a 90th percentile of 10 or 40 mg/m^3 for storage/drumming and 4.8 or 47 mg/m^3 for pilot plant waste disposal – it appears that these measurements were made during a pilot phase operation.

EU RAR (2002) also modelled exposure for different activities and concludes that P90 for a full-shift exposure measured in the pilot plant and for drumming, the reasonable worst-case scenario is estimated to be 10 mg/m^3. The EU RAR (2002) further estimates (models) that the reasonable worst-case scenario for short-term exposure is up to 150 mg/ m^3.

The most recent data provided through consultation is used for the assessment.

3.3.4.2 Pharmaceutical production (intentional use)

EU RAR (2002) reports measured data from 1997 (personal measurements) which suggest exposure levels of <3.6 mg/m^3 (full shift) during pharmaceutical production. Fixed and personal samples provided by the Finnish Environment Institute to EU RAR (2002) suggest a range between 1.8 and 18 mg/m^3 (full shift) with an arithmetic average of 6.5 mg/m^3 (full shift).

[21] STEL is the same as TWA most work automated/semi automated in closed system

3.3.4.3 Industrial use as a solvent and generation as by-product in the chemicals sector

The exposure levels modelled in EU RAR (2002) together with measured data led EU RAR (2002) to conclude that the typical exposure levels are around 40 mg/m^3, with modelled reasonable worst-case scenario during high exposure activities being modelled as 180 mg/m^3 (upper limit of assessment in the presence of Local Exhaust Ventilation, LEV). Short-term exposure is estimated as double this level at 360 mg/m^3.

Measured data (8-hour TWA) from the US published in 2014 and reported in EPA (2015) suggest that at a chemicals company where 1,4-dioxane is produced as a by-product in its manufacturing process, all measurements (including for activities drumming, sampling, emptying and boiling out vessels, the measured concentrations were always below the Limit of Detection. The highest LoD was 0.9 ppm (3.2 mg/m^3). Other measurements at other companies reported in EPA (2015) suggest similar results.

Data from Japan (taken between 1994 and 1996) and reported in ATDSR (2012) suggests that 1,4-dioxane was detected at only small concentrations (below 2.9 mg/m^3) in workplaces with solvent vapours.

Data received through consultation for this study suggest either exposure levels below the LoQ (in this case 18 mg/m^3) or 0.008 mg/m^3. In both cases, the relevant respondents use closed systems for production.

3.3.4.4 Laboratory use

EPA (2020) and Mohr et al (2020) report a max. TWA of 1.8 ppm (6.5 mg/m^3), presumably based on personal sampling in the US, originally published in the late 1990s. Other data in US EPA suggests typical concentrations of 5 mg/m^3; worst case 25 mg/m^3.

EU RAR (2002) reports measured data from the 1970s to the 1990s (personal measurements) which suggest exposure levels with median of 0.11 mg/m^3 (Range: 0-166 mg/m^3: P90: 0.58 mg/m^3) or a median <0.07 mg/m^3 (range <0.07-0.18 mg/m^3, P90: 0.15 mg/m^3).

3.3.4.5 Surfactants

Mohr et al (2020) report concentrations of 100-200 ppm before vacuum stripping but current potential for worker exposure only at 1ppm (3.6 mg/m^3). Mohr et al (2020) further note that this is typically a closed loop process with the potential for exposure being during the drumming off of the finished product. According to BaUA (2023), tripping can reduce 1,4-dioxane content down to 1-30 ppm for many surfactants, with 1,4-dioxane ending in the waste fraction.

Older data from Australia in NICNAS suggests levels below 1 ppm (3.6 mg/m^3) in personal samples from the drumming off area and estimated exposure not exceeding 9 ppm (32 mg/m^3) and less than 1 ppm (3.6 mg/m^3) in ventilated areas and below LoD in other production areas.

The limited number of consultation responses received from this sector are unclear but suggest that closed systems are either already in use or planning to be installed under the baseline scenario even in the absence of an additional OEL. There is some indication in one of the responses that a closed system can achieve concentrations below 7.3 mg/m^3; however, another response suggests that substitution would be required for one process already at 20 mg/m^3 and discontinuation would ensue in case of 7.3 mg/m^3.

3.3.4.6 Cosmetics

No data have been identified for the cosmetics sector.

3.3.5 Summary of exposure data by sector

The exposure data by sector are summarised below.

Table 3-12 Summary of exposure data by sector

Sector		AM	Median	P75	P90	P95	Max
Part of C20.1	Manufacture of 1,4-dioxane						Significantly <7.3
C21.1 and C21.2	Pharmaceutical production (intentional use)						<3.6
		6.5					18
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector		40				180 (but not 100% of the time) so 90 taken forward
							<3.2
							<2.9
							<18
							<0.008
M72.1	Laboratories						6.5
			5				25
			0.11		0.58		166
			<0.07		0.15		0.18
C20.4 excl. C20.42	Surfactants - presence as a minor constituent/impurity in the production of detergents, soaps, etc.		3.6				
							<3.6
							32 (but only if not ventilated)
						7.3	
C20.42	Cosmetics – generation as a by-product in the production of cosmetics						

Source: Section 3.3.4 of this report

3.3.6 Exposure levels with and without respiratory protective equipment (RPE)

Where reported together with the relevant data, no RPE adjustment was made.

3.3.7 Trends in exposure concentrations

No information on trends has been identified, although it appears that older sources of data typically provide higher exposure concentrations. However, due to the changes in the sectors and uses of 1,4-dioxane over time, such indications cannot be used to estimate a trend.

In the absence of specific information about a trend, it is assumed that future exposure concentrations are likely to remain at similar levels to the ones shown in this report.

3.3.8 Summary of exposure concentrations used for the further analysis

The exposure concentrations (8-hour TWA) without adjusting for RPE that are used as the starting point for the estimation of the distributions used for further analysis are shown below.

Table 3-13 Summary of exposure concentrations by sectors for 1,4-dioxane used as intermediate step for the estimation of the values for the further analysis – without adjustment for the use of RPE. All values in mg/m³ 8-hour TWA

Sector		AM	Median	P75	P90	P95	Max
Part of C20.1	Manufacture of 1,4-dioxane						Significantly <7.3
C21.1 and C21.2	Pharmaceutical production (intentional use)	3.9 (average of 6.5 and 1.2, i.e. AM of max. 3.6)					10.8 (average of 3.6 and 18)
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector		10.1 (adjusted from 22.8 based on 40/90)				22.8 (average of 90, 3.2, 2.9, 18, 0.008)
M72.1	Laboratories		1.7 (average of 5, 0.11 and 0.07)		3.6 (average of 0.58, 0.15 and an est. 10)		10.6 (average of 6.5, 25, 0.18, 166 eliminated as an outlier)
C20.4 excl. C20.42	Surfactants - presence as a minor constituent/impurity in the production of detergents, soaps, etc.		3.6			7.3	17.8 (average of

Sector		AM	Median	P75	P90	P95	Max
							3.6 and 32)
C20.42	Cosmetics – generation as a by-product in the production of cosmetics		3.6 (presumed same as surfactants)			7.3 (presumed same as surfactants)	17.8 (presumed same as surfactants)

Source: Study team on basis of information presented in this section.

The final exposure concentrations (8-hour TWA) without adjusting for RPE are shown below.

Table 3-14 Summary of exposure concentrations by sectors for 1,4-dioxane used as intermediate step for the estimation of the values for the further analysis – without adjustment for the use of RPE. All values in mg/m^3 8-hour TWA

Sector		AM	Median	P75	P90	P95	Max
Part of C20.1	Manufacture of 1,4-dioxane						Significantly <7.3
C21.1 and C21.2	Pharmaceutical production (intentional use)	3.9	3.6	4.6	5.8	6.6	10.8
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	10.5	10.1	12.1	14.3	15.8	22.8
M72.1	Laboratories	2.0	1.7	2.5	3.6	4.6	10.6
C20.4 excl. C20.42	Surfactants - presence as a minor constituent/impurity in the production of detergents, soaps, etc.	3.9	3.6	4.8	6.3	7.3	17.8
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	3.9	3.6	4.8	6.3	7.3	17.8

Source: Study team on basis of information presented in this section.

Although such information is not available from some sources, where it is indicated or can be inferred, measured or estimated exposure data in the literature are reported as ambient air concentrations without the use of RPE. This is unsurprising given the low air concentrations of 1,4-dioxane reported in the literature. As also noted in Section 3.5.4, it is expected that RPE is generally expected not to be worn, with PPE currently in use primarily focusing on issues such as dermal and eye exposure rather than inhalation (see also the results of the consultation carried out for this study summarised in Table 3-23 in Section 3.5.3). For this reason, no further adjustments to account for the use of RPE have been made to the data reported in the literature.

The nature of some of the sectors concerned (pharmaceutical industry, laboratories, etc.) where simple face masks may be worn for reasons other than reducing inhalation exposure, such as to preserve product or sample integrity, and the consultation results suggest that simple face masks may be worn in some cases. The cost model thus assumes a limited current use of simple face masks.

3.3.9 Values used in the benefits and costs models

In both the benefits and costs models, the exposed workers or enterprises with exposed workers are split into five groups representing the groups shown in Table 3-15. The exposure level assumed to be experienced by this group is calculated as shown in Table 3-15.

Table 3-15 Calculation of exposure levels (inhalable) used in benefits and costs models

Percentiles	Proportion of workers or enterprises	Calculation for exposure level assumed for modelling
0 - 50	50%	50th percentile
51 - 75	25%	Mean of 50th and 75th percentiles
76 - 90	15%	Mean of 75th and 90th percentiles
91 - 95	5%	Mean of 90th and 95th percentiles
96 - 100	5%	Geometric mean of 95th and 100th percentiles

The values used in the benefit and cost models for the different concentration bands are given below for each of the sectors.

Table 3-16 Calculation of exposure levels (inhalable) used in benefits and costs models

Band	Sector	Exposure concentration (mg/m^3)	Range – low (mg/m^3)	Range – high (mg/m^3)	Calculation method
1	Sector 1 Manufacture of 1,4-dioxane	**0.0**	0.0	0.0	Calculation method: High
2	Sector 1 Manufacture of 1,4-dioxane	**0.0**	0.0	0.0	Calculation method: Arithmetic Mean
3	Sector 1 Manufacture of 1,4-dioxane	**0.0**	0.0	0.0	Calculation method: Arithmetic Mean
4	Sector 1 Manufacture of 1,4-dioxane	**0.0**	0.0	0.0	Calculation method: Arithmetic Mean
5	Sector 1 Manufacture of 1,4-dioxane	**0.0**	0.0	0.0	Calculation method: Geometric Mean (for the highest band)
1	Sector 2 (C21.1+C21.2): Pharmaceutical industry	**3.6**	0.0	3.6	Calculation method: High

Band	Sector	Exposure concentration (mg/m^3)	Range – low (mg/m^3)	Range – high (mg/m^3)	Calculation method
2	Sector 2 (C21.1+C21.2): Pharmaceutical industry	**4.1**	3.6	4.6	Calculation method: Arithmetic Mean
3	Sector 2 (C21.1+C21.2): Pharmaceutical industry	**5.2**	4.6	5.8	Calculation method: Arithmetic Mean
4	Sector 2 (C21.1+C21.2): Pharmaceutical industry	**6.2**	5.8	6.6	Calculation method: Arithmetic Mean
5	Sector 2 (C21.1+C21.2): Pharmaceutical industry	**8.4**	6.6	10.8	Calculation method: Geometric Mean (for the highest band)
1	Sector 3 (C20.1, C20.3 and C20.5): Chemicals	**10.1**	0.0	10.1	Calculation method: High
2	Sector 3 (C20.1, C20.3 and C20.5): Chemicals	**11.1**	10.1	12.1	Calculation method: Arithmetic Mean
3	Sector 3 (C20.1, C20.3 and C20.5): Chemicals	**13.2**	12.1	14.3	Calculation method: Arithmetic Mean
4	Sector 3 (C20.1, C20.3 and C20.5): Chemicals	**15.1**	14.3	15.8	Calculation method: Arithmetic Mean
5	Sector 3 (C20.1, C20.3 and C20.5): Chemicals	**19.0**	15.8	22.8	Calculation method: Geometric Mean (for the highest band)
1	Sector 4 (M72.1) Laboratories	**1.7**	0.0	1.7	Calculation method: High
2	Sector 4 (M72.1) Laboratories	**2.1**	1.7	2.5	Calculation method: Arithmetic Mean
3	Sector 4 (M72.1) Laboratories	**3.1**	2.5	3.6	Calculation method: Arithmetic Mean
4	Sector 4 (M72.1) Laboratories	**4.1**	3.6	4.6	Calculation method: Arithmetic Mean
5	Sector 4 (M72.1) Laboratories	**7.0**	4.6	10.6	Calculation method: Geometric Mean (for the highest band)
1	Sector 5 (C20.4 excl. C20.42) Surfactants	**3.6**	0.0	3.6	Calculation method: High
2	Sector 5 (C20.4 excl. C20.42) Surfactants	**4.2**	3.6	4.8	Calculation method: Arithmetic Mean

Band	Sector	Exposure concentration (mg/m^3)	Range – low (mg/m^3)	Range – high (mg/m^3)	Calculation method
3	Sector 5 (C20.4 excl. C20.42) Surfactants	**5.6**	4.8	6.3	Calculation method: Arithmetic Mean
4	Sector 5 (C20.4 excl. C20.42) Surfactants	**6.8**	6.3	7.3	Calculation method: Arithmetic Mean
5	Sector 5 (C20.4 excl. C20.42) Surfactants	**11.4**	7.3	17.8	Calculation method: Geometric Mean (for the highest band)
1	Sector 6 (C20.42) Cosmetics	**3.6**	0.0	3.6	Calculation method: High
2	Sector 6 (C20.42) Cosmetics	**4.2**	3.6	4.8	Calculation method: Arithmetic Mean
3	Sector 6 (C20.42) Cosmetics	**5.6**	4.8	6.3	Calculation method: Arithmetic Mean
4	Sector 6 (C20.42) Cosmetics	**6.8**	6.3	7.3	Calculation method: Arithmetic Mean
5	Sector 6 (C20.42) Cosmetics	**11.4**	7.3	17.8	Calculation method: Geometric Mean (for the highest band)

Source: Study team on the basis of the data presented in this report.

3.3.10 Dermal exposure

RAC (2020) discusses that there are different views in the literature on the degree of dermal absorption (i.e. skin penetration by 1,4-dioxane) but concludes by giving more weight to a recent study which suggests a higher rate of penetration to the skin. Based on a theoretical calculation of 8-hour exposure of two hands, it is concluded that there is a sufficient potential for dermal exposure to contribute to the total burden to propose a skin notation. Personal protective equipment (PPE) and actual exposure is not considered in RAC's calculation.

REACH registration CSRs provide modelled values for 'dermal exposure' and 'combined routes' which appear to provide an indication of the contribution of the dermal route to the total burden. This differs by CSR and PROC within a range between 2% and 97% (the average of all values across all PROCs and CSRs is 40%). However, it can be argued that modelled estimates produced by common modelling tools under REACH should not be taken as estimates of real exposure since they start from high conservative estimates and which are then refined in a stepwise approach until a point where exposure is below the Derived No-Effect Level (DNEL). Consequently, using the quantitative outcome from such a modelling exercise may not be suitable for the purposes of the cost-benefit analysis in this study.

3.4 Exposed workforce

3.4.1 Introduction

3.4.1.1 Workers with an existing health condition (optional)

It is expected that some workers may be suffering from relevant pre-existing conditions that may be exacerbated by exposure to 1,4-dioxane. For example, the prevalence of Chronic Kidney Disease (CKD) ranges between 3% in Norway to 17% in Northeast Germany (estimates derived in 2016).

3.4.2 Data on exposed workforce from national databases

The numbers of workers exposed to 1,4-dioxane have been estimated by CAREX Canada. An estimate of the exposed workforce in Canada was derived by CAREX Canada, with the results showing that approximately 3,000 Canadian workers were exposed to 1,4-dioxane. In this study, the largest exposed industry groups were pharmaceutical and medicine manufacturing, followed by professional, scientific and technical services, basic chemical manufacturing, and public administration.

The data from CAREX Canada are reproduced below.

Table 3-17 Exposure to 1,4-dioxane in CAREX Canada in 2016

Sector	Exposed workers in Canada	Proportion of industry exposed
Pharmaceutical and medicine manufacturing	910	3%
Professional, scientific and technical services	460	0%
Basic chemical manufacturing	180	1%
Public administration	170	0%
Soap, cleaning compound and toilet preparation manufacturing	120	1%

In Australia, NICNAS (1998) estimated 120 workers at four sites exposed during the manufacture of ethoxylated chemicals. Despite differences in population, this estimate is of the same order of magnitude as the number of workers exposure during soap, cleaning and toilet product manufacture reported above for Canada.

A study of solvent use in Japanese enterprises suggests that 1,4-dioxane is not a commonly used solvent (Nagasawa et al, 2011).

An older estimate (from the 1980s) is available for the United States from the Occupational Safety and Health Administration (OSHA) which reported 466,000 US workers potentially exposed to 1,4-dioxane. However, due to a more widespread use of 1,4-dioxane as a stabiliser of chlorinated solvents in the more distant past, this estimate is not further used in this study.

3.4.3 Average number of exposed workers per company (consultation)

Table 3-18 Survey result for average number of exposed workers per company

Sector	Number of workers per company exposed to 1,4-dioxane Average	Percentage of workers in companies exposed to 1,4-dioxane Average
C20.5 Manufacture of other chemical products	20-30	30%
C20.4 Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	30-40	100%
C20.1 Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms	30-40	35%

Source: Study team on basis of stakeholder responses.

3.4.4 Exposed workforce by sector

Table 3-19 Estimated number of workers in the EU27 exposed to 1,4-dioxane in the sectors retained for assessment

Sector		Number of exposed workers (range)	Number of exposed workers (point estimate taken forward)	Number of companies with exposed workers (range)	No. of companies with exposed workers (point estimate taken forward)
N/A	Manufacture of 1,4-dioxane	150[22]	150	2[23]	2
C21.1 and C21.2	Pharmaceutical production (intentional use)	11,000-19,000[24]	15,000	70-120[25]	95

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[22] Only one site was confirmed by consultation for this study. Based on the data on 1,4-dioxane production and import in ECHA (2022), it was estimated that no more than 50 workers are likely to be exposed at the second site. This is highly likely a significant overestimation.
[23] Based on information in ECHA (2022).
[24] Estimated 3% of the pharmaceutical sector based on CAREX Canada. Estimated for the EU based on 3% of employment in NACE C21.1 and NACE C21.2 in Eurostat (19,000) and extrapolation based on population from 910 exposed workers in Canada (11,000).
[25] Estimated 3% of the pharmaceutical sector based on CAREX Canada. Estimated for the EU based on 3% of enterprises in NACE C21.1 and NACE C21.2 in Eurostat. Lower number estimated based on the employment range where the lower end is based on population-based extrapolation from Canadian employment. Given that there are only 3 registrants for 1,4-dioxane in the pharmaceutical sector, this may be an overestimate.

Sector		Number of exposed workers (range)	Number of exposed workers (point estimate taken forward)	Number of companies with exposed workers (range)	No. of companies with exposed workers (point estimate taken forward)
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	2,100-8,800[26]	5,450	40-170[27]	105
M72.1	Laboratories	7,400[28]	7,400	1,480[29]	1,480
C20.4 excl. C20.42	Surfactants – presence as a minor constituent/impurity in the production of detergents, soaps, etc.	900-1,400[30]	1,150	41 - 64[31]	53
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	2,000[32]	2,000	70[33]	70
Total		-	**31,150**	**-**	**2,277**

Source: Study team based on information presented in this section.

[26] Estimated 1% of the basic chemicals sector based on CAREX Canada. Estimated for the EU based on 1% of employment in NACE C20.1 Eurostat (8,800) and extrapolation based on population from 180 exposed workers in Canada (2,100).

[27] Estimated 1% of basic chemical manufacturing based on CAREX Canada. Estimated for the EU based on 1% of enterprises in NACE C20.1, NACE 20.3 and NACE 20.5 in Eurostat. Lower number estimated based on the employment range where the lower end is based on population-based extrapolation from Canadian employment.

[28] Extrapolation based on population from 630 exposed workers in Canada in the professional, scientific and technical services and public administration.

[29] Number of entities not known but it is estimated that in laboratory services only a small number of workers per company are exposed (estimated 5) and, as a result, a large number of entities may be relevant.

[30] Estimated 1% of the detergents and soaps sector based on CAREX Canada. Estimated for the EU based on 1% of employment in NACE C20.4 excluding C20.42 perfumes and toilet preparations (900) and extrapolation based on population from 120 exposed workers in Canada (1,400).

[31] Estimated 1% of enterprises in CAREX Canada. Estimated for the EU based on 1% of enterprises in NACE C20.4 excluding C20.42 perfumes and toilet preparations in Eurostat (lower number). Higher number estimated based on the employment range where the lower end is based on population-based extrapolation from Canadian employment.

[32] Estimated based on 1% (similar to soaps and detergents) of NACE C20.42

[33] Estimated based on 1% (similar to soaps and detergents) of NACE C20.42

3.4.5 Trends in exposed workers

CAREX Canada reports an 18% decrease in workers exposed to 1,4-dioxane between 2006 and 2016- this suggests an annual decrease by 2%.

The general workforce trends in the relevant NACE sectors with worker exposure to 1,4-dioxane range from -2% to 6% per year. However, these general trends cannot be taken to be necessarily representative of the workers exposed to 1,4-dioxane due to the fact that companies with exposure to 1,4-dioxane account for a small proportion of some of these sectors.

In terms of future trends, the designation of 1,4-dioxane as an SVHC and Cat 1B carcinogen is likely to exert downward pressure on the extent occupational exposure to 1,4-dioxane. Impacts across the supply chain in terms of substitution are one of the expected impacts of the designation of a substance as an SVHC; this is referred to as the 'announcement effect'(Ciatti et al, 2021). Similarly, the classification of 1,4-dioxane as a Cat 1B carcinogen means that it has been brought into the scope of Directive 2004/37/EC (CMRD) with stronger requirements on substitution and closed system use than under Directive 98/24/EC (CAD).[34] This suggests that recent regulatory developments are likely to reduce the number of exposed workers and exposure concentrations. Whilst it is not possible to reliably quantify these effects, it is noted that CAREX Canada reports an 18% decrease in workers exposed to 1,4-dioxane in Canada between 2006 and 2016- this suggests that an annual decrease by 2% is possible in an industrialised nation.

The general workforce trends in the relevant NACE sectors with worker exposure to 1,4-dioxane range from 0% to 6% per year (trend derived from data for 2011 and the year for which the latest data are available in Eurostat for the relevant sector). An annual average trend weighted by the number of workers exposed to 1,4-dioxane in the relevant sectors (see Table 3-20 in Section 3.4.6) suggests an annual increase of employment of 2% across all of the relevant sectors with exposure to 1,4-dioxane. However, these general trends cannot be taken to be necessarily representative of the workers exposed to 1,4-dioxane due to the fact that companies with exposure to 1,4-dioxane account for a small proportion of overall employment in these sectors. It is thus not clear if the general workforce increases suggested by past trends can be taken as indicative of future increases in the number of workers exposed to 1,4-dioxane.

3.4.6 Summary of exposed workforce

Table 3-20 Estimated number of workers in the EU27 exposed to 1,4-dioxane in key sectors

Sector		Number of exposed workers	Total number of workers in NACE code	% of all workers in NACE code
N/A (part of C20.1)	Manufacture of 1,4-dioxane	150	548,777	0.03%

[34] Substitution: stricter requirement under the CMRD 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). See RPA (2019): 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, available at https://ec.europa.eu/social/BlobServlet?docId=21328&langId=en

Sector		Number of exposed workers	Total number of workers in NACE code	% of all workers in NACE code
C21.1 and C21.2	Pharmaceutical production (intentional use)	15,000	637,569	2%
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	5,450	869,517	0.6%
M72.1	Laboratories	7,400	505,291	1%
C20.4 excl. C20.42	Surfactants – presence as a minor constituent/impurity in the production of detergents, soaps, etc.	1,150	92,680	1%
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	2,000	198,169	1%
Total		**31,150**	**2,852,003**	**1%**

Source: Study team based on information presented in this section.

Table 3-21 Estimated number of workers in the EU27 exposed to 1,4-dioxane and companies with exposed workers in key sectors

Sector		Number of exposed workers	Number of companies with exposed workers	Total number of workers (exposed and unexposed) in companies	Number exposed per company	Percentage exposed in companies
N/A	Manufacture of 1,4-dioxane	150	2	150	75	57%
C21.1 and C21.2	Pharmaceutical production (intentional use)	15,000	95	20,000	158	1%

Sector		Number of exposed workers	Number of companies with exposed workers	Total number of workers (exposed and unexposed) in companies	Number exposed per company	Percentage exposed in companies
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as a by-product in the chemicals sector	5,450	105	7,300	52	1%
M72.1	Laboratories	7,400	1,480	9,900	5	0.04%
C20.4 excl. C20.42	Surfactants – presence as a minor constituent/impurity in the production of detergents, soaps, etc.	1,150	53	4,600	22	2%
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	2,000	70	8,000	29	1%
Total		**31,150**	**2,277**	**49,950**	**14**	**0.04%**

Source: Study team based on information presented in this section. For the total number of workers in companies where some workers are exposed, it is assumed that 100% of workers are exposed in production 75% in sectors where there is some intentional use and 25% in sectors where 1,4-dioxane is generated unintentionally.

3.5 Current risk management measures (RMMs)

3.5.1 Types of RMMs

Table 3-22 Hierarchy of measures to be applied by the employers, as listed in the CMRD

Type of measure	Measures specified in the CMD
Reducing the quantities of the chemical agents used (substitution and material reduction)	(a) limitation of the quantities of a carcinogen or mutagen at the place of work;
Reducing the number of workers exposed	(b) keeping as low as possible the number of workers exposed or likely to be exposed;
Reducing the concentration of the chemical agents at the workplace	(c) design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens or mutagens into the place of work;

Type of measure	Measures specified in the CMD
	(d) evacuation of carcinogens or mutagens at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;
	(e) use of existing appropriate procedures for the measurement of carcinogens or mutagens, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;
	(f) application of suitable working procedures and methods;
Reducing the exposure of workers by protective measures	(g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures;
	(h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces;
	(i) information for workers;
	(j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens or mutagens;
	(k) drawing up plans to deal with emergencies likely to result in abnormally high exposure;
Other measures	(l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers.

Source: CMRD

3.5.2 Current use of RMMs by sector

3.5.2.1 Data from Chemical Safety Reports (CSRs)

For both use as solvent as well as in polymerisation processes, the Process Categories (PROCs) in the REACH registration dossiers suggest relatively controlled activities with limited occupational exposure (ECHA, 2022).

3.5.3 Data from questionnaire survey

All companies that responded to the survey have a closed system in place for at least some processes or are planning to install a closed system in the future. Similarly, risk management measures (RMMs) reported in literature suggest widespread use of closed systems. The RMMs in place by respondents to the survey are summarised below.

Table 3-23 Companies' use of RMMs for individual process by sector based on consultation survey

Measure	% of respondents that use the measure for at least one process with worker exposure to 1,4-dioxane
Reducing the amount of substance used	20%
Reducing the number of workers exposed	0%

Measure	% of respondents that use the measure for at least one process with worker exposure to 1,4-dioxane
Rotating the workers exposed	20%
Redesign of work processes	0%
Closed systems	100%
Partial hood enclosures	0%
Open hoods over equipment or local extraction ventilation	60%
General ventilation	80%
Pressurised or sealed control cabs	20%
Simple enclosed control cabs	20%
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	0%
Powered air-purifying respirators	0%
Half and full facemasks (negative pressure respirators)	20%
Disposable respirators (FFP masks)	0%
Face screens, face shields, visors	20%
Goggles	60%
Gloves	80%
Continuous measurement to detect unusual exposures	20%
Training and education	60%
Cleaning	20%
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	20%
Provision of separate storage facilities for work clothes	20%
Formal/external RPE cleaning and filter changing regime	0%
Continuous measurement of air concentrations to detect unusual exposures	0%
Creating a culture of safety	60%

Measure	% of respondents that use the measure for at least one process with worker exposure to 1,4-dioxane
Partial substitution of 1,4-dioxane used in this activity in the past	0%
Discontinuation of part of the activity using 1,4-dioxane	0%
PPE is essential regardless of the OEL	80%

Source: Consultation survey

3.5.4 Use of personal protective equipment

PPE appears to be widely used but this primarily includes googles and gloves to prevent against dermal and eye exposure. RPE is less common – this is unsurprising given the low air concentrations of 1,4-dioxane reported by respondents to the survey.

3.5.5 Technical measures

Other technical measures commonly reported in the survey include open hoods or local exhaust ventilation and general ventilation.

3.6 Voluntary industry initiatives

No voluntary industry initiatives in the EU have been identified.

3.7 Examples of good/best practice

3.7.1 Use of closed systems

Use of closed systems can be seen as good/best practice and, considering the exposure data provided by respondents to the consultation for this study, it is a highly effective method of controlling occupational exposure in both sectors where 1,4-dioxane is intentionally used as well as in sectors where it is generated as an unwanted by-product or it is present as an impurity.

3.7.2 Use of continuous monitoring

Given that a STEL is considered, the use of continuous monitoring equipment that gives alarm when a particularly high concentration is detected may be a useful method of detecting abnormal exposures.

This is particularly significant considering that the odour threshold for 1,4-dioxane is 24 ppm (86 mg/m^3) (Mohr et al, 2020).

3.7.3 Use of sensitive methods for measurement

The Limit of Quantification (LoQ) in the measurement methods used by companies differs widely, with some methods not allowing determination of low exposure levels, e.g. below 18 mg/m^3. The use of sufficiently sensitive methods of measurement can therefore be seen as good practice.

3.7.4 Options for making good practice available to stakeholders

No options for making good practice available to stakeholders have been identified.

3.8 Standard monitoring methods/tools

3.8.1 Compliance monitoring

Procedures for monitoring of contaminants in the workplace are typically established by national guidelines prepared by the national working environment authorities. These guidelines would typically refer to European standards to be used for the monitoring.

As concerns the monitoring of substances in the workplace, guidelines refer to two Europe-an standards:

- EN 482:2012+A1:2015 : Workplace exposure. General requirements for the performance of procedures for the measurement of chemical agents.
- EN 689:2018+AC:2019: Workplace exposure. Measurement of exposure by inhalation to chemical agents. Strategy for testing compliance with occupational exposure limit values

The strategy described in EN 689:2018 gives a procedure for the employer to overcome the problem of variability and to use a relatively small number of measurements to demonstrate with a high degree of confidence that workers are unlikely to be exposed to concentrations exceeding the OELs. The procedures are further described in the Methodological Note.

As described in the Methodological Note, in order to undertake the screening tests, ideally an analytical method with a limit of quantification (LOQ) at 0.1 * OEL would be required; otherwise, it will be necessary to undertake more tests and the costs of monitoring increases. For the lowest of the reference values proposed by RAC this would correspond to 0.1 μg/m^3 for the inhalable fraction and 0.05 μg/m^3 for the respirable fraction.

3.8.2 Available analytical methods

The methods shown in Table 3-24 have validation data that demonstrate compliance with the requirements of the standard EN 482 or the potential to meet these requirements for some of the proposed OELs.

Table 3-24 Overview of sampling and analytical methods for monitoring of 1,4-dioxanein workplace air

No	Method/ Fraction	Analytical technique	LOQ and sampling volume and time	Similar methods/ comments	Reference
1	Air - DFG (German Research Foundation)	GC/FID, Desorption with CS_2	0.047 mg/m^3 (25L/ 8 hours)	Krämer, Hebisch, and Hartwig (2016)	Air - DFG (German Research Foundation)
2	Air - NIOSH 1602	GC/FID, Desorption with CS_2	1 mg/m^3 (10 L) (limit of detection)	NIOSH (1994)	Air - NIOSH 1602
3	Biomonitoring - HEAA in urine - DFG (German Research Foundation)	GC/MS	0.6 mg HEAA per litre urine (limit of detection)	Leng et al (2015)	Biomonitoring - HEAA in urine - DFG (German Research Foundation)

Notes: GC Gas chromatography; FID Flame Ionisation detection; MS Mass spectrometry

Input from consultation for this study suggests that the monitoring methods used by companies have an LoQ ranging from 0.42 mg/m^3 8-hour TWA (or even lower, possibly as low as <8 µg/m^3) to 18 mg/m^3 8-hour TWA and an LoD ranging from 0.14 mg/m^3 (or less, possibly as low as <8 µg/m^3) to 9 mg/m^3 (8 hour TWA). There are thus significant differences between individual companies in terms of their ability to measure low exposure concentrations, also considering the presence of other chemicals in the cases where 1,4 dioxane is an impurity in manufacturing processing.

3.8.3 Summary of monitoring methods/tools

The current monitoring methods allow the measurement of low exposure concentrations with a DFG method being available that has an LoQ of 0.047 mg/m^3 and some companies using methods with even lower LoQs. However, it appears that some companies may be relying on methods with a significantly higher LoQ.

3.9 Intermediate uses not covered by certain REACH procedures

Although the information in the registration dossier shows that some of its uses are considered intermediate use, 1,4-dioxane has a full registration.

3.10 Market analysis

3.10.1 Sources of data on enterprises with exposed workers

No sources of data reporting the numbers of enterprises with workers exposed to 1,4-dioxane reports have been identified. For this reason, the relevant numbers of companies have been estimated based on the proportion of the workforce in each sector that is exposed to 1,4-dioxane summarised in Section 3.4. The disadvantage of this approach is that exposed workers may be concentrated in specific enterprises and the numbers of enterprises with exposed workers presented in this study are thus likely to be overestimated.

3.10.2 Study team analysis of Eurostat, survey and industry data

The following Eurostat sectors have been identified as relevant:

- C21.1 Manufacture of basic pharmaceutical products
- C21.2 Manufacture of pharmaceutical preparations
- C20.1 Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms
- C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics
- C20.5 Manufacture of other chemical products
- M72.1 Research and experimental development on natural sciences and engineering
- C20.4 Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations, excluding C20.42 Manufacture of perfumes and toilet preparations
- C20.42 Manufacture of perfumes and toilet preparations

3.10.3 Summary of enterprises with exposed workers

Table 3-25 Estimated number of EU enterprises with workers exposed to 1,4-dioxane using Eurostat, survey and industry data

Sector		Number of enterprises in EU (Eurostat)	% of enterprises with exposed workers	Estimated enterprises with exposed workers in EU
Part of C20.1	Manufacture of 1,4-dioxane	8,280 (in C20.1)	0.02%	2
C21.1 and C21.2	Pharmaceutical production (intentional use)	3,983	2%	95
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	17,407	1%	105
M72.1	Laboratories	53,906	3%	1480
C20.4 excl. C20.42	Surfactants – presence as a minor constituent/impurity in the production of detergents, soaps, etc.	4,142	1%	53
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	7,000	1%	70

Source: Study team on basis of literature review and Eurostat Structural Business Statistics.

Note: For 'Manufacture of 1,4-dioxane', the proportion of relevant companies in C20.1 Chemicals is low because only companies producing 1,4-dioxane in the EU are counted, whilst C20.1 includes 'Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms'

3.10.4 Enterprises with exposed workers by sector and by size of enterprise

Table 3-26 Distribution of EU enterprises by sector and by size of enterprise according to Eurostat

Sector		Total number of enterprises	Percentage of enterprises		
			Small <50 employees	Medium 50-249 employees	Large >249 employees
Part of C20.1	Manufacture of 1,4-dioxane	8,280 (in C20.1)	86%	10%	4%[35]
C21.1 and C21.2	Pharmaceutical production (intentional use)	3,983	74%	14%	12%
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	17,407	87%	10%	3%

[35] However, given the information collected through literature review and consultation for this study, the subsequent analysis assumes that producers of 1,4-dioxane in the EU are large companies.

Sector		Total number of enterprises	Percentage of enterprises		
			Small <50 employees	Medium 50-249 employees	Large >249 employees
M72.1	Laboratories	53,906	97%	2%	0%
C20.4 excl. C20.42	Surfactants – generation as a by-product in the production of detergents, soaps, etc.	4,142	93%	5%	2%
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	7,000	93%	5%	2%

Source: Study team on basis of stakeholder result and Eurostat Structural Business Statistics.

Table 3-27 Estimated number of EU enterprises with exposed workers by sector and by size of enterprise

Sector		Number of enterprises			
		Small <50 employees	Medium 50-249 employees	Large >249 employees	Total
Part of C20.1	Manufacture of 1,4-dioxane	0	0	2	2
C21.1 and C21.2	Pharmaceutical production (intentional use)	71	13	11	95
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	90	11	4	105
M72.1	Laboratories	1,441	32	7	1,480
C20.4 excl. C20.42	Surfactants – generation as a by-product in the production of detergents, soaps, etc.	49	3	1	53
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	65	4	1	70

Source: Study team on basis of stakeholder result and Eurostat Structural Business Statistics.

3.10.5 Enterprises with exposed workers by size of enterprise and by Member State

Table 3-28 Estimated number of EU enterprises with exposed workers by size of enterprise by Member State

Member State	Number of enterprises			
	Small <50 employees	Medium 50-249 employees	Large >249 employees	Total
Austria	27	2	1	31
Belgium	28	3	1	32
Bulgaria	15	1	1	17
Croatia	10	1	0	11
Cyprus	0	0	0	0
Czechia	43	4	2	49
Denmark	24	2	1	27
Estonia	5	0	0	6
Finland	19	2	1	21
France	139	12	6	158
Germany	192	17	8	218
Greece	140	13	6	159
Hungary	78	7	3	88
Ireland	21	2	1	24
Italy	270	24	12	306
Latvia	8	1	0	9
Lithuania	25	2	1	28
Luxembourg	1	0	0	1
Malta	2	0	0	2
Netherlands	112	10	5	127
Poland	94	8	4	106
Portugal	32	3	1	36
Romania	26	2	1	30
Slovakia	20	2	1	23
Slovenia	26	2	1	30

Member State	Number of enterprises			
	Small <50 employees	Medium 50-249 employees	Large >249 employees	Total
Spain	152	14	7	172
Sweden	83	7	4	94
Grand Total	**1,593**	**142**	**70**	**1,805**

Source: Study team on basis of stakeholder result and Eurostat Structural Business Statistics.

Note: In the absence of specific data for 1,4-dioxane, generic company distribution data across Member States from Eurostat are used, these may not be fully representative of enterprises with workers exposed to 1,4-dioxane. Totals may not add up due to rounding.

Table 3-29 Estimated of enterprises with exposed workers by key sector and by Member State

MS	Part of C20.1 Manufacture of 1,4-dioxane	C21.1 and C21.2 Pharmaceutical production (intentional use)	C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector	M72.1 Laboratories	C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.	C20.42 Cosmetics – generation as a by-product in the production of cosmetics
Austria	0	2	1	25	1	2
Belgium	0	4	3	23	1	1
Bulgaria	0	1	2	11	1	2
Croatia	0	1	1	7	1	1
Cyprus	0	0	0	0	0	0
Czechia	0	2	7	38	1	1
Denmark	0	4	1	20	1	1
Estonia	0	0	0	6	0	0
Finland	0	1	1	19	0	0
France	0	5	7	121	10	15

MS	Part of C20.1 Manufacture of 1,4-dioxane	C21.1 and C21.2 Pharmaceutical production (intentional use)	C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector	M72.1 Laboratories	C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.	C20.42 Cosmetics – generation as a by-product in the production of cosmetics
Germany	1	15	15	175	5	7
Greece	0	3	3	149	2	2
Hungary	0	2	2	80	2	2
Ireland	0	5	1	18	0	0
Italy	1	10	17	261	7	10
Latvia	0	1	1	5	1	1
Lithuania	0	0	1	26	0	1
Luxembourg	0	0	0	1	0	0
Malta	0	1	0	1	0	0
Netherlands	0	5	4	113	2	3

MS	Part of C20.1 Manufacture of 1,4-dioxane	C21.1 and C21.2 Pharmaceutical production (intentional use)	C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector	M72.1 Laboratories	C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.	C20.42 Cosmetics – generation as a by-product in the production of cosmetics
Poland	0	10	11	71	6	8
Portugal	0	5	3	25	1	2
Romania	0	3	3	20	2	2
Slovakia	0	0	2	20	1	0
Slovenia	0	1	1	26	1	1
Spain	0	11	14	135	6	6
Sweden	0	3	2	86	1	2

Source: Study team on basis of stakeholder result and Eurostat Structural Business Statistics.

3.10.6 Cross border aspects

There are some limited indications that some of the relevant companies operate in more than one Member State. For example, one of the respondents to consultation for this study operates facilities in two Member States.

Companies that operate in several countries can be subject to different requirements in different Member States. The ratios between maximum and minimum national exposure limits in the EU are given below.

Table 3-30 Ratio between maximum and minimum OELs (mg/m³) and STELs (mg/m³) for 1,4-dioxane in those EU Member States where an OEL or STEL exists

Maximum, minimum	OEL	STEL
Maximum (mg/m³)	73 (AT, BE, BG, HR, CY, EE, FR, DE, EL, HU, IE, IT, LU, MT, PT, RO, SK, SI, ES)	150 (FI)
Minimum (mg/m³)	20 (LV, NL)	72 (DK)
Ratio maximum/minimum	3.65	2.08

Source: Study team on basis of information presented in this report.

3.10.7 Market trends

Market trends in the relevant sectors are summarised below. They show changes between 2011 and 2020 (the latest year for which data are available). These are used as background information when considering market trends, including in Section 4.7.

Table 3-31 Market trends

Sector	Total change in the number of enterprises between 2011 and 2020 (%)	Total number of enterprises, annual change between 2011 and 2020 (%)	Change in turnover between 2011 and 2020 (%)	Turnover, annual change between 2011 and 2020 (%)
C20.1_Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms	2%	0%	-7%	-1%
C20.3_Manufacture of paints, varnishes and similar coatings, printing ink and mastics	-13%	-2%	10%	1%
C20.4_Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	51%	5%	52%	5%
C20.42_Manufacture of perfumes and toilet preparations	75%	6%	77%	7%
C20.5_Manufacture of other chemical products	3%	0%	10%	1%

Sector	Total change in the number of enterprises between 2011 and 2020 (%)	Total number of enterprises, annual change between 2011 and 2020 (%)	Change in turnover between 2011 and 2020 (%)	Turnover, annual change between 2011 and 2020 (%)
C21.1_Manufacture of basic pharmaceutical products	18%	2%	53%	9%
C21.2_Manufacture of pharmaceutical preparations	9%	1%	74%	7%
M72.1_Research and experimental development on natural sciences and engineering	62%	6%	53%	5%

Source: Study team on basis of Eurostat Structural Business Statistics.

3.11 Alternatives

No information on potential alternatives has been provided by the consultees.

In case of unintentional generation as a by-product, an alternative production process would be required.

3.12 Impact of Covid 19 on current situation

No significant impact of Covid-19 on the current situation has been identified.

3.13 Current disease burden (CDB)

The current burden of disease for the relevant endpoints is estimated using the data in the preceding sections for exposed workers, combined with data on exposure concentrations and the exposure response relationship (ERR) and dose response relationship (DRR). The data combined with data on past trend in exposure concentrations and exposed workforce, latency and workforce turnover.

3.13.1 Past trend in exposure concentrations and exposed workforce

As noted in Sections 3.3.7 and 3.4.5, no change to exposure concentrations and an annual decrease in the number of workers by 2% are assumed.

3.13.2 Latency and workforce turnover

Latency is not expected to be relevant to the effects modelled for 1,4-dioxane (kidney and liver effects, local irritation in the nasal cavity).

The default value for staff turnover (5% per year) is used. As noted in the methodology note (RPA, 2023), the 5% per year is lower than the turnover ratios in most of the published literature and Eurostat, which are typically derived at the level of individual companies rather than sectors, with a 5% being appropriate to account for the fact that some workers may continue to work in the same sector and continue to be exposed to the same substances. Although this assumption may not be as appropriate for the sectors relevant to 1,4-dioxane as for the sectors relevant to the other substances assessed within this project, the 5% ratio is retained for purposes of consistency.

3.13.3 Current disease burden

Table 3-32 Current burden of disease due to current exposure (due to no latency, this reflects the current situation)

Endpoint	New cases per year (incidence) in 2023
CBD - no. of Kidney effects cases/year	12
CBD - no. of Liver effects cases/year	16
CBD - no. of Local irritation: effects in nasal cavity cases/year	110

Source: Study team on basis of information presented in this section.

3.13.4 Comparison with data on recognised cases and epidemiological data

No data on recognised cases or current/recent epidemiological studies carried out in Europe have been identified.

3.14 Summary of the current situation

3.14.1 Risk to workers' health

The estimates taken forward for the assessment of the options for 1,4 dioxane and for the 31,150 exposed workers are summarised below.

Table 3-33 Summary of estimates taken forward for the assessment of options

Health effects caused	Major occupational exposure route
Cancer	Inhalation, skin
Kidney effects	Inhalation, skin
Liver effects	Inhalation, skin
Local irritation in nasal cavity	Inhalation

Source: Study team.

However, since the risk of cancer is only expected to occur above saturation levels (humans 180 mg/m³), which is significantly above the current exposure levels, no estimates of cancer incidence have been derived in this report despite the fact that 1,4-dioxane is classified as Carcinogenic 1B.

Table 3-34 Summary of exposure concentrations (not adjusted for the use of RPE), exposed workforce and number of companies by sectors for 1,4-dioxane

Sector		Exposure concentration mg/m3			Number of exposed workers	Number of com-panies
		AM	Median	P95		
Part of C20.1	Manufacture of 1,4-dioxane			Signif-icantly <7.3	150	2

Sector		Exposure concentration mg/m3			Number of exposed workers	Number of companies
		AM	Median	P95		
C21.1 and C21.2	Pharmaceutical production (intentional use)	3.9	3.6	6.6	15,000	95
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	10.5	10.1	15.8	5,450	105
M72.1	Laboratories	2.0	1.7	4.6	7,400	1,480
C20.4 excl. C20.42	Surfactants – presence as a minor constituent/impurity in the production of detergents, soaps, etc.	3.9	3.6	7.3	1,150	53
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	3.9	3.6	7.3	2,000	70

Source: Study team.

The current disease burden estimated for the sectors in the table above are summarised below.

Table 3-35 Current disease burden related to occupational exposure to 1,4-dioxane (number of cases)

Carcinogen	Health effects caused	Current disease burden (number of cases in 2023)
1,4-dioxane	Kidney effects	12
	Liver effects	16
	Irritation in nasal cavity	110

Source: Study team.

3.14.2 Relationship with other EU policies

In 2021, 1,4-dioxane was included in the Substances of Very High Concern (SVHC) Candidate List for Authorisation according to REACH Art. 57 (a) and 57 (f), with this triggering substitution and information requirements.

A consultation on a potential REACH restriction on 1,4-dioxane in surfactants was open until July 2023.

3.14.3 National OELs

The current national OELs are summarised below.

Table 3-36 Summary of national OELs in EU Member States

Carcinogen	Lowest (strictest) national binding OEL (mg/m^3)	Highest (least strict) national binding OEL (mg/m^3)	Member States with no OEL
1,4-dioxane	20 (LT, NL)	73	None

Source: Study team on the basis of section 3.1.

The current national STELs are summarised below.

Table 3-37 Summary of national STELs in EU Member States

Carcinogen	Lowest (strictest) national binding STEL (mg/m^3)	Highest (least strict) national binding STEL (mg/m^3)	Member States with no STEL
1,4-dioxane	72 (DK)	150 (FI)	BE, BG, HR, CY, EE, EL, HU, IE, IT, LV. LU, MT, NL, PL, PT, RO, SK, ES

Source: Study team on the basis of section 3.1.

3.14.4 Potential for lowering exposure to 1,4-dioxane

The measured exposure levels are typically significantly lower than the current IOELV (73 mg/m^3) under the CAD, suggesting that the IEOLV is outdated.

Use of closed systems can be seen as good/best practice and, considering the exposure data provided by respondents to the consultation for this study, it is a highly effective method of controlling occupational exposure in both sectors where 1,4-dioxane is intentionally used as well as in sectors where it is generated as an unwanted by-product or it is present as an impurity.

However, closed systems cannot control all exposure situations and some exposure situations require additional control measures (e.g. drumming off, sample taking, etc.).

4 BASELINE SCENARIO

The baseline scenario describes how the problem is expected to evolve in case no action is taken at EU level.

This chapter comprises the following sections:

- Section 4.1: Impact of the implementation of other OELs
- Section 4.2: Effects of forthcoming changes in national OELs or protective regulation, self-regulatory initiatives
- Section 4.3: Effects of REACH
- Section 4.4: Effects of EU Strategic Foresight megatrends
- Section 4.5: Future trend in use of the substance(s)
- Section 4.6: Future trend in exposure concentrations due to technical improvements
- Section 4.7: Future trend in exposed workforce
- Section 4.8: Other factors of importance for the baseline
- Section 4.9: Future disease burden (FDB)
- Section 4.10: Summary of the baseline scenario

4.1 Impact of the implementation of other OELs

It is not expected that any of the EU OELs for other substances that have already been adopted but are not yet in force are likely to have a significant impact on occupational exposure to 1,4-dioxane.

4.2 Effects of forthcoming changes in national OELs or protective regulation, self-regulatory initiatives

No forthcoming changes in national OELs or other relevant national legislation have been identified.

4.3 Effects of REACH

As noted in Sections 1.1.2.1 and 4.8, the German Federal Institute for Occupational Safety and Health (BAuA) is currently carrying out research on a potential Annex XV restriction on the manufacture, placing on the market and use of 1,4-dioxane in surfactants, motivated by the need to prevent environmental emissions of 1,4-dioxane. The impact of a potential restriction on occupational exposure to 1,4-dioxane is unclear and was thus not taken into account in the baseline scenario.

4.4 Effects of EU Strategic Foresight megatrends

Some of the megatrends identified by the European Commission are relevant to future exposure to 1,4-dioxane. Specifically, the trends relating to growing consumption, shifting health challenges and accelerating technological change may be linked into sectors which are currently using 1,4-dioxane or in which it is generated as a by-product.

- Given the key sector of intentional use of 1,4-dioxane is the pharmaceutical industry, the megatrend of shifting health challenges means that this megatrend could affect the use of 1,4-dioxane. It is, however, not clear whether this trend is likely to increase or decrease the demand for 1,4-dioxane, which is used in the pharmaceutical industry as a solvent rather than an active ingredient, and it is therefore difficult to link its use with specific pharmaceuticals and public health developments.

- Growing consumption is likely to increase demand in the sectors where workers are exposed to 1,4-dioxane. For example, the global cosmetic product market is expected to grow significantly in the future.

- Acceleration of technological change – which is transforming production systems and reducing the number of workers, particularly in the manufacturing, should result in reduced exposure to workers.

4.5 Future trend in use of 1,4-dioxane

In terms of future trends, the designation of 1,4-dioxane as an SVHC and Cat 1B carcinogen is likely to exert downward pressure on the use of 1,4-dioxane. Impacts across the supply chain in terms of substitution are one of the expected impacts of the designation of a substance as an SVHC; this is referred to as the 'announcement effect'(Ciatti et al, 2021). Similarly, the classification of 1,4-dioxane as a Cat 1B carcinogen means that it has been brought into the scope of Directive 2004/37/EC (CMRD) with stronger requirements on substitution than under Directive 98/24/EC (CAD).[36] However, the megatrend of increased consumption is likely to increase overall demand, including for products in the supply chains that involve the use or generation as a by-product of 1,4-dioxane.

4.6 Future trend in exposure concentrations due to technical improvements

No information has been identified.

4.7 Future trend in exposed workforce

An increased use of closed systems is the key technical improvement for the reduction of exposure to 1,4-dioxane. The information on potential technical improvements collected through consultation for this study is limited and cannot be used to provide representative conclusions for the whole sector. However, it can be expected that the classification of 1,4-dioxane as a Cat 1B carcinogen which has brought it into the scope of Directive 2004/37/EC (CMRD) with stronger

[36] Substitution: stricter requirement under the CMRD than in the CAD: mandatory whenever workers 'are or are likely to be exposed', 'risk > slight risk' not a prerequisite. See RPA (2019): 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, available at https://ec.europa.eu/social/BlobServlet?docId=21328&langId=en

requirements on the use of closed systems than Directive 98/24/EC (CAD)[37] is likely to motivate an increased use of closed systems in companies with workers exposed to 1,4-dioxane.

The future trend considerations are summarised below.

Table 4-1 Summary of trend considerations for 1,4-dioxane (exposed workforce and exposure concentrations)

Consideration	Direction	Uncertainty	Conclusion
SVHC designation and inclusion in the CMRD	Potential reduction in the number of exposed workers and exposure concentrations.	Medium	Taken into account. Quantification not possible but past trend in Canada (-2% reduction in number of exposed worker per year can be used as proxy)
General employment trends in the relevant sectors (linked to output increases)	Potential increase in the numbers of exposed workers	Medium	Taken into account but unclear if general trends can be applied to workers exposed to 1,4-dioxane. Past trend across the relevant sectors (weighted to represent workers exposed to 1,4-dioxane): 2% increase per year
Potential REACH restriction	Unclear	High	Not taken into account
Megatrends (health challenges, growing consumption, technological change)	Unclear	High	A clear trend cannot be established and therefore specific trends cannot be quantitatively modelled

Source: Study team

The information in the table above suggests that possible trends could impact the extent of exposure in opposing directions (two considerations) or their direction is unclear (two considerations). All potential trends are associated with a medium or high degree of uncertainty and reliable quantification is not possible for any of them. As a result, in particular taking into account the opposing nature of the trends with a medium degree of uncertainty, an overall 'no change' trend is modelled in the baseline scenario.

4.8 *Other factors of importance for the baseline*

As noted in Section 1.1.2.1 and 4.3, the German Federal Institute for Occupational Safety and Health (BAuA) is currently carrying out research on a potential Annex XV restriction on the manufacture, placing on the market and use of 1,4-dioxane in surfactants, motivated by the need to prevent environmental emissions of 1,4-dioxane. The impact of the potential restriction on occupational exposure to 1,4-dioxane is unclear.

[37] Closed system: second RMM in the hierarchy under the CMD vs. no explicit reference to closed systems in the CAD (except for intermediates). See RPA (2019): 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, available at https://ec.europa.eu/social/BlobServlet?docId=21328&langId=en

4.9 *Future disease burden (FDB)*

4.9.1 *Future disease burden*

The future burden of disease under the baseline is summarised below.

Table 4-2 Baseline future burden of disease; staff turnover of 5% for all sectors

Endpoint	Number of cases over 40 years
Kidney effects	497
Liver effects	633
Local irritation: effects in nasal cavity	4,382

Source: Study team.

In Table 4-3, the number of cases is distributed on the sectors, where exposure takes place.

Table 4-3 Baseline future burden of disease; staff turnover of 5% for all sectors and kidney and liver effects and local irritation in the nasal cavity and trend in workforce of 5% per year

Sector		Number of cases over 40 years			Percent of total cases
		Kidney effects	Liver effects	Local irritation: effects in nasal cavity	
Part of C20.1	Manufacture of 1,4-dioxane	0	0	0	0%
C21.1 and C21.2	Pharmaceutical production (intentional use)	17	21	54	2%
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	467	595	4,210	96%
M72.1	Laboratories	0	0	0	0%
C20.4 excl. C20.42	Surfactants – presence as a minor constituent/impurity in the production of detergents, soaps, etc.	5	6	43	1%
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	8	11	75	2%

** Multiply of trend in workforce and exposure concentration*

Source: Study team.

Table 4-4 Baseline future burden of disease (PV40), 5% turnover of workforce a year, static discount rate

Sector		PV40 over 40 years, static discount rate Range of Method 1 – Method 2			
		Kidney effects M2 – M1	Liver effects M1 – M2	Local irritation: effects in nasal cavity M1 – M2	Total Low - high
Part of C20.1	Manufacture of 1,4-dioxane	€ 0 - € 0	€ 0 - € 0	€ 0 -€ 0	€ 0 -€ 0 (M1-M2)
C21.1 and C21.2	Pharmaceutical production (intentional use)	€ 13,603 - € 19,149	€ 18,215 - € 26,006	€ 46,149 - € 64,790	€ 83,513 - € 104,398 (M1-M2)
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	€ 377,661 - € 531,659	€ 505,904 - € 722,291	€ 3,614,141 - € 5,073,971	€ 4,651,705 - € 6,173,923 (M1-M2)
M72.1	Laboratories	€ 0 - € 0	€ 0 - € 0	€ 0 -€ 0	€ 0 -€ 0 (M1-M2)
C20.4 excl. C20.42	Surfactants – presence as a minor constituent/impurity in the production of detergents, soaps, etc.	€ 3,881 - € 5,464	€ 5,199 - € 7,423	€ 36,918 - € 51,831	€ 47,582 - € 63,135 (M1 – M2)
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	€ 6,750 - € 9,503	€ 9,042 - € 12,910	€ 19,149 - € 90,140	€ 82,751 - € 109,801 (M1 – M2)

Source: Study team.

Table 4-5 presents the baseline costs of ill health for workers (M1 and M2), employers and public authorities associated with the three health endpoints modelled for 1,4-dioxane. These figures represent the cost prior to any intervention being put in place to reduce exposure to 1,4-dioxane and reduce the number of resulting cases.

Table 4-5 Baseline costs of ill health for workers (M1 and M2), employers and public administrations (€ millions)

Sector	Workers and families (M1)	Workers and families (M2)	Employers	Public Authorities	Grand total (M1)	Grand total (M2)
Part of C20.1	€ 0.00	€ 0.00	€ 0.00	€ 0.00	€ 0.00	€ 0.00

Sector	Workers and families (M1)	Workers and families (M2)	Employers	Public Authorities	Grand total (M1)	Grand total (M2)
C21.1 and C21.2	€ 0.03	€ 0.05	€ 0.03	€ 0.03	€ 0.09	€ 0.11
C20.1, C20.3 and C20.5	€ 1.78	€ 3.07	€ 1.51	€ 1.90	€ 5.19	€ 6.48
M72.1	€ 0.00	€ 0.00	€ 0.00	€ 0.00	€ 0.00	€ 0.00
C20.4 excl. C20.42	€ 0.02	€ 0.03	€ 0.02	€ 0.02	€ 0.05	€ 0.07
C20.42	€ 0.03	€ 0.05	€ 0.03	€ 0.03	€ 0.09	€ 0.12
Total	€ 1.86	€ 3.20	€ 1.58	€ 1.98	€ 5.43	€ 6.77

Source: Study team.
Notes: Values for workers and values are calculated using two different methodologies (M1-M2), for more information on the differences between these methods, please see the methodological note. Grand total (M1) is the sum value of Workers & Families (M1), Employers, and Public Authorities. Grand total (M2) is the sum value of Workers & Families (M2), Employers, and Public Authorities

4.9.2 Legacy burden of disease

Previous OEL studies have not included the calculation of the future burden of disease from legacy exposure. The reason is that this burden of disease would not be affected by the assessed policy options and just be added to all scenarios and will make differences in the scenarios less prominent.

For the non-cancer endpoints, the latency time is assumed to be zero years and past exposure would not lead to future cases.

A latency period of several decades can generally be assumed for cancer. It is therefore possible that some of the current cancer incidence is associated with past exposure to 1,4-dioxane. However, the exposure data presented in Section 3.3 often relates to measurements made decades ago, and it is below saturation levels in humans (180 mg/m³) above which the risk of cancer arises, which suggests that the legacy burden is most likely small.

4.10 Summary of the baseline scenario

Table 4-6 Baseline scenario over 40 years for 1,4-dioxane

Item	Detail
Chemical agent	1,4-dioxane
Classification	Flam. Liq.2 Carc. 1B STOT SE 3 Eye Irrit. 2
Sectors	• Part of C20.1 Manufacture of 1,4-dioxane • C21.1 and C21.2 Pharmaceutical production (intentional use) • C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector • M72.1 Laboratories • C20.4 excl. C20.42 Surfactants – presence as a minor constituent/impurity in the production of detergents, soaps, etc. • C20.42 Cosmetics – generation as a by-product in the production of cosmetics
Period for estimation	40 years
Types of cancer caused	Not applicable
Other adverse health effects	Kidney effects, Liver effects, Local irritation: effects in nasal cavity
No. of exp. workers	31,150
Change exp. level	0%
Change no. of exp. workers	0%
Current disease burden (CDB) - no. of non-cancer cases/year (total for all non-cancer endpoints)	138
Future disease burden (FDB) - no. of non-cancer cases/year (total for all non-cancer endpoints)	138
FDB - no. of non-cancer cases over 40 years	5,512
CBD - no. of cases/year	12 (kidney effects) 16 (liver effects) 110 (local irritation: effects in the nasal cavity)
FBD - no. of cases/year	12 (kidney effects) 16 (liver effects) 110 (local irritation: effects in the nasal cavity)
FBD - no. of cases/ 40 years	497 (kidney effects) 633 (liver effects) 4,382 (local irritation: effects in the nasal cavity)
Estimated deaths due to FDB cancer over 40 years	0

Item	Detail
Estimated deaths due to FDB Kidney effects over 40 years	0
Estimated deaths due to FDB Liver effects over 40 years	0
Estimated deaths due to FDB Local irritation: effects in nasal cavity over 40 years	0
Monetary value FDB cancer over 40 years	0
Monetary value FDB other adverse health effects over 40 years	€ 5.43 million - € 6.77 million (M1 – M2)

Source: Study team summary on basis of the information presented in this chapter.

Table 4-7 Estimated number of exposed workers, expected number of cancers and other hazardous diseases cases and related health costs in case no action is taken (baseline scenario), over a 40 year period

Carcinogen	No. of exposed workers	Expected no. of cancer cases	Expected no. of cases of other adverse health effects	Estimated health costs, EUR	Possible underestimations (non exhaustive list)
1,4-dioxane	31,150	Not applicable	5,512	€ 5.43 million - € 6.77 million (M1 – M2	Some health endpoints could not be quantified

Source: Study team summary on basis of the information presented in this chapter.

5 POLICY OPTIONS

Throughout the analysis of benefits and costs, the following levels are used as reference OELs, STELs and BLVs for the assessment.

Table 5-1 Reference OEL (8-hr TWA) levels for 1,4-dioxane

Level	Reason for inclusion
73 mg/m^3 (20 ppm)	Current Indicative OEL under the Chemical Agents Directive[38]
36 mg/m^3 (10 ppm)	Most common value (mode) of OELs between 73 mg/m^3 and 20 mg/m^3 is 35 or 36 mg/m^3
20 mg/m^3 (5.5 ppm)	Lowest national OEL (Latvia & the Netherlands)
7.3 mg/m^3 (2 ppm)	RAC recommendation

Table 5-2 Reference STEL (15 min) levels for 1,4-dioxane

Level	Reason for inclusion
150 mg/m^3 (40 ppm)	Highest STEL in an EU Member State (Finland), also 146 mg/m^3 in Austria, Germany and Slovenia and 140 mg/m^3 in the Czech Republic and France
120 mg/m^3 (33 ppm)	Intermediate level at the mid point between 90 mg/m^3 and 150 mg/m^3
90 mg/m^3 (25 ppm)	Intermediate value, selected due to the fact that two Member States (Lithuania and Sweden) have a STEL of 90 mg/m^3
73 mg/m^3 (20 ppm)	RAC recommendation, also close to the lowest national STEL (72 mg/m^3 in Denmark)

Table 5-3 Reference BLV levels for 1,4-dioxane

Level (HEAA in urine/g Creatinine, at the end of exposure or shift)	Reason for inclusion
366 mg	Corresponds to an OEL of 73 mg/m^3 (20 ppm)
188 mg	Corresponds an OEL of 36 mg/m^3 (10 ppm), also similar to 200 mg BAT in DE
108 mg	Corresponds to an OEL of 20 mg/m^3 (5.5 ppm)
45 mg	RAC recommendation, corresponding to an OEL of 7.3 mg/m^3

[38] Table 4-1 suggests that all Member States have in place a value of 73 mg/m^3 or lower. This option is retained for the impact assessment so that the study team can check that all of the national OELs of 73 mg/m^3 or lower are binding.

6 BENEFITS OF THE MEASURES UNDER CONSIDERATION

This chapter comprises the following sections:

- Section 6.1: Summary of the assessment framework
- Section 6.2: Improved welfare, assumptions and avoided cases of ill health
- Section 6.3: Benefits to workers & families
- Section 6.4: Benefits to employers
- Section 6.5: Benefits to the public sector
- Section 6.6: Summary of the benefits of the measures.

6.1 Summary of the assessment framework

6.1.1 Summary of the key features of the model

The model developed to estimate the benefits in terms of reduced costs takes into account the cost categories set out in Table 6-1 below. More details are presented in the methodology report.

Table 6-1 The benefits framework

Category		Benefits	Notes
Direct	Improved welfare	Reduced healthcare costs	Avoided cost of medical treatment, including hospitalisation, surgery, consultations, radiation therapy, chemotherapy/immunotherapy, etc. Avoided private direct and indirect medical costs and rehabilitation costs
		Reduced informal care costs[39]	Avoided opportunity cost of unpaid care (i.e. the monetary value of the working and/or leisure time that relatives or friends provide to those with ill health)
		Reduced cost for employers	E.g. avoided costs due to insurance payments and absence from work
		Safety	Covered in first two health benefits
		Direct economic benefits	Not sure there are any direct economic benefits as they all result indirectly from health benefit. OR are the reduced costs for employers?
		Environment	See section 9, not monetised
	Improved market efficiency	Cost savings	Include higher economic productivity, improved allocation of resources, removal of regulatory or market failures or cost savings
		Improved information	Includes improved information availability

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

Category		Benefits	Notes
		Wider range of products/services	Enhanced product and service variety and quality for end consumers
Indirect	Indirect compliance benefits	Reduced mortality – productivity loss.	Avoided costs to society due to premature death
		Reduced morbidity – lost working days.	Avoided earnings and output due to absence from work due to illness or treatment
		Indirect benefits to administrations	Avoided tax revenue losses Avoided administrative and legal costs Avoided costs linked to the process of defining a national OEL
	Wider economic benefits	including higher GDP, productivity enhancements, greater employment rates, improved job quality etc.	Employment may increase as a result of industry 'clean up' due to better perception of workplaces and increased acceptability of risks
	Other, non-monetary benefits	Protection of fundamental rights, social cohesion, reduced gender discrimination, international and national stability	
Intangible	Improved welfare	Approach 1 WTP[40]: Mortality	A monetary value of the impact on quality of life of affected workers Avoided moral pain and suffering Avoided loss of present and future income Avoided cost of time claiming benefits, waiting for treatment etc. Reduction in insurance contributions
		Approach 1 WTP: Morbidity	
		Approach 2 DALY[41]: Mortality	
		Approach 2 DALY: Morbidity	

Source: Study team.

The abbreviations are explained in Table 6-2 below.

6.2 Improved welfare, assumptions and avoided cases of ill health

6.2.1 Benefits categories for improved welfare

The specific benefit categories for improved welfare are set out below.

Table 6-2 Overview of benefits categories for improved welfare

Category	Code	Cost to be avoided
Direct	*Ch*	Healthcare

40 Willingness to Pay: The maximum sum an individual is willing to pay for a service/goods in order to avoid loss, in this case, in terms of health treatment.

41 DALY = Disability Adjusted Life Year. DALY is whereby one year of health is lost. It is used to calculate the gap between current health status and the ideal health situation (WHO).

Category	Code	Cost to be avoided
	Ci	Informal care
	Ce	Total cost to an employer
Indirect	*Cp*	Productivity loss due to mortality
	Cl	Lost earnings due to morbidity
Intangible	*Cvsl*	Value of statistical life
	Cvsm	Value of cancer morbidity/value of statistical morbidity
	Cdaly	Value of DALYs

Source: Study team.

6.2.2 Relevant health endpoints for 1,4-dioxane

The relevant health endpoints for 1,4 dioxane are:

- Kidney effects
- Liver effects; and
- Local irritation in the nasal cavity.

Due to the fact that the current exposure levels are below the levels required to cause cancer, cancer does not form part of the assessment in this report.

6.2.3 Summary of the key assumptions for 1,4-dioxane

6.2.3.1 Onset of the disease

Table 6-3 Minimum & maximum exposure duration to develop a condition (MinEx & MaxEx)

Endpoint	MinEx (years)	MaxEx (years)
Kidney effects	0 (less than 1 year)	0 (less than 1 year)
Liver effects	0 (less than 1 year)	0 (less than 1 year)
Local irritation in the nasal cavity	0 (less than 1 year)	0 (less than 1 year)

Source: Study team.

Table 6-4 Latency by endpoint

Endpoint	Latency (years)
Kidney effects	0
Liver effects	0
Local irritation in the nasal cavity	0

Source: Study team.

6.2.3.2 The effects of the disease

The effects of the relevant endpoints for 1,4 dioxane are:

- Kidney effects: a range of severities are modelled by the DRR but these are most likely relatively mild and reversible, possibly undetected and untreated, akin to Acute Kidney Injury (AKI) stage 1;
- Liver effects: the effects modelled by the DRR are a pathological finding rather than a clinical indication, and as a result, the severity of potential effects is not known and the selected monetary value represents a range of potential severities; and
- Local irritation in the nasal cavity: the effects modelled by the DRR can encompass a range of severities and the approach to monetisation reflects this.

6.2.3.3 Treatment period and years lived with the disease.

Table 6-5 Treatment period

Type of illness	Treatment period (years)
Kidney effects	1 (assessment made on an annual basis)
Liver effects	1 (assessment made on an annual basis)
Local irritation in the nasal cavity	1 (assessment made on an annual basis)

Source: See Methodological note for more details.

Table 6-6 Years lived with disability/disease (YLD)

Type of illness	Treatment period (years)
Kidney effects	1 (assessment made on an annual basis)
Liver effects	1 (assessment made on an annual basis)
Local irritation in the nasal cavity	1 (assessment made on an annual basis)

Source: See Methodological note for more details.

6.2.3.4 Mortality rate and additional life expectancy at death

Table 6-7 Fatality rates (MoR)

Type of illness	MoR (years)
Kidney effects	0
Liver effects	0
Local irritation in the nasal cavity	0

Source: See Methodological note for more details.

Table 6-8 Additional life expectancy at death

Type of illness	Additional life expectancy at death (years)
Kidney effects	Not relevant
Liver effects	Not relevant
Local irritation in the nasal cavity	Not relevant

Source: See Methodological note for more details.

6.2.3.5 Cost of treatment

Table 6-9 Cost of healthcare treatment

Type of illness	Unit cost in €
Kidney effects	1,000
Liver effects	500
Local irritation in the nasal cavity	500

Source: See Methodological note for more details.

6.2.3.6 Willingness to Pay (WTP) values

Table 6-10 WTP for a avoid an effect

Type of illness	WTP, €
Kidney effects	1,000
Liver effects	1,000
Local irritation in the nasal cavity	500

Source : See the Methodological note for more details.

6.2.3.7 Disability weights

Table 6-11 Disability weights

Type of illness	During treatment	After treatment
Kidney effects	0.004	0
Liver effects	0.016	0
Local irritation in the nasal cavity	0.006	0

Source: See the Methodological note for more details.

6.2.3.8 Summary

Table 6-12 Unit costs used for the benefits assessment

Category	Code		Cost, €/case		
			Kidney effects	Liver effects	Local irritation in the nasal cavity
Direct	*Ch*	Healthcare	1,000	500	500
	Ci	Informal care	0	0	0
	Ce	Cost for employers	500	500	500[42]
Indirect	*Cp*	Mortality – productivity loss due to mortality	Not relevant	Not relevant	Not relevant
	Cl	Morbidity – lost working days due to morbidity	0	0	0
Intangible	*Cvsl*	Approach 1 WTP: Value of statistical life	Not relevant	Not relevant	Not relevant
	Cvsm	Approach 1 WTP: Value of cancer morbidity/value of statistical morbidity	1,000	1,000	500
	Cdaly	Approach 2 DALY: Value of DALYs	100,000	100,000	100,000

Note: Please note that cases are defined as a worker suffering from the relevant effect in any given year, i.e. a worker suffering from the same effect over several years is counted as multiple cases.

Source: Study team.

6.2.4 Avoided cases of ill health

Table 6-13 Avoided cases over 40 years for each OEL option

OEL option	Kidney effects	Liver effects	Local irritation in the nasal cavity
Avoided number of cases for each OEL option			
7.3 mg/m³ (2 ppm)	497	633	4,382
20 mg/m³ (5.5 ppm)	0	0	0
36 mg/m³ (10 ppm)	0	0	0
73 mg/m³ (20 ppm)	0	0	0
Baseline number of cases	497	633	4,382

Note: Please note that cases are defined as a worker suffering from the relevant effect in any given year, i.e. a worker suffering from the same effect over several years is counted as multiple cases.

Source: Study team.

[42] The costs to employers from serious illness or injury are reported in the Method Note. The value of €500 is taken as a proxy for minor effects.

Due to the absence of data on short-term exposure, it is assumed that a STEL is likely to have an effect corresponding to an OEL at 50% of its value. Due to absence of biomonitoring data, it is expected that the BLV policy options would have an effect at the corresponding OEL level based on the relationship established by ECHA (2022) – however, this does not take into account the potential for dermal exposure. Based on estimated data in the REACH CSRs, dermal exposure can be estimated to account for between 2% and 97% of the total intake of 1,4-dioxane, depending on the occupational activity.

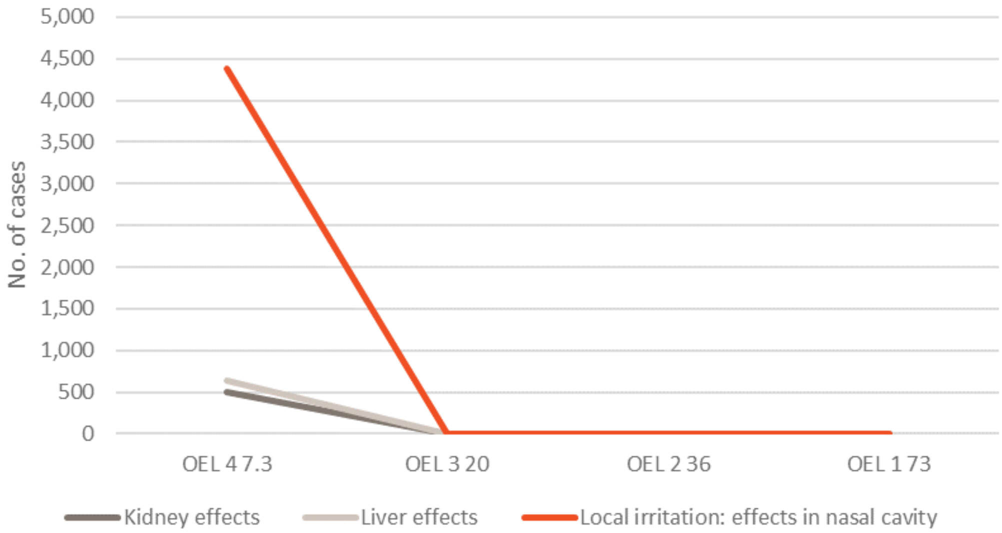

Figure 6-1 Cases over 40 years due in relation to different OEL levels (in mg/m³)

Note: Please note that cases are defined as a worker suffering from the relevant effect in any given year, i.e. a worker suffering from the same effect over several years is counted as multiple cases.

Source: Study team

If a worker complies with a BLV of 45 mg HEAA in urine/g creatinine, then the reduction in ill health will be greater than for an OEL of 7.3 mg/m³. For irritation in the nasal cavity, it is possible that there would be no additional reduction but an additional reduction can be expected for kidney and liver effects. However, there is insufficient information to quantify these additional reductions.

6.3 Benefits to workers & families

6.3.1 Avoided costs of ill health

The benefits that will be realised by exposed workers and their families are first of all intangible benefits of reduced morbidity rates. All the categories are presented in the table below.

Table 6-14 Benefits for workers and their families (avoided cost of ill health)

Stakeholder group	Costs	Method of summation
Workers/family	Ci, Cl, Cvsl, Cvcm, Cdaly	Method 1: CtotalWorker&Family=Ci+Cvsl+Cvcm Method 2: CtotalWorker&Family=Ci+Cl+Cdaly

Source: See the Methodological note for more details.

The benefits of each policy option (relative to the baseline) are summarised below. Method 1 relies on WTP values for morbidity, with the resulting estimates given in Table 6-15 and Figure 6-2.

Table 6-15 METHOD 1: Benefits to WORKERS & FAMILIES (relative to the baseline) (millions)

OEL option	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
7.3 mg/m^3	€ 0.3	€ 0.4	€ 1.2	€ 1.9
20 mg/m^3	€ 0	€ 0	€ 0	€ 0
36 mg/m^3	€ 0	€ 0	€ 0	€ 0
73 mg/m^3	€ 0	€ 0	€ 0	€ 0

Note: Workforce turnover 5% per year

Source: Study team.

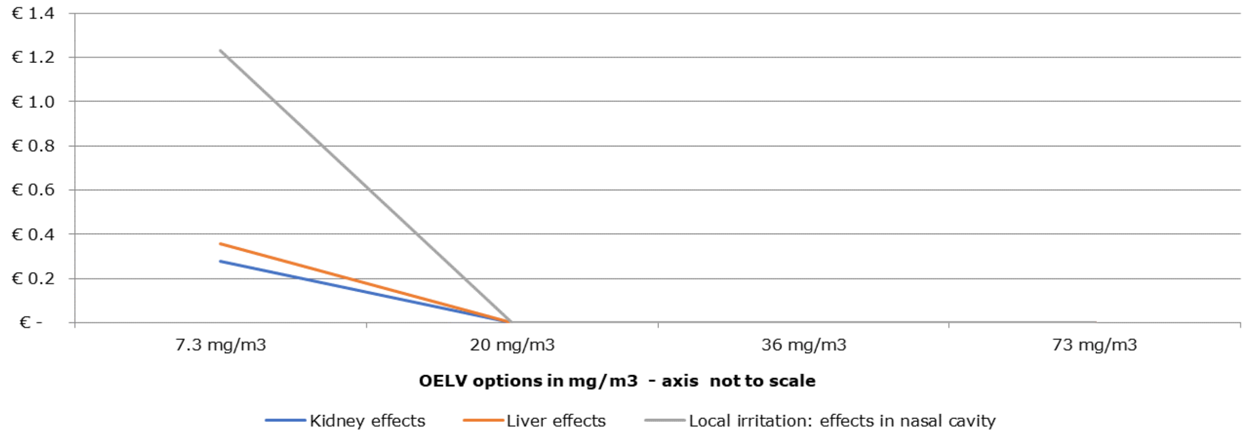

Figure 6-2 METHOD 1: Benefits to WORKERS & FAMILIES (policy options, relative to the baseline)

Source: Study team

Method 2 relies on monetised DALYs, with the estimates given in Table 6-16 and depicted in Figure 6-3.

Table 6-16 METHOD 2: Benefits to WORKERS & FAMLILIES (policy options, relative to the baseline), € millions

OEL option	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
7.3 mg/m^3	€ 0.1	€ 0.6	€ 2.5	€ 3.2
10 mg/m^3	€ 0	€ 0	€ 0	€ 0
36 mg/m^3	€ 0	€ 0	€ 0	€ 0
73 mg/m^3	€ 0	€ 0	€ 0	€ 0

Note: Workforce turnover 5% per year

Source: Study team.

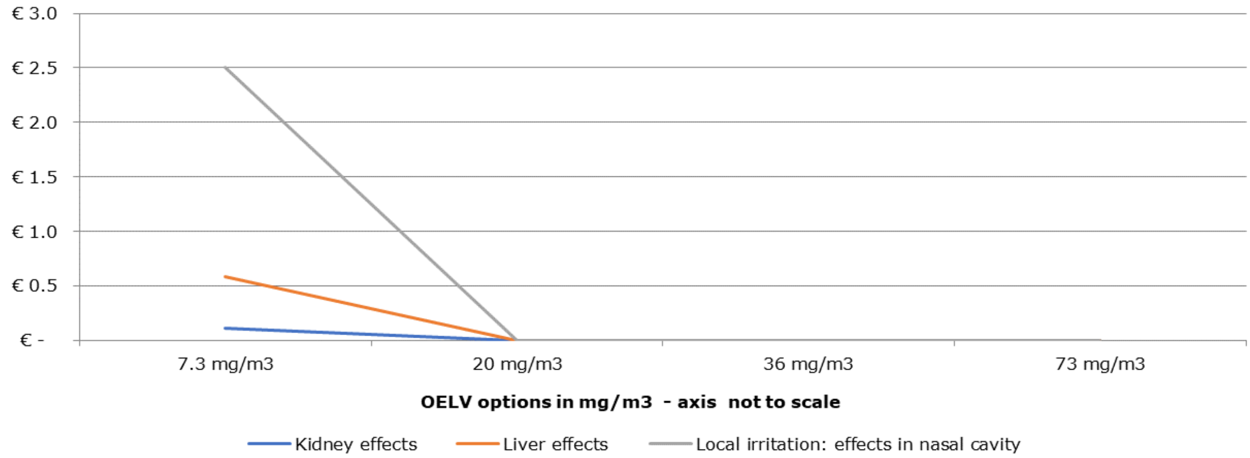

Figure 6-3 METHOD 2: Benefits to WORKERS & FAMILIES (policy options, relative to the baseline).

Source: Study team

6.3.2 Other benefits to workers and families

No other benefits have been identified.

6.4 Benefits to employers

6.4.1 Avoided costs of ill health

The benefits of each policy option are summarised below in Table 6-18 and depicted in Figure 6-4.

Table 6-18 Benefits to EMPLOYERS (OEL options, relative to the baseline), € millions

OEL option	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
7.3 mg/m^3	€ 0.1	€ 0.2	€ 1.27	€ 1.6
10 mg/m^3	€ 0	€ 0	€ 0	€ 0
36 mg/m^3	€ 0	€ 0	€ 0	€ 0
73 mg/m^3	€ 0	€ 0	€ 0	€ 0

Source: Study team.

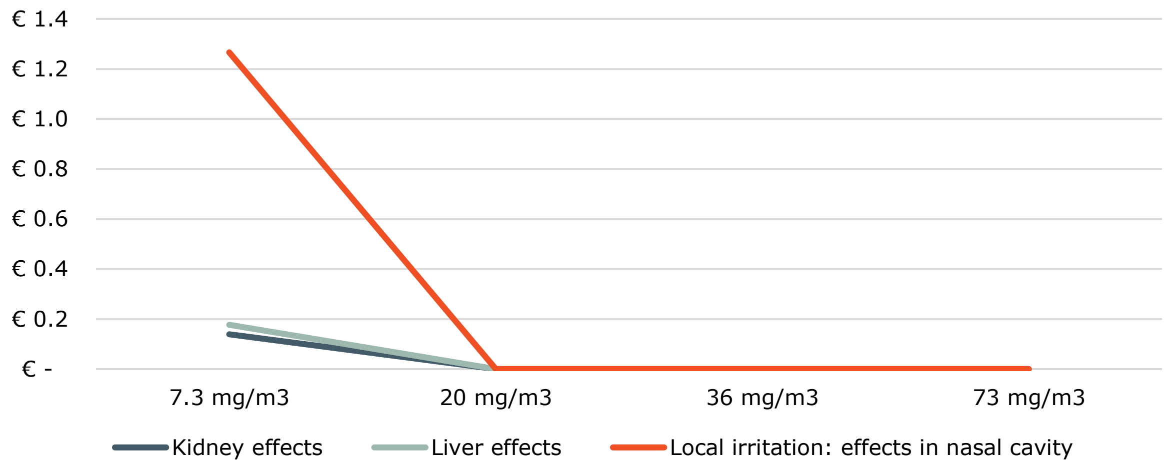

Figure 6-4 Benefits to EMPLOYERS (OEL options, relative to the baseline).

Source: Study team.

6.4.1.1 Better company image, public perception

If an OEL/STEL/BLV were to be established, work with 1,4-dioxane may be less perceived as a risky line of work associated with health issues, in particular given the prominence it has been given due to the recent reclassification of 1,4-dioxane as Carcinogenic 1B. As a result of such an improvement in the public image, companies may find it easier to recruit and retain staff, reducing the cost of recruitment and increasing the productivity of workers.

6.4.1.2 Level playing field

A reduction in the OELs is likely to improve the level playing field in the internal market, where some companies are subject to less stringent OELs than others. The ratio between the maximum and minimum national OEL is currently 3.65. It cannot be ruled out that since Member States can adopt more stringent national limits, some variation would still remain even after the introduction of a new EU OEL, STEL and/or BLV, especially for the policy options above the threshold for effects (e.g. OELs of 20, 36 and 73 mg/m^3).

6.4.1.3 One set of limit values across all Member States

The introduction of an OEL at the EU level are likely to have a positive impact on the creation of a more level playing field in the internal market. The establishment of the EU OEL should reduce the diversity of national OELs, and the resulting simplification would be beneficial to companies that operate in more than one Member State. However, according to the estimations based on Eurostat data, the majority of companies in the six relevant sectors are SMEs and it is unlikely that these companies are operating in multiple Member States. As noted in Table 3-26, the proportion of large companies in all relevant sectors in Eurostat is 4% or less, with the exception of C21.1 and C21.2 Pharmaceutical production, where 12% of the sector are large companies.

6.4.1.4 Moving away from RPE can be cheaper over a long period

As shown in Table 7-10, it is expected that savings could be realised by some companies with regard to operating costs, for example for companies that install fully closed systems and thus reduce expenditure on RPE.

6.5 Benefits to public administrations

6.5.1 Avoided costs of ill health

The benefits (avoided costs of ill health, relative to the baseline) for the public administrations are calculated using the method summarised Table 6-19 and shown in Figure 6-5. These costs include healthcare treatment costs, which assume that the costs are borne by the public administrations. These costs do not include informal care costs, which are costs for workers and families covered in section 6.3. The workforce turnover is 5% per year and a static discount rate of 3% is used.

Table 6-19 Benefits to the PUBLIC ADMINISTRATIONS (avoided cost of ill health)

Stakeholder group	Costs	Method of summation
Governments	Ch, part of Cp (loss of tax revenue), part of Cl (loss of tax revenue)	CtotalGov=Ch+0.2(Cp+Cl) (Note 1)

Note: 1 Assumes 20% tax
Source: Study team.

The benefits of each policy option (relative to the baseline) are summarised in Table 6-20 below and depicted in Figure 6-5.

Table 6-20 Benefits to the PUBLIC ADMINISTRATIONS (policy option, relative to the baseline), € millions

OEL option (Inhalable)	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
7.3 mg/m^3	€ 0.3	€ 0.18	€ 1.5	€ 2.0
20 mg/m^3	€ 0	€ 0	€ 0	€ 0
36 mg/m^3	€ 0	€ 0	€ 0	€ 0
73 mg/m^3	€ 0	€ 0	€ 0	€ 0

Source: Study team.

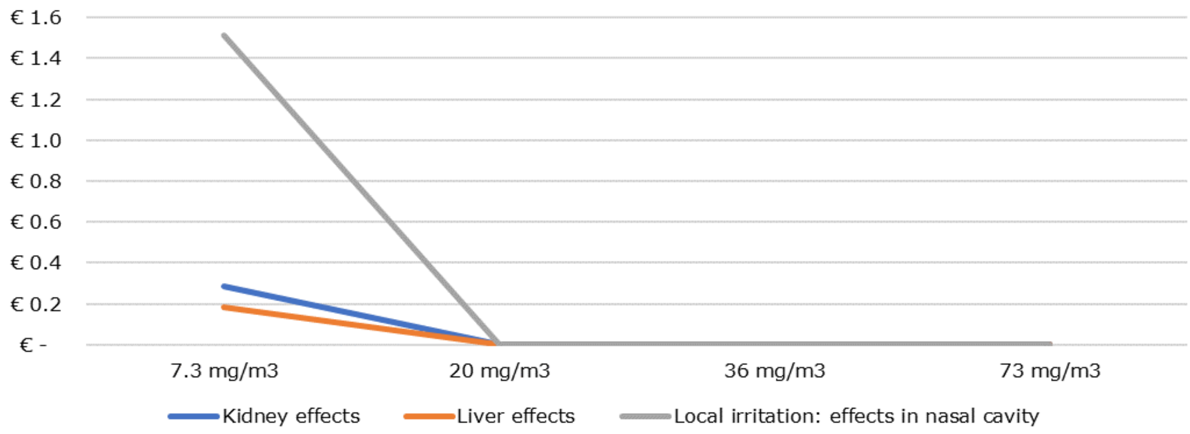

Figure 6-5 Benefits to the PUBLIC ADMINISTRATIONS (OEL options, relative to the baseline).

Source: Study team.

6.5.2 Other benefits to public administrations

6.5.2.1 Avoided costs linked to the process of defining a national OEL and BLV

The estimated avoided costs of potential revisions to national OELs are summarised in the table below. The estimates are based on the assumption that all Member States without a national OEL and/or BLV would want to implement one and that all Member States with an existing OEL and/or BLV would want to revise them to ensure higher degrees of worker protection. A more detailed explanation of the method used to derive these estimates is provided in the Methodological Note.

Table 6-20 Estimated avoided costs of having to revise national OELs in the future (€ millions)

Cost element	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³	Baseline
Avoided costs of revising OELs	€ 2.7	€ 1.8	€ 1.5	€ 1.4	€ 0.00

Source: Study team.

*Table 6-21 Estimated avoided costs of having to revise **national BLVs** in the future (€ millions)*

Cost element	45 mg HEAA in urine/g Creatinine	108 mg HEAA in urine/g Creatinine	188 mg HEAA in urine/g Creatinine	366 mg HEAA in urine/g Creatinine	Baseline
Avoided costs of revising OELs	€ 2.6	€ 2.6	€ 2.6	€ 2.6	€ 0.00

Source: Study team.

6.6 Summary of the benefits of the measures

6.6.1 Benefits from avoided ill health

Table 6-22 METHOD 1: Benefits from avoided ill health (OEL options, relative to the baseline)

OEL option	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
7.3 mg/m³ (2 ppm)	€ 631,096	€ 600,517	€ 4,195,687	€ 5,427,300
20 mg/m³ (5.5 ppm)	€ 0	€ 0	€ 0	€ 0
36 mg/m³ (10 ppm)	€ 0	€ 0	€ 0	€ 0
73 mg/m³ (20 ppm)	€ 0	€ 0	€ 0	€ 0

Source: Study team.

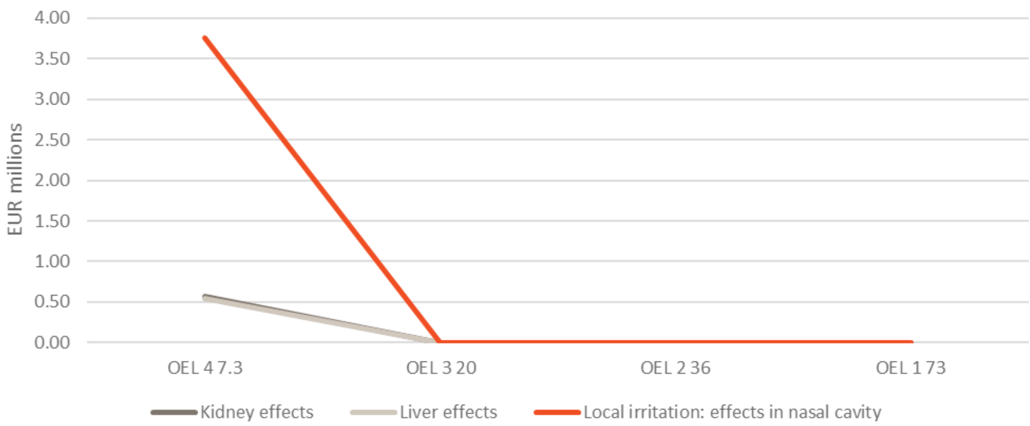

Figure 6-6 METHOD 1: Benefits from avoided ill health (OEL options, relative to the baseline).

Source: Study team.

The Method 1 benefits at different OEL options, split by sector are presented in Table 6-23.

Table 6-23 METHOD 1: Benefits from avoided ill health by sector by OEL options, relative to the baseline

Sector	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
7.3 mg/m³ (2 ppm)				
Part of C20.1	€ 0	€ 0	€ 0	€ 0
C21.1 and C21.2	€ 21,447	€ 20,401	€ 51,687	€ 93,535
C20.1, C20.3 and C20.5	€ 595,458	€ 566,612	€ 4,047,838	€ 5,209,910
M72.1	€ 0	€ 0	€ 0	€ 0

Sector	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
C20.4 excl. C20.42	€ 6,120	€ 5,823	€ 41,348	€ 53,292
C20.42	€ 10,643	€ 10,127	€ 71,911	€ 92,681
20 mg/m³ (5.5 ppm)				
Part of C20.1	€ 0	€ 0	€ 0	€ 0
C21.1 and C21.2	€ 0	€ 0	€ 0	€ 0
C20.1, C20.3 and C20.5	€ 0	€ 0	€ 0	€ 0
M72.1	€ 0	€ 0	€ 0	€ 0
C20.4 excl. C20.42	€ 0	€ 0	€ 0	€ 0
C20.42	€ 0	€ 0	€ 0	€ 0
36 mg/m³ (10 ppm)				
Part of C20.1	€ 0	€ 0	€ 0	€ 0
C21.1 and C21.2	€ 0	€ 0	€ 0	€ 0
C20.1, C20.3 and C20.5	€ 0	€ 0	€ 0	€ 0
M72.1	€ 0	€ 0	€ 0	€ 0
C20.4 excl. C20.42	€ 0	€ 0	€ 0	€ 0
C20.42	€ 0	€ 0	€ 0	€ 0
73 mg/m³ (20 ppm)				
Part of C20.1	€ 0	€ 0	€ 0	€ 0
C21.1 and C21.2	€ 0	€ 0	€ 0	€ 0
C20.1, C20.3 and C20.5	€ 0	€ 0	€ 0	€ 0
M72.1	€ 0	€ 0	€ 0	€ 0

Sector	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
C20.4 excl. C20.42	€ 0	€ 0	€ 0	€ 0
C20.42	€ 0	€ 0	€ 0	€ 0

Source: Study team.

Method 2 relies on monetised DALYs, with the results presented in Table 6-24 below. The total net benefits calculated on the basis of Method 2 are depicted in Figure 6-7. The workforce turnover is 5% per year and a static discount rate of 3% is used.

Table 6-24 METHOD 2: Benefits from avoided ill health (OEL options, relative to the baseline)

OEL option (Inhalable)	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
7.3 mg/m^3 (2 ppm)	€ 421,991	€ 807,062	€ 5,544,768	€ 6,773,820
20 mg/m^3 (5.5 ppm)	€ 0	€ 0	€ 0	€ 0
36 mg/m^3 (10 ppm)	€ 0	€ 0	€ 0	€ 0
73 mg/m^3 (20 ppm)	€ 0	€ 0	€ 0	€ 0

Source: Study team.

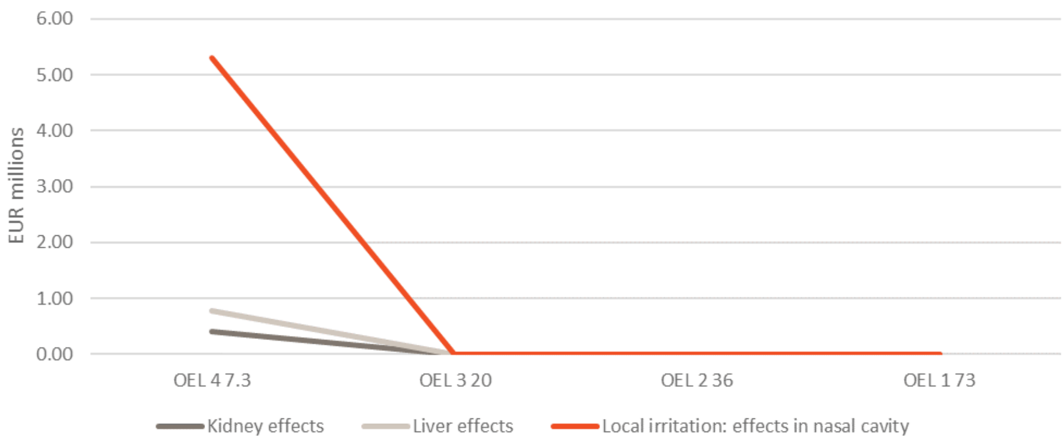

Figure 6-7 METHOD 2: Benefits from avoided ill health (OEL options, relative to the baseline).

Source: Study team.

The Method 2 benefits at different OEL options, split by sector are presented in Table 6-23.

Table 6-25 METHOD 2: Benefits from avoided ill health by sector by OEL options, relative to the baseline

Sector	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
7.3 mg/m³ (2 ppm)				
Part of C20.1	€ 0	€ 0	€ 0	€ 0
C21.1 and C21.2	€ 14,283	€ 27,306	€ 68,030	€ 109,618
C20.1, C20.3 and C20.5	€ 396,544	€ 758,406	€ 5,327,670	€ 6,482,619
M72.1	€ 0	€ 0	€ 0	€ 0
C20.4 excl. C20.42	€ 4,075	€ 7,794	€ 54,423	€ 66,292
C20.42	€ 7,088	€ 13,556	€ 94,647	€ 115,291
20 mg/m³ (5.5 ppm)				
Part of C20.1	€ 0	€ 0	€ 0	€ 0
C21.1 and C21.2	€ 0	€ 0	€ 0	€ 0
C20.1, C20.3 and C20.5	€ 0	€ 0	€ 0	€ 0
M72.1	€ 0	€ 0	€ 0	€ 0
C20.4 excl. C20.42	€ 0	€ 0	€ 0	€ 0
C20.42	€ 0	€ 0	€ 0	€ 0
36 mg/m³ (10 ppm)				
Part of C20.1	€ 0	€ 0	€ 0	€ 0
C21.1 and C21.2	€ 0	€ 0	€ 0	€ 0
C20.1, C20.3 and C20.5	€ 0	€ 0	€ 0	€ 0
M72.1	€ 0	€ 0	€ 0	€ 0
C20.4 excl. C20.42	€ 0	€ 0	€ 0	€ 0
C20.42	€ 0	€ 0	€ 0	€ 0

Sector	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
73 mg/m³ (20 ppm)				
Part of C20.1	€ 0	€ 0	€ 0	€ 0
C21.1 and C21.2	€ 0	€ 0	€ 0	€ 0
C20.1, C20.3 and C20.5	€ 0	€ 0	€ 0	€ 0
M72.1	€ 0	€ 0	€ 0	€ 0
C20.4 excl. C20.42	€ 0	€ 0	€ 0	€ 0
C20.42	€ 0	€ 0	€ 0	€ 0

Source: Study team.

Table 6-26 Overview of benefits (total for all provisions), € over 40 years (without transition measures)

Description	7.3 mg/m³ (2 ppm)	20 mg/m³ (5.5 ppm)	36 mg/m³ (10 ppm)	73 mg/m³ (20 ppm)	Comments
Avoided costs for workers & families	€ 1,863,281- € 3,203,143 (M1 – M2)	€ 0	€ 0	€ 0	
Avoided costs for employers	€ 1,582,097	€ 0	€ 0	€ 0	
Avoided costs for public administrations	€ 1,982,017	€ 0	€ 0	€ 0	

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

Source: Study team.

6.6.2 Other benefits

No other benefits have been identified.

6.6.3 Total benefits

Table 6-27 Overview of benefits (total for all provisions) from the OEL, € million over 40 years (without transition measures)

Description		7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Health and safety	Avoided costs for workers & families M1	€ 1.9	€ 0.0	€ 0.0	€ 0.0

Description		7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
	Avoided costs for workers & families M2	€ 3.2	€ 0.0	€ 0.0	€ 0.0
	Avoided costs for employers	€ 1.6	€ 0.0	€ 0.0	€ 0.0
	Avoided costs for public administrations	€ 2.0	€ 0.0	€ 0.0	€ 0.0
TOTAL BENEFITS (OEL)		**€ 4.9 – € 6.5 (M1 – M2)**	**€ 0.0**	**€ 0.0**	**€ 0.0**

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the relevant option are aggregated together). Totals may not add up due to rounding and addition methods to avoid double-counting.

Source: Study team.

In addition, it is likely that the introduction of the corresponding BLV will result in further avoided costs for workers & families, employers and public administrations, due to further reductions in ill health. In addition, as noted in Section 6.5. as noted in Section 6.5.2.1, introducing an EU-wide BLV is likely to save around €2.6 million to Member States due to the avoided need for Member States to develop and adopt their own BLVs.

7 COSTS OF THE MEASURES UNDER CONSIDERATION

This chapter comprises the following sections:

- Section 7.1: The cost framework
- Section 7.2: Direct compliance costs for companies
- Section 7.3: Indirect costs for companies
- Section 7.4: Costs for public administrations
- Section 7.5: Impact of transitional periods on costs
- Section 7.6: Summary of the costs of the measures

7.1 The cost framework

The costs assessed in this section, together with an indication of which stakeholders are likely to be affected, are presented Table 7-1 below.

Table 7-1 Impact of costs on different stakeholders

Type of cost		Citizens	Con-sumers	Work-ers	Busi-ness	Public admin-istra-tion
Direct costs						
Direct compliance costs	Adjustment costs - First year (RMMs) - Recurrent (RMMs) - Discontinuations - Air monitoring - Biomonitoring and health sur-veillance				✓	✓
	Administrative costs (Air monitoring and biomonitor-ing and health surveillance)				✓	✓
	Charges					
Enforcement costs	Transposition					✓
	Information & monitoring (Inspections by enforcement agencies)				✓	✓
	Inspections and sanctions				✓	✓
	Complaint handling				✓	✓

Type of cost		Citizens	Con-sumers	Work-ers	Busi-ness	Public admin-istra-tion
	Adjudication/litigation				✓	✓
Hassle costs					✓	✓
Indirect costs						
Indirect compliance costs			✓		✓	
Other indirect costs	Offsetting/substitution effects		✓		✓	✓
	Transaction costs		✓		✓	
	Opportunity costs		✓		✓	✓
	Reduced competition		✓		✓	
	Reduced market access		✓		✓	
	Reduced investment/innovation		✓		✓	

Source: Study team on the basis of the Better Regulation Toolbox (European Commission, 2023c).
Notes: ✓= key cost, quantified where possible, ✓= minor cost, covered qualitatively where possible

7.2 Direct compliance costs to companies

7.2.1 Introduction

This section summarises the key inputs and outputs of the cost model.

7.2.2 Summary of the key features of the cost model

The cost model used for 1,4-dioxane is the standard model used under previous RPA/COWI studies for most substances.

7.2.3 Number of enterprises at current exposure levels

The number of enterprises at different exposure levels (under the baseline) is given below.

Table 7-2 Estimated number of EU enterprises with workers exposed to 1,4-dioxane using Eurostat, survey and industry data at different exposure concentrations (mg/m³)

Sector		Number of enterprises in EU	Band 1 (50% of en-ter-prises)	Band 2 (25% of en-ter-prises)	Band 3 (15% of en-ter-prises)	Band 4 (5% of enter-prises)	Band 5 (5% of enter-prises)
Part of C20.1	Manufacture of 1,4-dioxane	8,280 (in C20.1)	0	0	0	0	0
C21.1 and C21.2	Pharmaceutical production (inten-tional use)	3,983	3.6	4.1	5.2	6.2	8.4

Sector		Number of enterprises in EU	Band 1 (50% of enterprises)	Band 2 (25% of enterprises)	Band 3 (15% of enterprises)	Band 4 (5% of enterprises)	Band 5 (5% of enterprises)
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	17,407	10.1	11.1	13.2	15.1	19
M72.1	Laboratories	53,906	1.7	2.1	3.1	4.1	7
C20.4 excl. C20.42	Surfactants – presence as a minor constituent/impurity in the production of detergents, soaps, etc.	4,142	3.6	4.2	5.6	6.8	11.4
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	7,000	3.6	4.2	5.6	6.8	11.4

Source: Study team. Note: This table distributes the total number of enterprises with exposed workers in the relevant sectors in Table 3-25 and assign them to exposure bands used in the model (see Table 13-3).

7.2.4 Estimated breakdown of RMMs used by enterprises

The estimated use of RMMs by enterprises used in the model is summarised below.

Table 7-3 Estimated use of control measures in companies used for modelling

Sector		Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	Simple enclosed cabin	Breathing apparatus	HEPA filter	Simple mask	Organisational measures	General dilution ventilation	No ventilation
		LEV3	LEV2	LEV1	WE2	WE1	RPE3	RPE2	RPE1	OH1	GDV1	GDV0
Part of C20.1	Manufacture of 1,4-dioxane	55%	20%	0%	5%	0%	0%	5%	5%	10%	0%	0%
C21.1 and C21.2	Pharmaceutical production (intentional use)	55%	20%	0%	5%	0%	0%	5%	5%	10%	0%	0%
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	55%	20%	0%	5%	0%	0%	5%	5%	10%	0%	0%
M72.1	Laboratories	0%	0%	40%	0%	0%	10%	10%	10%	10%	10%	10%

Sector		Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	Simple enclosed cabin	Breathing apparatus	HEPA filter	Simple mask	Organisational measures	General dilution ventilation	No ventilation
		LEV3	LEV2	LEV1	WE2	WE1	RPE3	RPE2	RPE1	OH1	GDV1	GDV0
C20.4 excl. C20.42	Surfactants – generation as a by-product in the production of detergents, soaps, etc.	55%	20%	0%	5%	0%	0%	5%	5%	10%	0%	0%
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	55%	20%	0%	5%	0%	0%	5%	5%	10%	0%	0%

7.2.5 Estimated average number of exposed workers per enterprise

Table 7-4 Estimated average number of exposed workers per enterprise by enterprise size

Sector		Total number of exposed workers	Average number of workers per company		
			Small <50 employees	Medium 50-249 employees	Large >249 employees
Part of C20.1	Manufacture of 1,4-dioxane	150	N/A	N/A	75
C21.1 and C21.2	Pharmaceutical production (intentional use)	15,000	38	120	975
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	5,450	41	74	233
M72.1	Laboratories	7,400	5	5	5
C20.4 excl. C20.42	Surfactants – generation as a by-product in the production of detergents, soaps, etc.	1,150	20	28	76
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	2,000	27	38	77

Source: Study team on basis of stakeholder result and Eurostat Structural Business Statistics.

7.2.6 Estimated average number of workstations per enterprise

Table 7-5 Estimated number of workstations per enterprise by size

Sector		Estimated number of workstations per enterprise by size			
		Small <50 employees	Medium 50-249 employees	Large >249 employees	Total number of enterprises
Part of C20.1	Manufacture of 1,4-dioxane	0	0	15	2
C21.1 and C21.2	Pharmaceutical production (intentional use)	19	24	195	95
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	21	15	47	105
M72.1	Laboratories	3	3	3	1,480
C20.4 excl. C20.42	Surfactants – generation as a by-product in the production of detergents, soaps, etc.	10	6	15	53
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	14	8	15	70

Note: Based on a default assumption of 2 workers per workstation in small companies and 5 workers per workstation in medium and large companies, with the exception of Sector 1 Manufacture of 1,4-dioxane and Sector 4: Laboratories where other assumptions have been used (Sector 1: 15 workers per workstation, Sector 4: 2 workers per workstation)

Source: Study team on basis of stakeholder result and Eurostat Structural Business Statistics.

7.2.7 Survey and stakeholder consultation data on adjustment costs

7.2.7.1 Survey - RMMs needed to achieve compliance

The RMMs needed to achieve compliance with the different policy options as reported in the survey are summarised below. It should be recalled that only a limited number of responses (a total of five) were received. For this reason, the results are not presented by sector but aggregated across sectors – this is seen as acceptable since the sectors where exposure to 1,4-dioxane are relatively similar (industrial/chemicals), with the exception of laboratories for which no consultation responses were received.

The percentages presented in the table below relate to processes rather than companies, with respondents typically having several processes where exposure to 1,4-dioxane occurs.

Table 7-6 Survey responses: measures required to achieve different OEL levels, % of processes (in brackets: number of processes)

Measure	Currently in place	73 mg/m³	36 mg/m³	20 mg/m³	7.3 mg/m³
No action required as OEL already achieved		58% (7)	58% (7)	50% (6)	33% (4)
Organisational and hygiene measures: Cleaning	25% (3)				
Organisational and hygiene measures: Continuous measurement of air concentrations to detect unusual exposures					
Organisational and hygiene measures: Continuous measurement to detect unusual exposures	8% (1)				17% (2)
Organisational and hygiene measures: Creating a culture of safety	67% (8)				
Organisational and hygiene measures: Formal/external RPE cleaning and filter changing regime					
Organisational and hygiene measures: Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	25% (3)				
Organisational and hygiene measures: Provision of separate storage facilities for work clothes	25% (3)				
Organisational and hygiene measures: Training and education	67% (8)				
Other	17% (2)	25% (3)	25% (3)	25% (3)	42% (5)
PPE (Personal Protective Equipment): Disposable respirators (FFP masks)					
PPE (Personal Protective Equipment): Face screens, face shields, visors	8% (1)				
PPE (Personal Protective Equipment): Gloves	92% (11)				25% (3)
PPE (Personal Protective Equipment): Goggles	75% (9)				25% (3)

Measure	Currently in place	73 mg/m³	36 mg/m³	20 mg/m³	7.3 mg/m³
PPE (Personal Protective Equipment): Half and full facemasks (negative pressure respirators)	8% (1)				
PPE (Personal Protective Equipment): Powered air-purifying respirators					
PPE (Personal Protective Equipment): PPE is essential regardless of the OEL	92% (11)				
PPE (Personal Protective Equipment): Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)					
Restructuring operations/processes: Redesign of work processes		8% (1)	8% (1)	8% (1)	17% (2)
Restructuring operations/processes: Reducing the amount of substance used	8% (1)	8% (1)			
Restructuring operations/processes: Reducing the number of workers exposed		8% (1)	8% (1)	8% (1)	
Restructuring operations/processes: Rotating the workers exposed	25% (3)	8% (1)	8% (1)	8% (1)	
Substitution or discontinuation: Discontinuation of part of the activity using 1,4-dioxane					
Substitution or discontinuation: Discontinuation of process using the substance					17% (2)
Substitution or discontinuation: Partial substitution of 1,4-dioxane used in this activity in the past					
Substitution or discontinuation: Substitution of substance				8% (1)	
Ventilation and extraction: Closed systems	67% (8)	17% (2)	17% (2)	17% (2)	25% (3)
Ventilation and extraction: General ventilation	58% (7)	8% (1)	8% (1)	8% (1)	17% (2)
Ventilation and extraction: Open hoods over equipment or local extraction ventilation	33% (4)				17% (2)

Measure	Currently in place	73 mg/m^3	36 mg/m^3	20 mg/m^3	7.3 mg/m^3
Ventilation and extraction: Partial hood enclosures					
Ventilation and extraction: Pressurised or sealed control cabs	8% (1)				
Ventilation and extraction: Simple enclosed control cabs	8% (1)				

Source: Stakeholder survey carried out for this study.

7.2.7.2 Survey - Companies' estimated costs of compliance

The estimated costs of compliance from the survey responses are given below. Due to the low number of responses to the survey, no differentiation between sectors is made.

Table 7-7 Survey responses: initial investment required to achieve different OEL levels

OEL option	< €10,000			€10,000 - €100,000			€100,000 - €1 million			> €1 million			No. of responses		
	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L
73 mg/m³		100% (2)					100% (1)						1	2	
36 mg/m³		100% (2)					100% (1)						1	2	
20 mg/m³		100% (2)					100% (1)						1	2	
7.3 mg/m³		67% (2)						33% (1)						3	

Table 7-8 Survey responses: annual recurring cost required to achieve different OEL levels

OEL option	< €1,000			€1,000 - €10,000			€10,000 - €100,000			> €100,000			No. of responses		
	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L
73 mg/m³		100% (2)		100% (1)									1	2	
36 mg/m³		100% (2)		100% (1)									1	2	
20 mg/m³		100% (2)		100% (1)									1	2	
7.3 mg/m³		67% (2)			33% (1)									3	

7.2.7.3 Survey - Lowest technically possible and economically feasible option

Only one respondent provided information in response to the survey question about the lowest technically and economically feasible concentrations noting that the lowest technically possible 15-minute concentration was in their view 20 ppm (73 mg/m^3) and the lowest economically viable 15-minute concentration was 5 ppm (18 mg/m^3).

7.2.7.4 Survey - EU Member State Authorities

No data on RMMs required to reduce exposure to 1,4-dioxane to specific levels have been provided by Member State authorities.

7.2.7.5 Surveys undertaken by industry associations

No surveys undertaken by industry associations have been identified.

7.2.8 Estimated adjustment costs

The total adjustment costs are estimated below for the different OEL options.

Table 7-9 Total PV adjustment costs over 40 years for the different OEL options by sector, excluding monitoring and administrative costs

Sector		Total PV cost by OEL option			
		73 mg/m^3	36 mg/m^3	20 mg/m^3	7.3 mg/m^3
Part of C20.1	Manufacture of 1,4-dioxane	0	0	0	0
C21.1 and C21.2	Pharmaceutical production (intentional use)	0	0	0	€0.9 million
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	0	0	0	€120.8 million
M72.1	Laboratories	0	0	0	-€1.1 million
C20.4 excl. C20.42	Surfactants – generation as a by-product in the production of detergents, soaps, etc.	0	0	0	€0.4 million
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	0	0	0	€0.5 million
Total		**0**	**0**	**0**	**€121 million**

Source: Study team. Note: Totals may not add up due to rounding.

The total costs of an OEL at 7.3 mg/m^3 are presented below split between initial costs and recurring annual costs.

The costs of transposition are estimated below for the different OEL policy options.

Table 7-10 Present Value (PV) cost of an OEL at 7.3 mg/m³

Total cost	Investment cost	Recurring annual cost
€121 million	€132 million	- €11 million

Source: Study team.

The total costs presented in Table 7-9 and Table 7-10 include discontinuation costs. The percentage of discontinuation costs in the total PV40 adjustment costs are estimated below.

Table 7-11 PV Discontinuation costs over 40 years as a percentage of total PV adjustment costs, by policy options, sector and company size

Sector		Discontinuation PV cost as % of total PV adjustment cost			
		73 mg/m³	36 mg/m³	20 mg/m³	7.3 mg/m³
Part of C20.1	Manufacture of 1,4-dioxane	0%	0%	0%	0%
C21.1 and C21.2	Pharmaceutical production (intentional use)	0%	0%	0%	0%
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	0%	0%	0%	85%
M72.1	Laboratories	0%	0%	0%	0%
C20.4 excl. C20.42	Surfactants – generation as a by-product in the production of detergents, soaps, etc.	0%	0%	0%	0%
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	0%	0%	0%	0%
Total		0%	0%	0%	**85%**

Source: Study team.

First year adjustment costs in Table 7-12 include the first year costs of purchasing/installing alternative RMMs, plus associated operating cost in the first year, minus the first year cost of operating existing RMMs which are being replaced.

Table 7-12 First year adjustment costs by policy options, sector and company size (excluding the costs of monitoring and associated administrative burden)

Sector	€ million			
	Small	Medium	Large	Total
7.3 mg/m³				
Part of C20.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C21.1 and C21.2	€ 1.5	€ 0.7	€ 2.3	€ 4.5
C20.1, C20.3 and C20.5	€ 28.6	€ 6.6	€ 8.2	€ 43.4
M72.1	€ 3.6	€ 0.2	€ 0.1	€ 3.9
C20.4 excl. C20.42	€ 0.5	€ 0.1	€ 0.1	€ 0.6
C20.42	€ 0.8	€ 0.1	€ 0.1	€ 1.0
Total	**€ 35.0**	**€ 7.6**	**€ 10.8**	**€ 53.4**
20 mg/m³				
Part of C20.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C21.1 and C21.2	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.1, C20.3 and C20.5	€ 0.0	€ 0.0	€ 0.0	€ 0.0
M72.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.4 excl. C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Total	**€ 0.0**	**€ 0.0**	**€ 0.0**	**€ 0.0**
36 mg/m³				
Part of C20.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C21.1 and C21.2	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.1, C20.3 and C20.5	€ 0.0	€ 0.0	€ 0.0	€ 0.0
M72.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.4 excl. C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0

Sector	€ million			
	Small	Medium	Large	Total
Total	**€ 0.0**	**€ 0.0**	**€ 0.0**	**€ 0.0**
73 mg/m³				
Part of C20.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C21.1 and C21.2	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.1, C20.3 and C20.5	€ 0.0	€ 0.0	€ 0.0	€ 0.0
M72.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.4 excl. C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Total	**€ 0.0**	**€ 0.0**	**€ 0.0**	**€ 0.0**

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

Table 7-13 illustrates the costs associated with company discontinuations. Discontinuations include proportions of companies, representing partial closure of companies or the cessation of production lines where exposures occur. Discontinuation costs may also represent high adjustment costs that cannot be easily modelled. For small and medium companies' discontinuations typically refer to the full closure of a company, whereas large companies are more likely to close specific production lines or absorb high adjustment costs.

Table 7-13 Discontinuation PV adjustment costs over 40 years by policy options, sector and company size

Sector	€ million			
	Small	Medium	Large	Total
7.3 mg/m³				
Part of C20.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C21.1 and C21.2	€ 17.8	€ 47.6	€ 36.8	€ 102.2
C20.1, C20.3 and C20.5	€ 0.0	€ 0.0	€ 0.0	€ 0.0
M72.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.4 excl. C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Total	**€ 17.8**	**€ 47.6**	**€ 36.8**	**€ 102.2**
20 mg/m³				
Part of C20.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C21.1 and C21.2	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.1, C20.3 and C20.5	€ 0.0	€ 0.0	€ 0.0	€ 0.0
M72.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.4 excl. C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Total	**€ 0.0**	**€ 0.0**	**€ 0.0**	**€ 0.0**
36 mg/m³				
Part of C20.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C21.1 and C21.2	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.1, C20.3 and C20.5	€ 0.0	€ 0.0	€ 0.0	€ 0.0
M72.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.4 excl. C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0

Sector	€ million			
	Small	Medium	Large	Total
Total	**€ 0.0**	**€ 0.0**	**€ 0.0**	**€ 0.0**
73 mg/m³				
Part of C20.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C21.1 and C21.2	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.1, C20.3 and C20.5	€ 0.0	€ 0.0	€ 0.0	€ 0.0
M72.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.4 excl. C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Total	**€ 0.0**	**€ 0.0**	**€ 0.0**	**€ 0.0**

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

Table 7-14 presents the recurrent costs for companies installing alternative RMMs. Recurrent costs are defined as those from year 2-40 and include 20 year reinvestment costs as well as operational costs. All negative values in this table are due to the avoided recurrent costs of existing RMMs over 40 years being greater than the cost of implementing new RMMs over 40 years. To repeat, this is most typical for sectors with existing reliance upon RMMs with high recurrent costs, such as RPE, moving to RMMs with lesser recurrent costs over the same period, such as closed systems.

Table 7-14 Recurrent PV adjustment costs over 40 years by policy options, sector and company size (excluding the costs of monitoring and associated administrative burden)

Sector	€ million			
	Small	Medium	Large	Total
7.3 mg/m³				
Part of C20.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C21.1 and C21.2	-€ 0.9	-€ 0.7	-€ 2.0	-€ 3.7
C20.1, C20.3 and C20.5	-€ 18.8	-€ 3.0	-€ 3.0	-€ 24.8
M72.1	-€ 5.2	€ 0.1	€ 0.1	-€ 5.0
C20.4 excl. C20.42	-€ 0.2	€ 0.0	€ 0.0	-€ 0.2
C20.42	-€ 0.4	€ 0.0	€ 0.0	-€ 0.4
Total	**-€ 25.5**	**-€ 3.7**	**-€ 5.0**	**-€ 34.2**
20 mg/m³				
Part of C20.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C21.1 and C21.2	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.1, C20.3 and C20.5	€ 0.0	€ 0.0	€ 0.0	€ 0.0
M72.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.4 excl. C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Total	**€ 0.0**	**€ 0.0**	**€ 0.0**	**€ 0.0**
36 mg/m³				
Part of C20.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C21.1 and C21.2	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.1, C20.3 and C20.5	€ 0.0	€ 0.0	€ 0.0	€ 0.0
M72.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.4 excl. C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0

Sector	€ million			
	Small	Medium	Large	Total
Total	**€ 0.0**	**€ 0.0**	**€ 0.0**	**€ 0.0**
73 mg/m^3				
Part of C20.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C21.1 and C21.2	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.1, C20.3 and C20.5	€ 0.0	€ 0.0	€ 0.0	€ 0.0
M72.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.4 excl. C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Total	**€ 0.0**	**€ 0.0**	**€ 0.0**	**€ 0.0**

Notes: Values in red are negative values even where they appear to be €0.0 due to rounding. Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

Table 7-15 illustrates the combined first year, recurrent, and discontinuation costs for all sectors, split by company size.

Table 7-15 Total PV adjustment costs over 40 years by policy options, sector and company size (excluding the costs of monitoring and associated administrative burden)

Sector	€ million			
	Small	Medium	Large	Total
7.3 mg/m³				
Part of C20.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C21.1 and C21.2	€ 0.6	€ 0.0	€ 0.3	€ 0.9
C20.1, C20.3 and C20.5	€ 27.6	€ 51.2	€ 41.9	€ 120.8
M72.1	-€ 1.6	€ 0.2	€ 0.2	-€ 1.1
C20.4 excl. C20.42	€ 0.2	€ 0.1	€ 0.1	€ 0.4
C20.42	€ 0.4	€ 0.1	€ 0.1	€ 0.5
Total	**€ 27.2**	**€ 51.6**	**€ 42.6**	**€ 121.4**
20 mg/m³				
Part of C20.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C21.1 and C21.2	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.1, C20.3 and C20.5	€ 0.0	€ 0.0	€ 0.0	€ 0.0
M72.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.4 excl. C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Total	**€ 0.0**	**€ 0.0**	**€ 0.0**	**€ 0.0**
36 mg/m³				
Part of C20.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C21.1 and C21.2	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.1, C20.3 and C20.5	€ 0.0	€ 0.0	€ 0.0	€ 0.0
M72.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.4 excl. C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0

Sector	€ million			
	Small	Medium	Large	Total
Total	**€ 0.0**	**€ 0.0**	**€ 0.0**	**€ 0.0**
73 mg/m³				
Part of C20.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C21.1 and C21.2	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.1, C20.3 and C20.5	€ 0.0	€ 0.0	€ 0.0	€ 0.0
M72.1	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.4 excl. C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
C20.42	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Total	**€ 0.0**	**€ 0.0**	**€ 0.0**	**€ 0.0**

Notes: Values in red are negative values even where they appear to be €0.0 due to rounding. Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

Due to lack of data, no costs for the STEL policy options could be estimated. However, it is expected that compliance with an OEL is likely to ensure compliance with a STEL at ten times the value of the OEL (see Table 14-6). Using this assumption, the costs of the different STEL options are estimated below. Please note that these costs overlap with the costs presented above for the different OEL options; in other words, compliance with an OEL of 7.3 mg/m³ is likely to also ensure compliance a STEL of 73 mg/m³. The other monetary values calculated using the same approach (factor of 10) so, for example, 120 mg/m³ is calculated based on a hypothetical OEL of 12 mg/m³.

Table 7-16 Total adjustment costs for the different STEL options (PV sum of total investment and recurring costs over 40 years)

STEL Option	€ total costs in Present Value (PV) over 40 years
150 mg/m³ (40 ppm)	€2.3 million
120 mg/m³ (33 ppm)	€5.7 million
90 mg/m³ (25 ppm)	€73 million
73 mg/m³ (20 ppm)	€121 million

Source: Study team.

Although adjustment costs for achieving the different BLV levels could be estimated on the basis of the corresponding OEL levels, it is likely that the equation used in RAC (2022) takes no (or limited) dermal intake into account. Should there be no dermal uptake of 1,4-dioxane, the costs of RMMs required to comply with a BLV would be the same as those of the corresponding OEL levels as determined by the equation in RAC (2022).

Any kind of direct contact may lead to dermal exposure: splashes, touching contaminated objects or surfaces. High vapour pressure of 1,4-dioxane leads to reduced potential to come into contact with contaminated surfaces/objects and also leads to reduced potential for skin exposure during removal of gloves. Where a BLV is exceeded, it may be because of inhalation and/or dermal exposure. Gloves plus potentially other protective PPE such as clothing, aprons, has the potential to reduce dermal exposure to negligible levels, if properly used. These additional costs cannot be quantified.

7.2.9 Monitoring costs

The costs are based on the following overall considerations:

- Additional monitoring would not be needed in Member States where the OEL is already at the level of the policy option or lower.
- Larger companies in general undertake monitoring more often than smaller companies.
- The percentage of companies which would need to monitor increases as the OEL decreases (the larger the difference between the new OEL and current exposure concentrations).
- Not all companies would need additional monitoring - some companies already undertake monitoring and some companies, in particular smaller companies, would install additional RMMs without monitoring.

For more information, see the Methodological Note.

The estimated monitoring costs are given in the table below. No costs additional to the baseline are expected to arise at an OEL of 73 mg/m^3 since companies are already expected to be operating significantly below this level. Some companies are expected to check that they are complying with levels of 36 mg/m^3 and 20 mg/m^3 (e.g. by being at 10% or less in a procedure foreseen in EN689). However, a more significant number of companies are expected to remeasure under the most stringent policy option of 7.3 mg/m^3.

Table 7-17 Estimated costs of air monitoring costs in € over 40 years, based on two campaigns[43]

Sector	Total costs € (based on two campaigns)			
	Small	Medium	Large	Total
7.3 mg/m^3				
Part of C20.1	€ 0	€ 0	€ 25,952	€ 25,952

[43] Two campaigns have been included in this study to provide a conservative estimate of air monitoring costs and their associated administrative burden. Where no changes to existing RMMs are needed, it is possible a second campaign may not be needed and therefore these costs may be an overestimate. The magnitude of this overestimate will not impact the outcome of this study and can be seen as a conservative estimate.

Sector	Total costs € (based on two campaigns)			
	Small	Medium	Large	Total
C21.1 and C21.2	€ 60,398	€ 113,225	€ 142,736	€ 316,360
C20.1, C20.3 and C20.5	€ 76,561	€ 95,806	€ 51,904	€ 224,272
M72.1	€ 1,225,833	€ 278,709	€ 90,832	€ 1,595,374
C20.4 excl. C20.42	€ 41,683	€ 26,129	€ 12,976	€ 80,788
C20.42	€ 55,294	€ 34,839	€ 12,976	€ 103,109
TOTAL	**€ 1,459,769**	**€ 548,708**	**€ 337,376**	**€ 2,345,855**
20 mg/m³				
Part of C20.1	€ 0	€ 0	€ 1,758	€ 1,758
C21.1 and C21.2	€ 20,438	€ 8,188	€ 9,058	€ 37,684
C20.1, C20.3 and C20.5	€ 26,337	€ 7,043	€ 3,348	€ 36,729
M72.1	€ 407,465	€ 19,799	€ 5,662	€ 432,926
C20.4 excl. C20.42	€ 14,204	€ 1,903	€ 829	€ 16,936
C20.42	€ 18,831	€ 2,536	€ 829	€ 22,195
TOTAL	**€ 487,275**	**€ 39,469**	**€ 21,484**	**€ 548,228**
36 mg/m³				
Part of C20.1	€ 0	€ 0	€ 1,758	€ 1,758
C21.1 and C21.2	€ 18,601	€ 7,452	€ 8,243	€ 34,296
C20.1, C20.3 and C20.5	€ 25,020	€ 6,691	€ 3,181	€ 34,892
M72.1	€ 362,291	€ 17,604	€ 5,034	€ 384,929
C20.4 excl. C20.42	€ 13,636	€ 1,827	€ 796	€ 16,258
C 20.42	€ 17,690	€ 2,382	€ 778	€ 20,850
TOTAL	**€ 437,238**	**€ 35,956**	**€ 19,790**	**€ 492,983**
73 mg/m³				

Sector	Total costs € (based on two campaigns)			
	Small	Medium	Large	Total
Part of C20.1	€ 0	€ 0	€ 0	€ 0
C21.1 and C21.2	€ 0	€ 0	€ 0	€ 0
C20.1, C20.3 and C20.5	€ 0	€ 0	€ 0	€ 0
M72.1	€ 0	€ 0	€ 0	€ 0
C20.4 excl. C20.42	€ 0	€ 0	€ 0	€ 0
C 20.42	€ 0	€ 0	€ 0	€ 0
TOTAL	**€ 0**	**€ 0**	**€ 0**	**€ 0**

Source: Study team.

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

7.2.10 Air monitoring administrative costs

The estimated administrative costs associated with the monitoring costs estimated above are given in the table below. Similar to the costs estimated above, no costs additional to the baseline are expected to arise at an OEL of 73 mg/m^3 with some companies remeasuring at levels of 36 mg/m^3 and 20 mg/m^3 and a more significant number of companies remeasuring under the most stringent policy option of 7.3 mg/m^3.

Table 7-18 Estimated costs of administrative burden of air monitoring by sector and policy option discounted as appropriate over 40 years

Sector	Total costs € (based on two campaigns)			
	Small	Medium	Large	Total
7.3 mg/m^3				
Part of C20.1	€ 0	€ 0	€ 11,491	€ 11,491
C21.1 and C21.2	€ 16,997	€ 35,561	€ 63,200	€ 115,757
C20.1, C20.3 and C20.5	€ 21,545	€ 30,090	€ 22,982	€ 74,617
M72.1	€ 344,965	€ 87,534	€ 40,218	€ 472,717
C20.4 excl. C20.42	€ 11,730	€ 8,206	€ 5,745	€ 25,682

Sector	Total costs € (based on two campaigns)			
	Small	Medium	Large	Total
C20.42	€ 15,561	€ 10,942	€ 5,745	€ 32,248
TOTAL	**€ 410,798**	**€ 172,333**	**€ 149,381**	**€ 732,512**
20 mg/m³				
Part of C20.1	€ 0	€ 0	€ 1,149	€ 1,149
C21.1 and C21.2	€ 6,369	€ 3,499	€ 5,921	€ 15,789
C20.1, C20.3 and C20.5	€ 8,208	€ 3,010	€ 2,189	€ 13,406
M72.1	€ 126,984	€ 8,460	€ 3,701	€ 139,145
C20.4 excl. C20.42	€ 4,427	€ 813	€ 542	€ 5,782
C 20.42	€ 5,869	€ 1,083	€ 542	€ 7,494
TOTAL	**€ 151,857**	**€ 16,864**	**€ 14,044**	**€ 182,764**
36 mg/m³				
Part of C20.1	€ 0	€0	€ 1,149	€ 1,149
C21.1 and C21.2	€ 5,797	€ 3,184	€ 5,389	€ 14,370
C20.1, C20.3 and C20.5	€ 7,797	€ 2,859	€ 2,079	€ 12,736
M72.1	€ 112,906	€ 7,522	€ 3,291	€ 123,719
C20.4 excl. C20.42	€ 4,249	€ 781	€ 520	€ 5,550
C20.42	€ 5,513	€ 1,018	€ 509	€ 7,040
TOTAL	**€ 136,263**	**€ 15,363**	**€ 12,937**	**€ 164,563**
73 mg/m³				
Part of C20.1	€ 0	€ 0	€ 0	€ 0
C21.1 and C21.2	€ 0	€ 0	€ 0	€ 0
C20.1, C20.3 and C20.5	€ 0	€ 0	€ 0	€ 0
M72.1	€ 0	€ 0	€ 0	€ 0

Sector	Total costs € (based on two campaigns)			
	Small	Medium	Large	Total
C20.4 excl. C20.42	€ 0	€ 0	€ 0	€ 0
C 20.42	€ 0	€ 0	€ 0	€ 0
TOTAL	**€ 0**	**€ 0**	**€ 0**	**€ 0**

Source: Study team.

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

7.2.11 Aggregated costs for companies by sector

Table 7-19 Aggregated PV costs of adjustment, air monitoring and administrative burden discounted over 40 years, by sector, by OEL policy options, € million

Sector	Total costs OEL options, € millions			
	7.3 mg/m3	20 mg/m3	36 mg/m3	73 mg/m3
Part of C20.1	€ 0.04	€ 0.00	€ 0.00	€ 0.00
C21.1 and C21.2	€ 1.30	€ 0.05	€ 0.05	€ 0.00
C20.1, C20.3 and C20.5	€ 121.13	€ 0.05	€ 0.05	€ 0.00
M72.1	€ 0.93	€ 0.57	€ 0.51	€ 0.00
C20.4 excl. C20.42	€ 0.48	€ 0.02	€ 0.02	€ 0.00
C 20.42	€ 0.68	€ 0.03	€ 0.03	€ 0.00
TOTAL	**€ 124.55**	**€ 0.76**	**€ 0.68**	**€ 0.00**

Source: Study team.

Notes: Totals may not add up due to rounding. Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Table 7-20 Aggregated PV costs of adjustment, air monitoring and administrative burden discounted over 40 years, by sector, by OEL policy options and by size, € million

Sector	**Total costs OEL options, € millions**		
	Small	**Medium**	**Large**
7.3 mg/m³			
Part of C20.1	€ 0.00	€ 0.00	€ 0.04
C21.1 and C21.2	€ 0.64	€ 0.14	€ 0.52
C20.1, C20.3 and C20.5	€ 27.71	€ 51.35	€ 42.07
M72.1	-€ 0.01	€ 0.60	€ 0.33
C20.4 excl. C20.42	€ 0.29	€ 0.10	€ 0.10
C20.42	€ 0.45	€ 0.13	€ 0.10
Total	**€ 29**	**€ 52**	**€ 43**
20 mg/m³			
Part of C20.1	€ 0.00	€ 0.00	€ 0.04
C21.1 and C21.2	€ 0.03	€ 0.01	€ 0.01
C20.1, C20.3 and C20.5	€ 0.42	€ 0.02	€ 0.01
M72.1	€ 0.14	€ 0.01	€ 0.00
C20.4 excl. C20.42	€ 0.02	€ 0.00	€ 0.00
C20.42	€ 0.01	€ 0.00	€ 0.00
Total	**€ 0.62**	**€ 0.05**	**€ 0.06**
36 mg/m³			
Part of C20.1	€ 0.00	€ 0.00	€ 0.00
C21.1 and C21.2	€ 0.02	€ 0.01	€ 0.01
C20.1, C20.3 and C20.5	€ 0.03	€ 0.01	€ 0.01
M72.1	€ 0.48	€ 0.03	€ 0.01
C20.4 excl. C20.42	€ 0.02	€ 0.00	€ 0.00
C20.42	€ 0.02	€ 0.00	€ 0.00

Sector	Total costs OEL options, € millions		
	Small	Medium	Large
Total	**€ 0.57**	**€ 0.05**	**€ 0.03**
73 mg/m³			
Part of C20.1	€ 0.00	€ 0.00	€ 0.00
C21.1 and C21.2	€ 0.00	€ 0.00	€ 0.00
C20.1, C20.3 and C20.5	€ 0.00	€ 0.00	€ 0.00
M72.1	€ 0.00	€ 0.00	€ 0.00
C20.4 excl. C20.42	€ 0.00	€ 0.00	€ 0.00
C20.42	€ 0.00	€ 0.00	€ 0.00
Total	**€ 0.00**	**€ 0.00**	**€ 0.00**

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

7.2.12 Additional costs of biomonitoring

The additional costs of the BLV options (in addition to the adjustment costs) are summarised below. These are the costs of biomonitoring, health surveillance and administrative costs. They include the costs of biomonitoring, including collection of the samples, the analysis of the samples, as well as health surveillance of the relevant workers.

Some companies are expected to conduct health surveillance already to refine their risk assessment or to comply with national BLVs. The model is developed under the following overall considerations:

- Additional monitoring would not be needed where the current exposure levels are significantly below the OEL that corresponds to the relevant BLV option (see Section 5 of this report). An explanation of this approach can also be found in section 7.3.1 of the Methodological Note.

- The percentage of exposed workers which would need biomonitoring and health surveillance increases as the BLV decreases.

It is assumed that those companies that monitor would need one initial and one or two additional biomonitoring and health surveillance campaigns:

- For all companies that monitor at all, one monitoring campaign to establish whether and which RMMs are required.

- For 1,4-dioxane, with the exception of situations where inhalation exposure is already at levels significantly below the OEL that corresponds to the relevant BLV, two monitoring campaigns are expected to be required (given the fact that biomonitoring does appears not to be generally undertaken at present).

Table 7-21 PV of the biomonitoring and health surveillance discounted over 40 years, by sector, by BLV policy options, € millions

Sector	Additional biomonitoring costs per BLV option, € million							
	45 mg HEAA in urine/g Creatinine		108 mg HEAA in urine/g Creatinine		188 mg HEAA in urine/g Creatinine		366 mg HEAA in urine/g Creatinine	
	Biomonitoring and health surveillance cost	Associated administrative cost	Biomonitoring and health surveillance cost	Associated administrative cost	Biomonitoring and health surveillance cost	Associated administrative cost	Biomonitoring and health surveillance cost	Associated administrative cost
Part of C20.1	€ 0.04	€ 0.01	€ 0.04	€ 0.01	€ 0.04	€ 0.01	€ 0.03	€ 0.01
C21.1 and C21.2	€ 57.16	€ 1.09	€ 9.55	€ 0.19	€ 4.26	€ 0.09	€ 2.76	€ 0.09
C20.1, C20.3 and C20.5	€ 39.99	€ 1.75	€ 39.99	€ 1.75	€ 3.47	€ 0.16	€ 1.00	€ 0.07
M72.1	€ 7.32	€ 2.59	€ 4.71	€ 1.69	€ 2.10	€ 0.79	€ 1.36	€ 0.79
C20.4 excl. C20.42	€ 4.39	€ 0.40	€ 0.73	€ 0.07	€ 0.33	€ 0.03	€ 0.21	€ 0.03
C 20.42	€ 7.62	€ 0.51	€ 1.27	€ 0.09	€ 0.57	€ 0.04	€ 0.37	€ 0.04
Total	**€ 116.52**	**€ 6.35**	**€ 56.30**	**€ 3.79**	**€ 10.76**	**€ 1.11**	**€ 5.72**	**€ 1.03**

Source: Study team.

Notes: Totals may not add up due to rounding. Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Table 7-22 PV of the biomonitoring and health surveillance discounted over 40 years, by sector, by BLV policy options, by size, € millions

Sector	Biomonitoring and health surveillance cost			Associated administrative cost		
	Small	Medium	Large	Small	Medium	Large
45 mg HEAA in urine/g Creatinine						
Part of C20.1	€ -	€ -	€ 0.04	€ -	€ -	€ 0.01
C21.1 and C21.2	€ 1.89	€ 6.04	€ 49.24	€ 0.44	€ 0.24	€ 0.41
C20.1, C20.3 and C20.5	€ 4.98	€ 8.45	€ 26.56	€ 1.07	€ 0.39	€ 0.29
M72.1	€ 2.31	€ 1.86	€ 3.15	€ 2.36	€ 0.16	€ 0.07
C20.4 excl. C20.42	€ 0.69	€ 1.00	€ 2.70	€ 0.30	€ 0.06	€ 0.04
C20.42	€ 1.39	€ 2.08	€ 4.15	€ 0.40	€ 0.07	€ 0.04
Total	**€ 11.26**	**€ 19.42**	**€ 85.84**	**€ 4.58**	**€ 0.92**	**€ 0.84**
108 mg HEAA in urine/g Creatinine						
Part of C20.1	€ -	€ -	€ 0.04	€ -	€ -	€ 0.01
C21.1 and C21.2	€ 0.32	€ 1.01	€ 8.22	€ 0.08	€ 0.04	€ 0.07
C20.1, C20.3 and C20.5	€ 4.98	€ 8.45	€ 26.56	€ 1.07	€ 0.39	€ 0.29
M72.1	€ 1.49	€ 1.20	€ 2.02	€ 1.54	€ 0.10	€ 0.04

Sector	Biomonitoring and health surveillance cost			Associated administrative cost		
	Small	Medium	Large	Small	Medium	Large
C20.4 excl. C20.42	€ 0.11	€ 0.17	€ 0.45	€ 0.05	€ 0.01	€ 0.01
C20.42	€ 0.23	€ 0.35	€ 0.69	€ 0.07	€ 0.01	€ 0.01
Total	**€ 7.13**	**€ 11.17**	**€ 38.00**	**€ 2.81**	**€ 0.56**	**€ 0.42**
188 mg HEAA in urine/g Creatinine						
Part of C20.1	€ -	€ -	€ 0.04	€ -	€ -	€ 0.01
C21.1 and C21.2	€ 0.14	€ 0.45	€ 3.67	€ 0.04	€ 0.02	€ 0.03
C20.1, C20.3 and C20.5	€ 0.43	€ 0.73	€ 2.30	€ 0.10	€ 0.04	€ 0.03
M72.1	€ 0.66	€ 0.53	€ 0.90	€ 0.72	€ 0.05	€ 0.02
C20.4 excl. C20.42	€ 0.05	€ 0.07	€ 0.20	€ 0.02	€ 0.00	€ 0.00
C20.42	€ 0.10	€ 0.15	€ 0.31	€ 0.03	€ 0.01	€ 0.00
Total	**€ 1.39**	**€ 1.95**	**€ 7.42**	**€ 0.91**	**€ 0.11**	**€ 0.09**
366 mg HEAA in urine/g Creatinine						
Part of C20.1	€ -	€ -	€ 0.03	€ -	€ -	€ 0.01
C21.1 and C21.2	€ 0.09	€ 0.29	€ 2.37	€ 0.04	€ 0.02	€ 0.03

Sector	Biomonitoring and health surveillance cost			Associated administrative cost		
	Small	Medium	Large	Small	Medium	Large
C20.1, C20.3 and C20.5	€ 0.12	€ 0.21	€ 0.67	€ 0.05	€ 0.02	€ 0.01
M72.1	€ 0.43	€ 0.35	€ 0.58	€ 0.72	€ 0.05	€ 0.02
C20.4 excl. C20.42	€ 0.03	€ 0.05	€ 0.13	€ 0.02	€ 0.00	€ 0.00
C20.42	€ 0.07	€ 0.10	€ 0.20	€ 0.03	€ 0.01	€ 0.00
Total	**€ 0.75**	**€ 1.00**	**€ 3.98**	**€ 0.86**	**€ 0.09**	**€ 0.08**

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

7.2.13 Regulatory charges

No regulatory charges are foreseen due to the introduction of an EU level OEL.

7.2.14 Comparison of costs estimates

A comparison of the cost estimates is presented in Section 7.6.

7.3 Indirect costs for companies

Indirect costs could arise in terms of the availability of products, the choice and quality of products, as well as possible ripple effects through the value chain; these types of costs are also discussed in more detail in Section 8 on Market Effects.

7.4 Costs for public administrations

7.4.1 Costs of transposition

The costs of transposition are estimated below for the different OEL policy options based on the numbers of Member States that would have to change their OEL (or introduce a new OEL).

If Member States introduce multiple OELs at the same time, the costs of transposition may be less than if each OEL is introduced individually. However, the study team does not know which, if any, OELs will actually be introduced and when, and therefore this factor cannot be incorporated into the cost of transposition.

Table 7-23 Transposition costs for Member State public administrations (OELs)

Member States: situation	No. Member States	Transposition cost per Member State	Total cost across the EU
7.3 mg/m³			
No OEL	0	€ 50,000	€ 0
Mixture of OELs	27	€ 30,000	€ 810,000
Existing OELs	27	€ 0	€ 0
Total cost			**€ 810,000**
20 mg/m³			
No OEL	0	€ 50,000	€ 0
Mixture of OELs	25	€ 30,000	€ 750,000
Existing OELs	2	€ 0	€ 0
Total cost			**€ 750,000**
36 mg/m³			
No OEL	0	€ 50,000	€ 0
Mixture of OELs	22	€ 30,000	€ 660,000

Member States: situation	No. Member States	Transposition cost per Member State	Total cost across the EU
Existing OELs	5	€ 0	€ 0
Total cost			**€ 660,000**
73 mg/m³			
No OEL	0	€ 0	€ 0
Mixture of OELs	0	€ 0	€ 0
Existing OELs	27	€ 0	€ 0
Total cost			**€ 0**

Source: Study team.

The costs of transposition are estimated below for the different BLV policy options based on the numbers of Member States that would have to introduce a BLV (or change their current BLV).

Given that Member States are likely to introduce an OEL and BLV at the same time, the costs presented below may be an overestimate. On the other hand, introducing a BLV is expected to be more complicated than introducing an OEL and, as a result, the costs in the table below may be an underestimate.

*Table 7-24 Transposition costs for Member State public administrations (**BLVs)***

Member States: situation	No. Member States	Transposition cost per Member State	Total cost across the EU
45 mg HEAA in urine/g Creatinine			
No BLV	25	€ 50,000	€ 1,250,00-
Mixture of BLVs	2	€ 30,000	€ 60,000
Existing BLV	0	€ 0	€ 0
Total cost			**€ 1,310,000**
108 mg HEAA in urine/g Creatinine			
No BLV	25	€ 50,000	€ 1,250,00-
Mixture of BLVs	2	€ 30,000	€ 60,000
Existing BLV	0	€ 0	€ 0
Total cost			**€ 1,310,000**
188 mg HEAA in urine/g Creatinine			
No BLV	25	€ 50,000	€ 1,250,00-
Mixture of BLVs	2	€ 30,000	€ 60,000

Member States: situation	No. Member States	Transposition cost per Member State	Total cost across the EU
Existing BLV	0	€ 0	€ 0
Total cost			**€ 1,310,000**
366 mg HEAA in urine/g Creatinine			
No BLV	25	€ 50,000	€ 1,250,00-
Mixture of BLVs	1	€ 30,000	€ 30,000
Existing BLV	1	€ 0	€ 0
Total cost			**€ 1,280,000**

Source: Study team.

7.4.2 Enforcement costs

The enforcement, monitoring and adjudication costs depend on the number of companies that will be covered by the policy option. In principle, national authorities are supposed to inspect companies already as they have the general obligation to protect workers. The enforcement costs depend on the inspection regime in each Member State, however such costs for each Member State are unknown (and by extent are not estimated in this study). Despite this some costs are expected for each Member State authority.

7.5 Impact of transitional periods on costs

A transitional period is not considered for 1,4-dioxane.

7.6 Summary of costs of the measures for the policy options

The costs for the OEL options are summarised below.

Table 7-25 Overview of costs of OEL options, € millions over 40 years (without transition measures)

Description	Stakeholders affected	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Adjustment costs (first year)	Business	€ 132.4	€ 0.0	€ 0.0	€ 0.0
Adjustment costs (recurrent)	Business	-€ 11.0	€ 0.0	€ 0.0	€ 0.0
Adjustment costs (discontinuations)	Business	€ 102.2	€ 0.0	€ 0.0	€ 0.0
Monitoring costs (air monitoring)	Business	€ 2.3	€ 0.5	€ 0.5	€ 0.0
Administrative costs (air monitoring)	Business	€ 1.5	€ 0.2	€ 0.2	€ 0.0
OEL transposition costs	Public authorities	€ 0.8	€ 0.8	€ 0.7	€ 0.0

Description	Stakeholders affected	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Avoided costs of setting national OELs	Public authorities	-€ 2.7	-€ 1.8	-€ 1.5	-€ 1.4
Single-market	Consumers	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Social costs (employment)	Workers & families	€ 12.6	€ 0.0	€ 0.0	€ 0.0
Total across all sectors /companies /stakeholders for the relevant OEL policy option		€ 135.9	-€ 0.3	-€ 0.1	-€ 1.4

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

Source: Study team.

A corresponding table to the one above for the combined OEL and BLV options is presented below. Since the additional adjustment costs for companies and benefits from reduced ill health from adding a BLV to an OEL cannot be estimated with a sufficient degree of robustness, they are not included in the quantified impacts in the table below which provides an overview for the combined OEL and BLV options, taking into account the costs of biomonitoring in addition to the costs presented above for the OEL options alone.

*Table 7-26 Overview of costs of combined **OEL and BLV policy options**, € millions over 40 years (without transition measures)*

Description	Stakeholders affected	7.3 mg/m3 and 45 mg HEAA in urine/g Creatinine	20 mg/m3 and 108 mg HEAA in urine/g Creatinine	36 mg/m3 and 188 mg HEAA in urine/g Creatinine	73 mg/m3 and 366 mg HEAA in urine/g Creatinine
Adjustment costs (first year)	Business	€ 132.4	€ 0.0	€ 0.0	€ 0.0
Adjustment costs (recurrent)	Business	-€ 11.0	€ 0.0	€ 0.0	€ 0.0
Adjustment costs (discontinuations)	Business	€ 102.2	€ 0.0	€ 0.0	€ 0.0
Monitoring costs (air monitoring)	Business	€ 2.3	€ 0.5	€ 0.5	€ 0.0
Administrative costs (air monitoring)	Business	€ 1.5	€ 0.2	€ 0.2	€ 0.0
OEL transposition costs	Public authorities	€ 0.8	€ 0.8	€ 0.7	€ 0.0
Avoided costs of setting national OELs	Public authorities	-€ 2.7	-€ 1.8	-€ 1.5	-€ 1.4
Biomonitoring costs	Business	€ 116.5	€ 56.3	€ 10.8	€ 5.7

Description	Stakeholders affected	7.3 mg/m3 and 45 mg HEAA in urine/g Creatinine	20 mg/m3 and 108 mg HEAA in urine/g Creatinine	36 mg/m3 and 188 mg HEAA in urine/g Creatinine	73 mg/m3 and 366 mg HEAA in urine/g Creatinine
Administrative costs linked to biomonitoring	Business	€ 6.4	€ 3.8	€ 1.1	€ 1.0
BLV transposition costs	Public authorities	€ 1.3	€ 1.3	€ 1.3	€ 1.3
Avoided costs of setting national BLVs	Public authorities	-€ 2.6	-€ 2.6	-€ 2.6	-€ 2.6
Single-market	Consumers	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Social costs (employment)	Workers & families	€ 12.6	€ 0.0	€ 0.0	€ 0.0
Total across all sectors /companies /stakeholders for the combined OEL and BLV policy option		**€ 257.5**	**€ 58.5**	**€ 10.5**	**€ 4.1**

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

Source: Study team.

8 MARKET EFFECTS

This chapter comprises the following sections:

- Section 8.1: Overall impact
- Section 8.2: Research and innovation
- Section 8.3: Single market
- Section 8.4: Competitiveness of EU businesses
- Section 8.5: Employment.
- Section 8.6: Summary of the market effects

8.1 Overall impact

Overall, market impacts (in terms of the effect on the single market, R&D, competitiveness of EU businesses and employment) are strongly influenced by two key drivers, the extent to which costs are incurred to comply with the OEL and by the feasibility of meeting the required air concentrations. In extreme cases, companies will be forced out of business if they are unable to meet the OELs at a cost that maintains profitability.

The likely costs that would be incurred at each of the OEL options considered in this study are set out in section 7 above. These have then been modelled to predict the likely number of companies (or business units) that would discontinue operations.

Table 8-1 provides estimates of the compliance costs that are estimated to be incurred on a per company basis (discounted at 3% over 40 years) including the cost of discontinuations. The rest of the section provides an analysis of the likely impacts arising from the key drivers of competition in both the EU and overseas markets. Zero values indicate there are no costs for adjustment as enterprises are already achieving the OEL level.

Table 8-1 Total PV compliance costs (RMMs, discontinuations, monitoring and administrative costs) per company to comply with OELs over 40 years, additional to the baseline (€ million)

Sector	Compliance cost per business, OEL in mg/m³ (€ million)			
	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Part of C20.1	€ 0.02	€ 0.002	€ 0.002	€ 0.0
C21.1 and C21.2	€ 0.01	€ 0.001	€ 0.0005	€ 0.0
C20.1, C20.3 and C20.5	€ 1.16	€ 0.0005	€ 0.0005	€ 0.0
M72.1	€ 0.001	€ 0.0004	€ 0.0003	€ 0.0
C20.4 excl. C20.42	€ 0.01	€ 0.0004	€ 0.0004	€ 0.0

Sector	Compliance cost per business, OEL in mg/m³ (€ million)			
	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
C20.42	€ 0.01	€ 0.0004	€ 0.0004	€ 0.0
Total	**€ 0.07**	**€ 0.0004**	**€ 0.0004**	**€ 0.0**

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

A corresponding table to the one above for the combined OEL and BLV options is presented below. Since the additional adjustment costs for companies and benefits from reduced ill health from adding an OEL to a BLV cannot be estimated with a sufficient degree of robustness, they are not included in the quantified impacts in the table below which provides an overview for the combined OEL and BLV options, taking into account the costs of biomonitoring in addition to the costs presented above for the OEL options alone.

*Table 8-2 PV compliance costs (RMMs, discontinuations, monitoring and administrative costs of the OELs and biomonitoring and the associated administrative costs for the BLV) per company to comply with **combined OEL and BLV policy options** over 40 years, additional to the baseline (€ million)*

Sector	Compliance cost per business, OEL in mg/m³ (€ million)			
	7.3 mg/m³ and 45 mg HEAA in urine/g Creatinine	20 mg/m³ and 108 mg HEAA in urine/g Creatinine	36 mg/m³ and 188 mg HEAA in urine/g Creatinine	73 mg/m³ and 366 mg HEAA in urine/g Creatinine
Part of C20.1	€ 0.045	€ 0.027	€ 0.027	€ 0.020
C21.1 and C21.2	€ 0.628	€ 0.103	€ 0.046	€ 0.030
C20.1, C20.3 and C20.5	€ 1.553	€ 0.398	€ 0.035	€ 0.010
M72.1	€ 0.007	€ 0.005	€ 0.002	€ 0.001
C20.4 excl. C20.42	€ 0.103	€ 0.016	€ 0.007	€ 0.004
C20.42	€ 0.129	€ 0.020	€ 0.009	€ 0.006
Total	**€ 0.137**	**€ 0.034**	**€ 0.007**	**€ 0.004**

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

Table 8-3 Total PV compliance costs (RMMs, discontinuations, monitoring and administrative costs) per company to comply with OELs over 40 years, additional to the baseline, by size (€ million)

Sector	Compliance cost per business, OEL in mg/m³ by size (€ million)		
	Small	Medium	Large
7.3 mg/m³			
Part of C20.1	N/A	N/A	€ 0.02
C21.1 and C21.2	€ 0.01	€ 0.01	€ 0.05
C20.1, C20.3 and C20.5	€ 0.31	€ 4.67	€ 10.52
M72.1	€ 0.00	€ 0.02	€ 0.05
C20.4 excl. C20.42	€ 0.01	€ 0.03	€ 0.10
C20.42	€ 0.01	€ 0.03	€ 0.10
Total	**€ 0.02**	**€ 0.83**	**€ 1.66**
20 mg/m³			
Part of C20.1	N/A	N/A	€ 0.0015
C21.1 and C21.2	€ 0.0004	€ 0.0009	€ 0.0014
C20.1, C20.3 and C20.5	€ 0.0004	€ 0.0009	€ 0.0014
M72.1	€ 0.0004	€ 0.0009	€ 0.0013
C20.4 excl. C20.42	€ 0.0004	€ 0.0009	€ 0.0014
C20.42	€ 0.0004	€ 0.0009	€ 0.0014
Total	**€ 0.0004**	**€ 0.0009**	**€ 0.0014**
36 mg/m³			
Part of C20.1	N/A	N/A	€ 0.0015
C21.1 and C21.2	€ 0.0003	€ 0.0008	€ 0.0012
C20.1, C20.3 and C20.5	€ 0.0004	€ 0.0009	€ 0.0013
M72.1	€ 0.0003	€ 0.0008	€ 0.0012

Sector	Compliance cost per business, OEL in mg/m³ by size (€ million)		
	Small	Medium	Large
C20.4 excl. C20.42	€ 0.0004	€ 0.0009	€ 0.0013
C20.42	€ 0.0004	€ 0.0009	€ 0.0013
Total	**€ 0.0003**	**€ 0.00008**	**€ 0.0012**
73 mg/m³			
Part of C20.1	N/A	N/A	€ 0.0
C21.1 and C21.2	€ 0.0	€ 0.0	€ 0.0
C20.1, C20.3 and C20.5	€ 0.0	€ 0.0	€ 0.0
M72.1	€ 0.0	€ 0.0	€ 0.0
C20.4 excl. C20.42	€ 0.0	€ 0.0	€ 0.0
C20.42	€ 0.0	€ 0.0	€ 0.0
Total	**€ 0.0**	**€ 0.0**	**€ 0.0**

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

Adding the costs of biomonitoring to the costs in the table above, the table below presents the (partial) costs for combined OEL and BLV options. Since the additional adjustment costs for companies and benefits from reduced ill health from adding an OEL to a BLV cannot be estimated with a sufficient degree of robustness, they are not included in the quantified impacts in the table below which (in addition to the preceding table) takes into account the costs of biomonitoring.

*Table 8-4 PV compliance costs (**total OEL costs and biomonitoring costs**) per company to comply with **combined OEL and BLV options** over 40 years, additional to the baseline, by size (€ million)*

Sector	Compliance cost per business, by size (€ million)		
	Small	Medium	Large
7.3 mg/m3 and 45 mg HEAA in urine/g Creatinine			
Part of C20.1	N/A	N/A	€ 0.045
C21.1 and C21.2	€ 0.043	€ 0.493	€ 4.564
C20.1, C20.3 and C20.5	€ 0.377	€ 5.474	€ 17.233
M72.1	€ 0.003	€ 0.083	€ 0.510
C20.4 excl. C20.42	€ 0.030	€ 0.383	€ 2.840
C20.42	€ 0.038	€ 0.568	€ 4.290
Total	**€ 0.027**	**€ 1.154**	**€ 4.997**
20 mg/m3 and108 mg HEAA in urine/g Creatinine			
Part of C20.1	N/A	N/A	€ 0.027
C21.1 and C21.2	€ 0.006	€ 0.082	€ 0.755
C20.1, C20.3 and C20.5	€ 0.068	€ 0.805	€ 6.714
M72.1	€ 0.003	€ 0.042	€ 0.296
C20.4 excl. C20.42	€ 0.004	€ 0.061	€ 0.461
C20.42	€ 0.005	€ 0.091	€ 0.701
Total	**€ 0.006**	**€ 0.187**	**€ 1.479**
36 mg/m^3 and 188 mg HEAA in urine/g Creatinine			
Part of C20.1	N/A	N/A	€ 0.027
C21.1 and C21.2	€ 0.003	€ 0.037	€ 0.338
C20.1, C20.3 and C20.5	€ 0.006	€ 0.071	€ 0.584
M72.1	€ 0.001	€ 0.019	€ 0.133
C20.4 excl. C20.42	€ 0.002	€ 0.024	€ 0.201

Sector	Compliance cost per business, by size (€ million)		
	Small	Medium	Large
C20.42	€ 0.002	€ 0.041	€ 0.311
Total	**€ 0.002**	**€ 0.033**	**€ 0.290**
73 mg/m3 and 366 mg HEAA in urine/g Creatinine			
Part of C20.1	N/A	N/A	€ 0.020
C21.1 and C21.2	€ 0.002	€ 0.024	€ 0.218
C20.1, C20.3 and C20.5	€ 0.002	€ 0.021	€ 0.170
M72.1	€ 0.001	€ 0.013	€ 0.086
C20.4 excl. C20.42	€ 0.001	€ 0.017	€ 0.130
C20.42	€ 0.002	€ 0.028	€ 0.200
Total	**€ 0.001**	**€ 0.017**	**€ 0.156**

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

The annual turnover and gross operating surplus, by sector and size of companies are presented below. Further analysis below compares the total compliance costs over the 40-year period with turnover and gross operating surplus of the same 40-year period.

Table 8-5 Average turnover per company based on Eurostat figures, by size and sector (€, millions)

Sector	Small	Medium	Large
Part of C20.1	€ 2.26	€ 56.09	€ 697.80
C21.1 and C21.2	€ 1.61	€ 41.30	€ 697.78
C20.1, C20.3 and C20.5	€ 2.23	€ 47.92	€ 515.77
M72.1	€ 0.31	€ 13.63	€ 91.83
C20.4 excl. C20.42	€ 0.75	€ 26.23	€ 267.53
C20.42	€ 0.84	€ 29.29	€ 294.60

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

Table 8-6 Average gross operating surplus per company based on Eurostat figures, by size and sector (€, millions)

Sector	Small	Medium	Large
Part of C20.1	€ 0.23	€ 5.59	€ 69.59
C21.1 and C21.2	€ 0.27	€ 6.98	€ 117.98
C20.1, C20.3 and C20.5	€ 0.23	€ 4.89	€ 52.59
M72.1	GOS data not available	GOS data not available	GOS data not available
C20.4 excl. C20.42	€ 0.08	€ 2.92	€ 29.78
C20.42	€ 0.10	€ 3.35	€ 33.71

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

Based on the estimated number of small, medium, and large companies, as well as Eurostat data on the turnover and gross operating surplus of companies in different size classes and sectors where exposure to 1,4-dioxane can occur, the likely significance of the compliance costs modelled in Section 7 is estimated in Table 8-7. The average annual turnover of companies (which is presented in Table 8-5) has been used to calculate PV40 costs, additional to the baseline, as a percentage of 40 years (discounted) turnover.

The comparison of total compliance costs (adjustment costs, such as additional first year and recurrent RMMs, discontinuations, and air monitoring, plus administrative costs) to turnover and gross operating surplus is an indicator of the overall impact to the sector over time. The discontinuation costs are sometimes a reflection of the high cost of measures that need to be implemented, where the model is insufficiently sensitive to describe and categorise them.

Table 8-7 Total PV compliance costs for the OEL options (RMMs, discontinuations, monitoring and administrative burden) as percentage of turnover discounted over 40 years, by policy options, sector and company size and proportion of companies discontinuing at least a part of their business

Sector	Compliance cost as percentage of turnover by size and sector			Percentage of companies discontinuing
	Small	Medium	Large	
7.3 mg/m³				
Part of C20.1			0.000%	0%
C21.1 and C21.2	0.014%	0.001%	0.000%	0%
C20.1, C20.3 and C20.5	0.345%	0.244%	0.051%	6%
M72.1	0.000%	0.003%	0.001%	0%
C20.4 excl. C20.42	0.020%	0.003%	0.001%	0%
C20.42	0.021%	0.003%	0.001%	0%
20 mg/m³				
Part of C20.1			0.000%	0%
C21.1 and C21.2	0.001%	0.000%	0.000%	0%
C20.1, C20.3 and C20.5	0.000%	0.000%	0.000%	0%
M72.1	0.003%	0.000%	0.000%	0%
C20.4 excl. C20.42	0.001%	0.000%	0.000%	0%
C20.42	0.001%	0.000%	0.000%	0%
36 mg/m³				
Part of C20.1			0.000%	0%
C21.1 and C21.2	0.001%	0.000%	0.000%	0%
C20.1, C20.3 and C20.5	0.000%	0.000%	0.000%	0%
M72.1	0.003%	0.000%	0.000%	0%
C20.4 excl. C20.42	0.001%	0.000%	0.000%	0%
C20.42	0.001%	0.000%	0.000%	0%
73 mg/m³				

Sector	Compliance cost as percentage of turnover by size and sector			Percentage of companies discontinuing
	Small	Medium	Large	
Part of C20.1	0.000%	0.000%	0.000%	0%
C21.1 and C21.2	0.000%	0.000%	0.000%	0%
C20.1, C20.3 and C20.5	0.000%	0.000%	0.000%	0%
M72.1	0.000%	0.000%	0.000%	0%
C20.4 excl. C20.42	0.000%	0.000%	0.000%	0%
C20.42	0.000%	0.000%	0.000%	0%

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

A corresponding table to the one above for the combined OEL and BLV options is presented below. Since the additional adjustment costs for companies and benefits from reduced ill health from adding a BLV to an OEL cannot be estimated with a sufficient degree of robustness, they are not included in the quantified impacts in the table below which provides an overview for the combined OEL and BLV options, taking into account the costs of biomonitoring in addition to the costs presented above for the OEL options alone.

Table 8-8 *Total PV compliance costs of **combined OEL and BLV options** (RMMs, discontinuations, monitoring and administrative burden, biomonitoring and the associated administrative burden) as percentage of turnover discounted over 40 years, by policy options, sector and company size and proportion of companies discontinuing at least a part of their business Note: For the BLV component, only partial costs and benefits have been included in the calculation and the totals do not include the adjustment costs and potential health savings additional to the OEL.*

Sector	Compliance cost as percentage of turnover by size and sector			Percentage of companies discontinuing
	Small	Medium	Large	
7.3 mg/m3 and 45 mg HEAA in urine/g Creatinine				
Part of C20.1			0.00%	0%
C21.1 and C21.2	0.10%	0.05%	0.03%	0%
C20.1, C20.3 and C20.5	0.47%	0.32%	0.11%	6%
M72.1	0.04%	0.02%	0.02%	0%
C20.4 excl. C20.42	0.13%	0.06%	0.04%	0%
C20.42	0.16%	0.08%	0.06%	0%
20 mg/m3 and108 mg HEAA in urine/g Creatinine				
Part of C20.1			0.00%	0%
C21.1 and C21.2	0.02%	0.01%	0.00%	0%
C20.1, C20.3 and C20.5	0.13%	0.07%	0.06%	0%
M72.1	0.03%	0.01%	0.01%	0%
C20.4 excl. C20.42	0.02%	0.01%	0.01%	0%
C20.42	0.02%	0.01%	0.01%	0%
36 mg/m^3 and 188 mg HEAA in urine/g Creatinine				
Part of C20.1			0.00%	0%
C21.1 and C21.2	0.01%	0.00%	0.00%	0%
C20.1, C20.3 and C20.5	0.01%	0.01%	0.00%	0%
M72.1	0.02%	0.01%	0.01%	0%
C20.4 excl. C20.42	0.01%	0.00%	0.00%	0%

Sector	Compliance cost as percentage of turnover by size and sector			Percentage of companies discontinuing
	Small	Medium	Large	
C20.42	0.01%	0.01%	0.00%	0%
73 mg/m3 and 366 mg HEAA in urine/g Creatinine				
Part of C20.1			0.00%	0%
C21.1 and C21.2	0.00%	0.00%	0.00%	0%
C20.1, C20.3 and C20.5	0.00%	0.00%	0.00%	0%
M72.1	0.01%	0.00%	0.00%	0%
C20.4 excl. C20.42	0.01%	0.00%	0.00%	0%
C20.42	0.01%	0.00%	0.00%	0%

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team

The compliance costs as a percentage of gross operating surplus are presented below.

Table 8-9 Total PV compliance costs (RMMs, discontinuations, monitoring and administrative burden) as percentage of gross operating surplus discounted over 40 years, by policy options, sector and company size and proportion of companies discontinuing at least a part of their business

Sector	Compliance cost as percentage of gross operating surplus by size and sector			Percentage of companies discontinuing
	Small	Medium	Large	
7.3 mg/m³				
Part of C20.1			0.001%	0%
C21.1 and C21.2	0.083%	0.004%	0.001%	0%
C20.1, C20.3 and C20.5	3.384%	2.388%	0.500%	6%
M72.1	GOS data not available	GOS data not available	GOS data not available	0%
C20.4 excl. C20.42	0.177%	0.028%	0.008%	0%
C20.42	0.182%	0.024%	0.007%	0%
20 mg/m³				

Sector	Compliance cost as percentage of gross operating surplus by size and sector			Percentage of companies discontinuing
	Small	Medium	Large	
Part of C20.1			0.000%	0%
C21.1 and C21.2	0.003%	0.000%	0.000%	0%
C20.1, C20.3 and C20.5	0.004%	0.000%	0.000%	0%
M72.1	GOS data not available	GOS data not available	GOS data not available	0%
C20.4 excl. C20.42	0.011%	0.001%	0.000%	0%
C20.42	0.010%	0.001%	0.000%	0%
36 mg/m³				
Part of C20.1			0.000%	0%
C21.1 and C21.2	0.003%	0.000%	0.000%	0%
C20.1, C20.3 and C20.5	0.004%	0.000%	0.000%	0%
M72.1	GOS data not available	GOS data not available	GOS data not available	0%
C20.4 excl. C20.42	0.011%	0.001%	0.000%	0%
C20.42	0.009%	0.001%	0.000%	0%
73 mg/m³				
Part of C20.1			0.000%	0%
C21.1 and C21.2	0.000%	0.000%	0.000%	0%
C20.1, C20.3 and C20.5	0.000%	0.000%	0.000%	0%
M72.1	GOS data not available	GOS data not available	GOS data not available	0%
C20.4 excl. C20.42	0.000%	0.000%	0.000%	0%
C20.42	0.000%	0.000%	0.000%	0%

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

A corresponding table to the one above for the combined OEL and BLV options is presented below. Since the additional adjustment costs for companies and benefits from reduced ill health from adding an OEL to a BLV cannot be estimated with a sufficient degree of robustness, they are not included in the quantified impacts in the table below which provides an overview for the combined OEL and BLV options, taking into account the costs of biomonitoring in addition to the costs presented above for the OEL options alone.

*Table 8-10 Total PV compliance costs for the **combined OEL and BLV policy options** (RMMs, discontinuations, monitoring and administrative burden for the OEL and biomonitoring and the associated administrative costs for the BLV) as percentage of gross operating surplus discounted over 40 years, by policy options, sector and company size and proportion of companies discontinuing at least a part of their business*

Sector	Compliance cost as percentage of gross operating surplus by size and sector			Percentage of companies discontinuing
	Small	Medium	Large	
7.3 mg/m³ and 45 mg HEAA				
Part of C20.1			0.003%	0%
C21.1 and C21.2	0.675%	0.301%	0.165%	0%
C20.1, C20.3 and C20.5	6.985%	4.767%	1.396%	6%
M72.1	GOS data not available	GOS data not available	GOS data not available	0%
C20.4 excl. C20.42	1.608%	0.559%	0.406%	0%
C20.42	1.599%	0.721%	0.542%	0%
20 mg/m³ and 108 mg HEAA				
Part of C20.1			0.002%	0%
C21.1 and C21.2	0.095%	0.050%	0.027%	0%
C20.1, C20.3 and C20.5	1.252%	0.701%	0.544%	0%
M72.1	GOS data not available	GOS data not available	GOS data not available	0%
C20.4 excl. C20.42	0.195%	0.089%	0.066%	0%
C20.42	0.214%	0.116%	0.089%	0%
36 mg/m³ and 188 mg HEAA				
Part of C20.1			0.002%	0%
C21.1 and C21.2	0.045%	0.023%	0.012%	0%
C20.1, C20.3 and C20.5	0.116%	0.062%	0.047%	0%
M72.1	GOS data not available	GOS data not available	GOS data not available	0%

Sector	Compliance cost as percentage of gross operating surplus by size and sector			Percentage of companies discontinuing
	Small	Medium	Large	
C20.4 excl. C20.42	0.097%	0.035%	0.029%	0%
C20.42	0.102%	0.052%	0.039%	0%
73 mg/m³ and 366 mg HEAA				
Part of C20.1			0.001%	0%
C21.1 and C21.2	0.029%	0.015%	0.008%	0%
C20.1, C20.3 and C20.5	0.035%	0.018%	0.014%	0%
M72.1	GOS data not available	GOS data not available	GOS data not available	0%
C20.4 excl. C20.42	0.054%	0.024%	0.019%	0%
C20.42	0.066%	0.035%	0.025%	0%

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

Table 8-11 provides an overview of the aggregated first year compliance costs for companies that continue. First year costs include the initial capital expenditure of installing alternative RMMs as well as one year of alternative operational costs (minus one year of existing RMM operational costs), one year of air monitoring costs and their associated administrative burden, and one year of biomonitoring costs.

A comparison of first year's compliance cost with annual turnover and annual operating surplus provides an indication of whether the initial investments could be preventive and force companies to cease their activities. In the case of the OELs of 73 mg/m^3, 36 mg/m^3, and 20 mg/m^3, limited impacts are expected. In the case of an OEL of 7.3 mg/m^3, the costs are always below 1.6% of the turnover, or in the case of the chemicals sector (C20.1, C20.3 and C20.5), the costs are less than 14.3% of turnover. This suggests that the first year costs are likely to be moderate compared with the relevant companies' turnover.

Table 8-11 First year compliance costs (RMMs, monitoring and administrative burden), by policy options, sector and company size (minus discontinuations) (€, millions)

Sector	First year compliance costs			Total
	Small	Medium	Large	
7.3 mg/m³				
Part of C20.1	N/A	N/A	€ 0.00	100%
C21.1 and C21.2	€ 28.60	€ 6.60	€ 8.20	100%
C20.1, C20.3 and C20.5	€ 3.60	€ 0.20	€ 0.10	94%
M72.1	€ 0.50	€ 0.10	€ 0.10	100%
C20.4 excl. C20.42	€ 0.80	€ 0.10	€ 0.10	100%
C20.42	€ 1.50	€ 0.70	€ 2.30	100%
Total	**€ 35.0**	**€ 7.6**	**€ 10.8**	**100%**
20 mg/m³				
Part of C20.1	N/A	N/A	€ 0.00	100%
C21.1 and C21.2	€ 0.01	€ 0.01	€ 0.01	100%
C20.1, C20.3 and C20.5	€ 0.02	€ 0.01	€ 0.00	100%
M72.1	€ 0.28	€ 0.02	€ 0.00	100%
C20.4 excl. C20.42	€ 0.01	€ 0.00	€ 0.00	100%
C20.42	€ 0.01	€ 0.00	€ 0.00	100%
Total	**€ 0.33**	**€ 0.04**	**€ 0.01**	**100%**
36 mg/m³				
Part of C20.1	€ 0.00	€ 0.00	€ 0.00	100%
C21.1 and C21.2	€ 0.01	€ 0.01	€ 0.01	100%
C20.1, C20.3 and C20.5	€ 0.02	€ 0.01	€ 0.00	100%
M72.1	€ 0.25	€ 0.01	€ 0.00	100%
C20.4 excl. C20.42	€ 0.01	€ 0.00	€ 0.00	100%
C20.42	€ 0.01	€ 0.00	€ 0.00	100%

Sector	First year compliance costs			Total
	Small	Medium	Large	
Total	**€ 0.30**	**€ 0.03**	**€ 0.01**	**100%**
73 mg/m³				
Part of C20.1	€ 0.00	€ 0.00	€ 0.00	100%
C21.1 and C21.2	€ 0.00	€ 0.00	€ 0.00	100%
C20.1, C20.3 and C20.5	€ 0.00	€ 0.00	€ 0.00	100%
M72.1	€ 0.00	€ 0.00	€ 0.00	100%
C20.4 excl. C20.42	€ 0.00	€ 0.00	€ 0.00	100%
C20.42	€ 0.00	€ 0.00	€ 0.00	100%
Total	**€ 0.00**	**€ 0.00**	**€ 0.00**	**100%**

Source: Study team.

A corresponding table to the one above for the combined OEL and BLV options is presented below. Since the additional adjustment costs for companies and benefits from reduced ill health from adding an OEL to a BLV cannot be estimated with a sufficient degree of robustness, they are not included in the quantified impacts in the table below which provides an overview for the combined OEL and BLV options, taking into account the costs of biomonitoring in addition to the costs presented above for the OEL options alone.

*Table 8-12 First year compliance costs for **combined OEL and BLV options** (for the OEL: RMMs, monitoring and administrative burden; for the BLV: biomonitoring costs and the associated administrative costs), by policy options, sector and company size (minus discontinuations) (€, millions)*

Sector	First year compliance costs			Total
	Small	Medium	Large	
7.3 mg/m³ and 45 mg HEAA				
Part of C20.1	N/A	N/A	€ 0.0	100%
C21.1 and C21.2	€ 28.9	€ 7.1	€ 11.7	100%
C20.1, C20.3 and C20.5	€ 4.3	€ 0.9	€ 2.0	94%
M72.1	€ 1.1	€ 0.3	€ 0.3	100%
C20.4 excl. C20.42	€ 0.9	€ 0.2	€ 0.3	100%
C20.42	€ 1.7	€ 0.9	€ 2.6	100%

Sector	First year compliance costs			Total
	Small	Medium	Large	
Total	**€ 36.9**	**€ 9.2**	**€ 16.9**	**100%**
20 mg/m³ and 108 mg HEAA				
Part of C20.1	N/A	N/A	€ 0.01	100%
C21.1 and C21.2	€ 0.08	€ 0.16	€ 1.34	100%
C20.1, C20.3 and C20.5	€ 1.02	€ 1.26	€ 4.30	100%
M72.1	€ 0.81	€ 0.20	€ 0.33	100%
C20.4 excl. C20.42	€ 0.04	€ 0.03	€ 0.07	100%
C20.42	€ 0.06	€ 0.05	€ 0.11	100%
Total	**€ 2.00**	**€ 1.69**	**€ 6.16**	**100%**
36 mg/m³ and 188 mg HEAA				
Part of C20.1	N/A	N/A	€ 0.04	100%
C21.1 and C21.2	€ 0.16	€ 0.38	€ 3.08	100%
C20.1, C20.3 and C20.5	€ 0.47	€ 0.62	€ 1.93	100%
M72.1	€ 1.47	€ 0.47	€ 0.76	100%
C20.4 excl. C20.42	€ 0.07	€ 0.06	€ 0.17	100%
C20.42	€ 0.12	€ 0.13	€ 0.26	100%
Total	**€ 2.30**	**€ 1.65**	**€ 6.24**	**100%**
73 mg/m³ and 366 mg HEAA				
Part of C20.1	N/A	N/A	€ 0.04	100%
C21.1 and C21.2	€ 0.13	€ 0.31	€ 2.40	100%
C20.1, C20.3 and C20.5	€ 0.17	€ 0.23	€ 0.68	100%
M72.1	€ 1.15	€ 0.40	€ 0.60	100%
C20.4 excl. C20.42	€ 0.05	€ 0.05	€ 0.13	100%
C20.42	€ 0.10	€ 0.11	€ 0.20	100%

Sector	First year compliance costs			Total
	Small	Medium	Large	
Total	**€ 1.60**	**€ 1.10**	**€ 4.05**	**100%**

Source: Study team.

Table 8-13 First year costs compliance costs (RMMs, monitoring and administrative burden) minus discontinuation as percentage of annual turnover, by policy options, sector and company size, and the proportion of companies expected to continue operations

Sector	First year costs % of annual turnover (incurred by % of companies continuing)			% of companies that continue operating
	Small	Medium	Large	
7.3 mg/m³				
Part of C20.1	N/A	N/A	0.001%	100%
C21.1 and C21.2	1.314%	0.152%	0.032%	100%
C20.1, C20.3 and C20.5	14.279%	1.259%	0.399%	94%
M72.1	0.991%	0.086%	0.026%	100%
C20.4 excl. C20.42	1.332%	0.105%	0.031%	100%
C20.42	1.552%	0.107%	0.029%	100%
20 mg/m³				
Part of C20.1	N/A	N/A	0.000%	100%
C21.1 and C21.2	0.012%	0.001%	0.000%	100%
C20.1, C20.3 and C20.5	0.009%	0.001%	0.000%	100%
M72.1	0.062%	0.004%	0.001%	100%
C20.4 excl. C20.42	0.026%	0.002%	0.000%	100%
C20.42	0.024%	0.002%	0.000%	100%
36 mg/m³				
Part of C20.1	N/A	N/A	0.000%	100%
C21.1 and C21.2	0.011%	0.001%	0.000%	100%
C20.1, C20.3 and C20.5	0.009%	0.001%	0.000%	100%

Sector	First year costs % of annual turnover (incurred by % of companies continuing)			% of companies that continue operating
	Small	Medium	Large	
M72.1	0.055%	0.003%	0.001%	100%
C20.4 excl. C20.42	0.025%	0.002%	0.000%	100%
C20.42	0.022%	0.002%	0.000%	100%
73 mg/m³				
Part of C20.1	N/A	N/A	0.000%	100%
C21.1 and C21.2	0.000%	0.000%	0.000%	100%
C20.1, C20.3 and C20.5	0.000%	0.000%	0.000%	100%
M72.1	0.000%	0.000%	0.000%	100%
C20.4 excl. C20.42	0.000%	0.000%	0.000%	100%
C20.42	0.000%	0.000%	0.000%	100%

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

A corresponding table to the one above for the combined OEL and BLV options is presented below. Since the additional adjustment costs for companies and benefits from reduced ill health from adding an OEL to a BLV cannot be estimated with a sufficient degree of robustness, they are not included in the quantified impacts in the table below which provides an overview for the combined OEL and BLV options, taking into account the costs of biomonitoring in addition to the costs presented above for the OEL options alone.

*Table 8-14 First year compliance costs for **combined OEL and BLV options** (for the OEL: RMMs, monitoring and administrative burden; for the BLV: biomonitoring costs and the associated administrative costs) minus discontinuation as percentage of annual turnover, by policy options, sector and company size, and the proportion of companies expected to continue operations*

Sector	First year costs % of annual turnover (incurred by % of companies continuing)			% of companies that continue operating
	Small	Medium	Large	
7.3 mg/m³ and 45 mg HEAA				
Part of C20.1	N/A	N/A	0.001%	100%
C21.1 and C21.2	1.545%	0.246%	0.077%	100%

Sector	First year costs % of annual turnover (incurred by % of companies continuing)			% of companies that continue operating
	Small	Medium	Large	
C20.1, C20.3 and C20.5	14.618%	1.394%	0.490%	94%
M72.1	1.133%	0.123%	0.061%	100%
C20.4 excl. C20.42	1.659%	0.214%	0.103%	100%
C20.42	1.931%	0.254%	0.129%	100%
20 mg/m^3 and 108 mg HEAA				
Part of C20.1	N/A	N/A	0.001%	100%
C21.1 and C21.2	0.070%	0.029%	0.017%	100%
C20.1, C20.3 and C20.5	0.507%	0.237%	0.208%	100%
M72.1	0.181%	0.046%	0.052%	100%
C20.4 excl. C20.42	0.100%	0.034%	0.028%	100%
C20.42	0.116%	0.045%	0.038%	100%
36 mg/m^3 and 188 mg HEAA				
Part of C20.1	N/A	N/A	0.003%	100%
C21.1 and C21.2	0.146%	0.070%	0.040%	100%
C20.1, C20.3 and C20.5	0.234%	0.117%	0.094%	100%
M72.1	0.329%	0.108%	0.120%	100%
C20.4 excl. C20.42	0.189%	0.072%	0.062%	100%
C20.42	0.226%	0.110%	0.087%	100%
73 mg/m^3 and 366 mg HEAA				
Part of C20.1	N/A	N/A	0.003%	100%
C21.1 and C21.2	0.114%	0.058%	0.031%	100%
C20.1, C20.3 and C20.5	0.085%	0.044%	0.033%	100%
M72.1	0.257%	0.092%	0.093%	100%

Sector	First year costs % of annual turnover (incurred by % of companies continuing)			% of companies that continue operating
	Small	Medium	Large	
C20.4 excl. C20.42	0.136%	0.064%	0.049%	100%
C20.42	0.183%	0.094%	0.068%	100%

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

Table 8-15 First year compliance costs (RMMs, monitoring and administrative burden) minus discontinuation as a percentage of annual gross operating surplus, by policy options, sector and company size, and the proportion of companies expected to continue operations

Sector	First year costs % of gross operating surplus (incurred by % of companies continuing)			% of companies continuing operations
	Small	Medium	Large	
7.3 mg/m³				
Part of C20.1	0.000%	0.000%	0.014%	100%
C21.1 and C21.2	7.775%	0.898%	0.189%	100%
C20.1, C20.3 and C20.5	140.028%	12.351%	3.913%	94%
M72.1	GOS data not available	GOS data not available	GOS data not available	100%
C20.4 excl. C20.42	11.960%	0.939%	0.275%	100%
C20.42	13.563%	0.933%	0.258%	100%
20 mg/m³				
Part of C20.1	0.000%	0.000%	0.001%	100%
C21.1 and C21.2	0.072%	0.007%	0.001%	100%
C20.1, C20.3 and C20.5	0.088%	0.010%	0.001%	100%
M72.1	GOS data not available	GOS data not available	GOS data not available	100%
C20.4 excl. C20.42	0.237%	0.017%	0.002%	100%
C20.42	0.207%	0.015%	0.002%	100%
36 mg/m³				

Sector	First year costs % of gross operating surplus (incurred by % of companies continuing)			% of companies continuing operations
	Small	Medium	Large	
Part of C20.1	0.000%	0.000%	0.001%	100%
C21.1 and C21.2	0.066%	0.006%	0.001%	100%
C20.1, C20.3 and C20.5	0.084%	0.010%	0.001%	100%
M72.1	GOS data not available	GOS data not available	GOS data not available	100%
C20.4 excl. C20.42	0.228%	0.016%	0.002%	100%
C20.42	0.195%	0.014%	0.002%	100%
73 mg/m³				
Part of C20.1	0.000%	0.000%	0.000%	100%
C21.1 and C21.2	0.000%	0.000%	0.000%	100%
C20.1, C20.3 and C20.5	0.000%	0.000%	0.000%	100%
M72.1	GOS data not available	GOS data not available	GOS data not available	100%
C20.4 excl. C20.42	0.000%	0.000%	0.000%	100%
C20.42	0.000%	0.000%	0.000%	100%

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

A corresponding table to the one above for the combined OEL and BLV options is presented below. Since the additional adjustment costs for companies and benefits from reduced ill health from adding an OEL to a BLV cannot be estimated with a sufficient degree of robustness, they are not included in the quantified impacts in the table below which provides an overview for the combined OEL and BLV options, taking into account the costs of biomonitoring in addition to the costs presented above for the OEL options alone.

Table 8-16 *First year compliance costs for* ***combined OEL and BLV options*** *(for the OEL: RMMs, monitoring and administrative burden; for the BLV: biomonitoring costs and the associated administrative costs) minus discontinuation as a percentage of annual gross operating surplus, by policy options, sector and company size, and the proportion of companies expected to continue operations*

Sector	First year costs % of gross operating surplus (incurred by % of companies continuing)			% of companies continuing operations
	Small	Medium	Large	
7.3 mg/m³ and 45 mg HEAA				
Part of C20.1	N/A	N/A	0.014%	100%
C21.1 and C21.2	7.834%	0.922%	0.200%	100%
C20.1, C20.3 and C20.5	140.168%	12.407%	3.951%	94%
M72.1	GOS data not available	GOS data not available	GOS data not available	100%
C20.4 excl. C20.42	12.090%	0.981%	0.303%	100%
C20.42	13.699%	0.988%	0.295%	100%
20 mg/m³ and 108 mg HEAA				
Part of C20.1	0.000%	0.000%	0.001%	100%
C21.1 and C21.2	0.087%	0.014%	0.005%	100%
C20.1, C20.3 and C20.5	0.294%	0.109%	0.088%	100%
M72.1	GOS data not available	GOS data not available	GOS data not available	100%
C20.4 excl. C20.42	0.266%	0.029%	0.013%	100%
C20.42	0.240%	0.031%	0.016%	100%
36 mg/m³ and 188 mg HEAA				
Part of C20.1	0.000%	0.000%	0.002%	100%
C21.1 and C21.2	0.100%	0.023%	0.011%	100%
C20.1, C20.3 and C20.5	0.177%	0.058%	0.040%	100%
M72.1	GOS data not available	GOS data not available	GOS data not available	100%
C20.4 excl. C20.42	0.294%	0.043%	0.026%	100%

Sector	First year costs % of gross operating surplus (incurred by % of companies continuing)			% of companies continuing operations
	Small	Medium	Large	
C20.42	0.268%	0.054%	0.035%	100%
73 mg/m³ and 366 mg HEAA				
Part of C20.1	0.000%	0.000%	0.001%	100%
C21.1 and C21.2	0.029%	0.015%	0.008%	100%
C20.1, C20.3 and C20.5	0.035%	0.018%	0.014%	100%
M72.1	GOS data not available	GOS data not available	GOS data not available	100%
C20.4 excl. C20.42	0.054%	0.024%	0.019%	100%
C20.42	0.066%	0.035%	0.025%	100%

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

*Table 8-17 Approximate first year **BLV monitoring costs** as percentage of annual turnover, by policy options and sector*

Sector	BLV monitoring costs as % of annual turnover (incurred by % of companies continuing)			
	45 mg HEAA in urine/g Creatinine	108 mg HEAA in urine/g Creatinine	188 mg HEAA in urine/g Creatinine	366 mg HEAA in urine/g Creatinine
Part of C20.1	0.123%	0.123%	0.123%	0.067%
C21.1 and C21.2	1.891%	1.891%	1.891%	1.327%
C20.1, C20.3 and C20.5	1.762%	1.762%	1.762%	1.007%
M72.1	3.374%	3.374%	3.374%	1.858%
C20.4 excl. C20.42	2.593%	2.593%	2.593%	1.777%
C20.42	3.481%	3.481%	3.481%	2.519%

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Source: Study team.

8.2 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. 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 it is conducive to invest in R&D activities.

Table 8-18 provides estimates of average R&D expenditures for small, medium and large companies in the sectors with workers exposed to 1,4-dioxane, based on Eurostat data. Clearly significant investment is being made in large enterprises across the different sectors.

Table 8-18 Average annual R&D expenditure per company, by company size, by sector (€)

Sector	Average annual R&D expenditure per company (€)		
	Small	Medium	Large
Part of C20.1	€ 421	€ 1,258	€ 6,252
C21.1 and C21.2	€ 320	€ 1,558	€ 12,690
C20.1, C20.3 and C20.5	€ 892	€ 1,987	€ 5,051
M72.1	€ 4,771	€ 4,606	€ 7,238
C20.4 excl. C20.42	€ 819	€ 1,651	€ 5,461
C20.42	€ 819	€ 1,651	€ 5,461

Source: Eurostat (2018)

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

Notes cont.: 1. In most cases, R&D expenditure is not available at the level of the specific subsector in Eurostat. In these cases, the next level where data was available has been taken as a proxy for the sub-sector using 1,4-dioxane, and so may be under- or over-estimated.

2. Data gaps exist for some Member States. In these cases, the most recent data was used.

3. Data in Eurostat is not presented by company size. It is assumed that share of R&D expenditure between different sized companies is the same as the share for turnover (based on 2018 data)

The annualised adjustment costs for implementing RMMs are either expected to be modest when compared with R&D expenditure and are thus unlikely to significantly slow down R&D efforts.

Table 8-19 Annualised adjustment costs (additional to the baseline) for businesses implementing RMMs as a percentage of R&D expenditure

Sector	Cost as percentage of R&D expenditure by sector			
	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Part of C20.1	0.0000%	0.0000%	0.0000%	0.0000%
C21.1 and C21.2	0.0000%	0.0000%	0.0000%	0.0000%
C20.1, C20.3 and C20.5	0.0025%	0.0000%	0.0000%	0.0000%
M72.1	0.0000%	0.0000%	0.0000%	0.0000%
C20.4 excl. C20.42	0.0000%	0.0000%	0.0000%	0.0000%
C20.42	0.0000%	0.0000%	0.0000%	0.0000%

Source: Study team on the basis of calculations performed in the study and Eurostat.

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

8.3 Single market

8.3.1 Competition

Table 8-20 below includes the initial screening of impacts on competition in order to focus the analysis on those impacts likely to be the most significant. The most significant impacts are further explored in the following paragraphs.

The answers in the table are the overall assessment following by a more sector specific considerations.

Table 8-20 Screening of competition impacts

Impacts	Key questions	Yes/ No/ Possibly/ Not clear
Existing firms	Additional costs?	Yes
	Scale of costs significant?	Possibly
	Old firms affected more than new?	No
	Location influences?	Possibly
	Some firms will exit the market?	Yes
	Are competitors limited in growth potential?	Possibly
	Increased collusion likely?	Not clear
New entrants	Restrict entry?	Possibly

Impacts	Key questions	Yes/ No/ Possibly/ Not clear
Prices	Increased prices for consumers	No
Non-price impacts	Product quality/variety affected?	No
	Impact on innovation	No
Upstream and downstream market	Will OELs affect vertically integrated companies more or less than non-integrated ones?	Not clear
	Will OELs encourage greater integration and market barriers?	Nor clear
	Will OELs affect bargaining power of buyers or suppliers?	Not clear

Source: Study team.

8.3.1.1 Existing firms

The analysis presented in the next section indicates that the number of firms likely to exit the market in the six sectors identified as using 1,4-dioxane is low (6 SME companies out of the 1,779 SMEs with exposed workers would cease operation under the most stringent policy option, i.e. 7.3 mg/m^3) and most companies will continue their operations. This is because many organisations are already operating at exposure levels lower than the policy options or are able to implement RMM that can help them achieve the policy option.

8.3.1.2 Firms leaving the market (discontinuations)

The numbers of firms leaving the market are summarised below.

Table 8-21 Estimates of companies or business units that will discontinue operation under different OEL options by sector and size of enterprise

Sector	7.3 mg/m³			20 mg/m³			36 mg/m³			73 mg/m³		
	S	M	L	S	M	L	S	M	L	S	M	L
Total	**5**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

Source: Study team.

Table 8-22 Companies discontinuing at different OEL options by sector

Sector	Number of enterprises in EU (Eurostat)	Estimated enterprise with exposed workers in EU	No. of discontinuations	Discontinuations as a % of enterprises	Discontinuations as a % of enterprises with exposed workers
7.3 mg/m³					
Part of C20.1	8,280	2	0	0%	0%
C21.1 and C21.2	3,983	95	0	0%	0%

Sector	Number of enterprises in EU (Eurostat)	Estimated enterprise with exposed workers in EU	No. of discontinuations	Discontinuations as a % of enterprises	Discontinuations as a % of enterprises with exposed workers
C20.1, C20.3 and C20.5	17,407	105	6	0.0003%	6%
M72.1	53,906	1,480	0	0%	0%
C20.4 excl. C20.42	4,142	53	0	0%	0%
C20.42	7,000	70	0	0%	0%

Source: Study team.

Notes: Part of C20.1: Manufacture of 1,4-dioxane; C21.1 and C21.2 Pharmaceutical production (intentional use); C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector; M72.1 Laboratories; C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; C20.42 Cosmetics – generation as a by-product in the production of cosmetics

8.3.1.3 New entrants

Significant capital expenditures are often incurred by new start-ups when entering the market. When entering the market companies are required to monitor exposure and so costs of running monitoring campaigns for start-ups cannot be attributed to the introduction of OELs. However, as limit values become lower more precise and more expensive monitoring techniques are required, potentially increasing the costs of the monitoring campaign and making entry to the market more challenging.

Initial expenditures required for new start-ups (to ensure that exposure to 1,4-dioxane is lower than the required OEL) could represent a barrier to trade for potential new entrants to the market. As OELs become lower, the investment required increases, making entry to the market more difficult. However, considering that the additional investments (as a proportion of turnover) foreseen for businesses in the six sectors for all OEL scenarios is minor, as shown in Section 8.1, it is not envisaged that the introduction of OELs will have a significant impact on new entrants compared with existing firms.

8.3.2 Internal market

The impact on simplification/level playing field is approximated below drawing on the current national OELs.

The introduction of an OEL at the EU level are likely to have a positive impact on the simplification of the existing rules and the creation of a more level playing field in the internal market. The establishment of the EU OEL should reduce the diversity of national OELs, and the resulting simplification would be beneficial to companies that operate in more than one Member State. However, according to the estimations based on Eurostat data, the majority of companies in the six relevant sectors are SMEs and it is unlikely that these companies are operating in multiple Member States.

Table 8-23 Simplification/level playing field

Policy option	Number of MS currently above the policy option
7.3 mg/m^3	27
20 mg/m^3	25
36 mg/m^3	22
73 mg/m^3	0

Source: Study team.

8.3.3 Consumers

No changes in processes or substitutions that may increase the costs of products for consumers are anticipated for any of the policy options.

8.4 Competitiveness of EU businesses

The introduction of harmonised OEL/STELs could have an impact on companies' cost competitiveness but will be more significant for the lower OEL/STEL options.

8.4.1 Sectors affected

Based on the tables in Section 8.1 there are a few sectors that systematically come up as experiencing negative financial impacts from the introduction of an OEL at the most stringent policy option (7.3 mg/m^3), although not severe when expressed in terms of turnover and gross operating surplus (GOS):

- C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector;
- C21.1 and C21.2 Pharmaceutical production (intentional use);
- C20.4 excl. C20.42 Surfactants – generation as a by-product in the production of detergents, soaps, etc.; and
- C20.42 Cosmetics – generation as a by-product in the production of cosmetics.

There is also scope for companies to experience some cost savings by switching to more effective RMM that have a higher initial capital investment but a lower cost over 40 years (discounted).

No sectors would be adversely affected due to the introduction of any of the three higher policy options (i.e. 20 mg/m^3, 36 mg/m^3 or 73 mg/m^3).

8.4.2 SME competitiveness

SMEs are likely to be higher impacted by regulatory changes that introduce substantial adjustment or administrative costs as their limited size often makes it more difficult to access capital, and most often at a higher cost of capital than large enterprises (Tool #22 of the Better Regulation Toolbox). As shown in Section 8.1. small and medium companies have comparatively higher costs relative to turnover at the most stringent policy option, this is particularly apparent in the C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals sector

– the costs as proportion of turnover equal 0.34% and 0.24% for small and medium enterprises, respectively, compared with 0.051% for large enterprises. This suggests that small and medium enterprises may find it more difficult to comply, compared with large companies. A significant impact on their competitiveness is, however, not expected.

8.4.3 Cost competitiveness

The introduction of harmonised OEL/BLV is likely to have a limited impact on companies' cost competitiveness and will be more significant for the most stringent policy option (7.3 mg/m^3). As indicated previously, the increase in costs due to having to implement more or better RMMs represents the burden of compliance on companies. This would make those companies incurring these costs less competitive where they are competing with companies already compliant at this level.

8.4.4 Capacity to innovate

The diversion of costs away from R&D may occur due to overall cost impacts of having to invest in RMMs to meet the prescribed OEL/BLV. However, Table 8-19 suggests that such diversion is unlikely be to significant compared with the total R&D expenditure and as such it is unlikely to significantly affect the companies' capacity to innovate.

8.4.5 International competitiveness

Table 8-24 below draws on information provided in Section 3.1. The table below provides information for OELs and STELs only since the only non-EU country with BLV identified by the study team is Switzerland (400 mg 2-Hydroxyethoxyacetic acid/g creatinine).

If EU companies are required to comply with stricter OEL/STEL/BLV than those in effect in third countries, they will be at a disadvantage when compared to their competitors from third countries with higher OEL/STEL/BLV who will be able to operate without incurring additional capital and operating costs. In certain cases, where they have existing plants in third countries, EU companies with exposure to 1,4-dioxane might have the incentive to shift EU operations away from the EU. However, the additional costs per company expressed as a percentage of turnover are relatively limited and this is less likely to happen in the case of SMEs and in the case of sectors with less international competition or where relocation is difficult (e.g. laboratories).

Table 8-24 OELs and STELs in selected non-EU countries

Country	OEL (mg/m³)	Specification of OEL	STEL [mg/m³]	Specification of STEL
Australia	36	- Carc, Sk	-	
Brazil	-		-	
Canada, Ontario	20	- value only given in ppm	-	
Canada, Québec	72	- Carc, Sk	-	
China	-		-	
India	-		-	
Japan, MHLW	10	- value only given in ppm	-	
Japan, JOSH	3.6	- Carc, Sk	-	

Country	OEL (mg/m³)	Specification of OEL	STEL [mg/m³]	Specification of STEL
Norway	18	- Carc, Sk	36	- 15 min average value, Sk
Russia	10 (V)		-	
South Korea	20	- value only given in ppm, Sk	-	
Switzerland	72	- Carc, Sk	144	- Carc, Sk
United Kingdom	73	- Sk	-	
USA, ACGIH	20	- value only given in ppm, Carc, Sk	-	
USA, NIOSH	-		3.6	- ceiling limit value (30 min), Carc
USA, OSHA	360	- Sk	-	

Source: Information presented in section 3.1.

8.5 Employment

The calculation of the social cost of unemployment has been performed on the application of 'valuing the social costs of job losses in applications for authorisation' by Dubourg (2016). See the Methodological Note for more information.

Employment impacts will result from companies forced to cease operations involving 1,4-dioxane if they cannot comply with the OEL/BLV. The results suggest that 6 companies active in the *C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals* sector with 140 employees in total could potentially be impacted under the 7.3 mg/m^3 policy option. The associated social costs resulting from discontinuances would equal € 13 million. Employment impacts are not expected to arise for other policy options.

The study team recognises that the number of unemployed workers as a result of discontinuation may not fully reflect the reality that many employees may be retained in alternative roles or reemployed by competitors. Modelling assumes all discontinuations in small and medium sized enterprises would result in discontinuation of the enterprises or significant proportions of production lines. Alternatively modelling assumes 10% of discontinuations in large enterprises would result in full closure, whereas 90% would either close production lines, find alternatives, or simply absorb costs.

The study team is not able to quantify or comment on the proportion of jobs retained/reemployed, and subsequently the figures above present a worst-case scenario of redundancy.

The wider social costs of companies discontinuing such as the strategic costs of not competing, the impact on the overall market and the wider cost to a community of losing many jobs in one location are not included because the study team has no means of quantifying them.

8.6 Summary of market effects

No market effects are expected at OEL levels of 20 mg/m^3, 36 mg/m^3 and 73 mg/m^3. An OEL of and 7.3 mg/m^3 would have some impacts on the market due to the required compliance costs and discontinuations (6 enterprises). It is estimated that 140 employees could potentially lose their jobs in the *C20.1, C20.3 and C20.5 Industrial use as a solvent and generation as by-product in the chemicals* sector and the associated social costs resulting from discontinuations would equal € 13 million.

Whilst the implementation of new OELs would result in greater harmonisation of health and employment standards across the EU, it is possible that they could also create a disadvantage for established companies. The increase in costs due to having to implement more or better RMMs represents the burden of compliance on companies. This would make those companies incurring these costs less competitive where they are competing with companies not using 1,4-dioxane and with any companies already compliant at this level. However, given the data presented earlier in this chapter, the degree of competitiveness impacts is likely to be moderate.

The costs and discontinuations expected to be incurred by industry under any of the OEL policy options are not likely to result in price increases for consumers.

9 ENVIRONMENTAL IMPACTS

This chapter comprises the following sections:

- Section 9.1: Potential environmental impacts
- Section 9.2: Current environmental exposure to the substance
- Section 9.3: Direct impact on the environment
- Section 9.4: Indirect impacts on the environment and environmental legislation
- Section 9.5: Summary of environmental impacts

9.1 Potential environmental impacts

The overall approach to the assessment of the environmental impacts, based on the Better Regulation (BR) Toolbox for environmental impacts (BR Tool #36) is described in the Methodological note. Initially the key questions listed in section 3.3. of the BR Tool #36 have been screened in order to identify which questions is relevant for the introduction of an OEL and should be answered in the impact assessment. From this screening the following potential environmental impacts are included in the assessment for 1,4-dioxane:

- Issues relating to the implementation and enforcement of existing environmental legislation – section 9.4
- Climate change including impacts on climate neutrality objectives – section 9.4
- Air, Water, Biodiversity and Soil – section 9.3
- Waste – section 9.4
- Zero pollution and toxicity – section 9.3
- Efficient use of resources – section 9.4
- Circular economy – section 9.4
- International environmental effects – section 9.4

It is also noted that a call for evidence by the German Federal Institute for Occupational Safety and Health (BAuA) was open until 20 July 2023 on a potential Annex XV restriction on the manufacture, placing on the market and use of 1,4-dioxane in surfactants, motivated by the need to prevent environmental emissions of 1,4-dioxane. The expected date of submission of the restriction proposal is 2024.

9.2 Current environmental exposure to the substance

9.2.1 Persistent, bio-accumulative, and toxic (PBT) screening

1,4-dioxane does not have any harmonised classifications for environmental hazards. It may be persistent (P) (or even very persistent vP) and mobile (M); however, it does not meet the criteria for being bio-accumulative (B) or toxic (T). In the ECHA substance portal, 1,4-dioxane is indicated as under assessment for PBT properties. The following table outlines both the PBT status as well as the harmonised classification for 1,4-dioxane in respect to the environment.

Table 9-1 PBT assessment and harmonised classification with regard to the environment for 1,4-dioxane

Substance		**P**	**B**	**T**	**PBT**	**Harmonised classification (environ-ment)**	**Notes**
1,4-dioxane	Yes	No	No	No		None	Aquatic Chronic 2 (H411) self-classifi-cation

PBT: Persistent, Bio-accumulative and Toxic.

Sources: ECHA Substance Portal, Registration Dossiers and CLP.

9.2.2 Current environmental exposure

9.2.2.1 Sources

The sources of environmental releases that are relevant to this study include air and water emissions from both intentional use of 1,4-dioxane, its generation as by-product as well as article service life (EU RAR, 2022). 1,4-dioxane has a high vapour pressure which makes its release into the air more likely (US EPA, 2015).

The assessment in EU RAR (2002) takes into account the following anthropogenic sources of 1,4-dioxane include:

- Production
- Processing
- End-use
- Unintentional formation

9.2.2.2 Background exposure

No background exposure data have been identified. The EU RAR notes that 1,4-dioxane can occur in some natural products (foods) and further notes that, although there are no data on the levels of 1,4-dioxane in these products, the levels are expected to be low.

The total human intake data at the regional level estimated in EU RAR (2002) are summarised below.

Table 9-2 Regional scale air concentrations and total human intake

Parameter (unit)	**Value**
Intake (mg/kg/d)	$4.5.10^{-5}$
Predicted environmental concentration (PEC) (μg/m³)	0.02

Dioxane has also been detected in drinking water. EU RAR (2002) reports measured concentrations of 1,4-dioxane in drinking water of 0.01 - 2.1 μg/l in the United States in 1975 and 0.5 μg/l in the Netherlands (after 1996).

9.2.2.3 Environmental levels in relation to hazard data

The information in Table 9-2 and REACH registration CSRs indicates that, where occupational exposure is involved, the key source of 1,4-dioxane intake is occupational exposure rather than background concentrations in the environment.

9.3 Direct impact on the environment

The table below indicates the potential alternative RMMs which may be implemented under each of the policy options and the potential impact this might have on environmental releases of harmful substances and energy consumption.

Table 9-3 Primary and alternative RMMs for each OEL option, together with the broad environmental impact

Primary RMM	Alternative primary RMM for each OEL policy option				Broad environmental impacts
	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³	
Closed systems	Discontinuation	Discontinuation	N/A	N/A	Reduction in 1,4-dioxane emissions
Partially closed systems	Closed system Discontinuation	Closed system Discontinuation	Closed system Discontinuation	N/A	Reduction in 1,4-dioxane emissions
Open hoods over equipment or local extraction ventilation	Closed system	Closed system	Closed System	N/A	Reduction in 1,4-dioxane emissions
HEPA filter based RPE	Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	N/A	No impact
General dilution ventilation	Closed system Partially Closed System Open hoods over equipment or local extraction ventilation Discontinuation	Closed system Partially Closed System Open hoods over equipment or local extraction ventilation Discontinuation	Closed system Partially Closed System Open hoods over equipment or local extraction ventilation	N/A	Increased/ Reduction in 1,4-dioxane emissions
No ventilation	General dilution ventilation Closed system Partially Closed System	General dilution ventilation Closed system Partially Closed System	General dilution ventilation Closed system Partially Closed System	N/A	Increased/ Reduction in 1,4-dioxane emissions

Primary RMM	Alternative primary RMM for each OEL policy option				Broad environmental impacts
	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³	
	Open hoods over equipment or local extraction ventilation Discontinuation	Open hoods over equipment or local extraction ventilation Discontinuation	Open hoods over equipment or local extraction ventilation		

Source: Study team.

Based on the RMMs suggested as alternatives to the primary RMMs existing across industries with 1,4-dioxane exposure, it can be expected that the introduction of an OEL at the level of 7.3 mg/m³ will likely improve the direct environmental impacts of the various sectors. This is because the majority of alternative RMMs to be implemented result in increased enclosure of processes and as such mean lower levels of emissions to the air. In the cases where discontinuations occur this would result in a total reduction of direct 1,4-dioxane emissions, whilst for closed and partially closed systems fugitive emissions and emissions during maintenance/filling/sampling operations may still occur.

It is difficult to predict if the above changes will impact direct emissions to water. However, greater capture of 1,4-dioxane that prevents emissions into the air may result in increased emissions into wastewater.

9.4 Indirect impacts on the environment and environmental legislation

9.4.1 EU Green Deal

In 2019 the European Commission announced the European Green Deal to encourage future policies to be developed in line with minimal adverse impacts on the environment and to support efforts to move to sustainable practices (European Commission, 2019). This section reviews the implementation of OELs 1,4-dioxane in the context of the key elements of the Green Deal. This is also in line with the approach described in chapter 36 of the better regulation toolbox.

Table 9-4 outlines the key elements put forward in the EU Green Deal and contains a short overview of the expected impact (positive or negative) of introducing OELs for 1,4 - dioxane on the progress towards each of these elements. A short explanation is given to indicate the justification for the expected impact.

Table 9-4 Potential for OELs to impact benefits of the EU Green Deal

Elements of the EU Green Deal	OELs impact (Yes/No)	Comment
Increasing the EU's climate ambition for 2030 and 2050	No	The introduction of an new OEL is not expected to have impacts on these elements of the EU Green Deal
Supplying clean affordable and secure energy	No	
Mobilising industry for a clean and circular economy	No	
Building and renovating in an energy and resource efficient way	No	

Elements of the EU Green Deal	OELs impact (Yes/No)	Comment
Accelerating the shift to sustainable and smart mobility	No	
Designing a fair, healthy and environmentally-friendly food system	No	
Preserving and restoring ecosystems and biodiversity	No	
Zero pollution ambition for a toxic-free environment	Yes	It is possible that greater use of closed systems may reduce emissions but if more 1,4-dioxane is disposed of into wastewater, presence in water bodies might increase

Source: Study team

9.4.2 European Climate Law

No impacts are expected.

9.4.3 Waste management and disposal

No impacts are expected.

9.4.4 Resource consumption and circular economy

No impacts are expected.

9.4.5 Global impacts

No impacts are expected.

9.4.6 Green initiatives

No impacts are expected.

9.5 Summary of environmental impacts

1,4-dioxane is persistent/very persistent but does not meet the criteria for classification as bio-accumulative or toxic. The environmental concerns about 1,4-dioxane are largely tied to its releases into wastewater and its presence in drinking water.

Introducing a new OEL is not expected to have significant direct or indirect impacts on the environment or environmental legislation/targets.

10 OTHER IMPACTS

This chapter comprises the following sections:

- Section 10.1: Impacts on fundamental rights, including equality
- Section 10.2: Subsidiarity and proportionality principles
- Section 10.3: Impacts on digitalisation
- Section 10.4: Contributions to the UN sustainable development goals
- Section 10.5: Summary of other impacts

10.1 Impacts on EU Strategic Goals

In June 2019, the European Council agreed the EU's agenda for the next five years, setting out the priority areas for the European Council and establishing guidance for the work programmes of all parts of the EU (Council of the European Union, 2019).

It focuses on four priorities:

- Protecting citizens and freedoms;
- Developing a strong and vibrant economic base;
- Building a climate-neutral, green, fair and social Europe; and
- Promoting European interests and values on the global stage.

The introduction of any of the policy options for 1,4-dioxane is unlikely to impact any of the above points. This is due to the fact that only a limited number of stakeholders are expected to be affected and the impacts on citizen freedoms, economic stability, climate adaptability and wider European interests will not be impacted (positively or negatively).

Additionally, consideration has been given to the EU Commission priority areas for 2019-2024. These are assessed in the table below.

Table 10-1 Potential for OELs to impact benefits of the EU Green Deal

EU Commission Priority Areas 2019-2024	OELs impact (Yes/No)	Comment
A European Green Deal		See section 9.4.1
A Europe Fit for the Digital Age		See section 10.3
An Economy that Works for People		See sections 8.3 and 8.4
A Stronger Europe in the World	Yes	The introduction of OELs will help to affirm the EU's reputation of delivering safe workplaces and respecting the fundamental rights of EU workforce. If OELs are set at a disproportionately low level however this could

EU Commission Priority Areas 2019-2024	OELs impact (Yes/No)	Comment
		compromise the attractiveness of EU to international business and so to meet this priority area a balance should be found.
Promoting our European Way of Life	Yes	The introduction of EU Binding OELs will mean all member states are subject to the same regulation of hazardous substances set out in the CMRD. EU OELs therefore support an equal approach to chemical risk management and a united Europe when dealing with external markets.
A New Push for European Democracy	No	The introduction of OELs for *1,4-dioxane* does not impact the push for a maintained and renewed European democracy.

Source: Study team

10.2 Impacts on fundamental rights, including equality

Article 31.1 of the Charter of Fundamental Rights of the European Union states that "*Every worker has the right to working conditions which respect his or her health, safety and dignity*" (European Commission, 2012). In the case of 1,4-dioxane, some of the policy options lead to the improvement in health of the workers – these impacts are already considered under 'social impacts' in Section 6.

10.3 Impacts on digitalisation

The Commission has in its 2030 Digital Compass Communication (European Commission, 2023) set out a vision, targets and avenues for a successful digital transformation of Europe by 2030. To support this process, the Commission committed to assess how the options under consideration reflect the 'digital by default' principle and contribute to the digital transformation.

As before the impact of the policy options for 1,4-dioxane will not result in any changes to wider European digitalisation plans either in a positive or negative way.

10.4 Contributions to the UN sustainable development goals

The third UN sustainable development goal (UNDP, 2023), which calls for "*good health and wellbeing - improved worker and family health*" is directly relevant to the setting of limit values for 1,4-dioxane.

The policy options that reduce worker exposure to 1,4-dioxane would also contribute towards SDG 8 which calls for "Decent work & economic growth" in particular towards the targets for:

- (8.2) Achieving higher levels of economic productivity through diversification, technological upgrading and innovation, including through a focus on high-value added and labour-intensive sectors.

- (8.8) Protecting labour rights and promoting safe and secure working environments for all workers, including migrant workers, in particular women migrants, and those in precarious employment.

There could be some limited positive impact of OELs for 1,4-dioxane on wider UN sustainable development goals in case it leads to an increased implementation of fully closed systems, which prevent air emissions of 1,4-dioxane (SDG 15). However, should this lead to increased emissions to water, there could be a limited negative impact (SDG 14).

10.5 Summary of other impacts

Table 10-2 below gives a total summary of the other impacts expected to arise as a consequence of introducing limit values for 1,4-dioxane. As stated throughout this section, the impacts are likely to be limited.

Table 10-2 Summary of other impacts

Other impacts	Impacts
EU Strategic goals	None
Fundamental rights	Improved worker health.
Digitalisation	None
UN Sustainable Development Goals – Goals 3, 8, 14 and 15	Potential for improved health and reduced emissions into the air but it is unclear whether this would not increase emissions into wastewater

11 DISTRIBUTION OF THE IMPACTS

The impacts identified under the previous tasks will be broken down by stakeholder type and a systematic analysis of who will bear the costs and accrue the benefits will be provided.

This chapter comprises the following sections:

- Section 11.1: Businesses
- Section 11.2: SMEs
- Section 11.3: Workers
- Section 11.4: Consumers
- Section 11.5: Taxpayers/public authorities
- Section 11.6: Specific Member States/regions
- Section 11.7: Summary of distribution of the impacts

11.1 Businesses

The costs and benefits for businesses (relative to the baseline) are summarised in Table 11-1 for the different policy options.

The average benefits per enterprise for companies that continue in business are reported in table below are based on workforce with a turnover of 5%, which effectively means that on average workers spend 20 years working in an environment with 1,4 - dioxane.

A comparison of costs and benefits to employers in the table below indicates that that RMM adjustment, monitoring costs and administrative burden over a period of 40 years are significantly higher than the value of benefits returned to an enterprise for the following OEL options – 7.3 mg/m^3, 20 mg/m^3, 36 mg/m^3. No costs or benefits are expected to be incurred by employers at 73 mg/m^3. The majority of costs are attributable to adjustment costs (first year and recurrent).

Table 11-1 Costs and benefits to EMPLOYERS from an OEL (PV over 40 years, policy options relative to the baseline)

Costs and benefits to employers	7.3 mg/m^3	20 mg/m^3	36 mg/m^3	73 mg/m^3
Total benefits for employers (avoided disruption)	€ 1,582,097	€ 0	€ 0	€ 0
Total RMM adjustment, monitoring, and administrative costs	€ 124,554,145	€ 730,991	€ 657,547	€ 0
Number of companies minus those discontinuing	1,799	1,805	1,805	1,805
Benefits (avoided disruption) per enterprise	€ 704	€ 0	€ 0	€ 0
Adjustment, monitoring and admin costs per enterprise	€ 69,235	€ 405	€ 364	€ 0

Source: Study team.

The costs and benefits to employers from the combined OEL and BLV options are summarised below, based on partial quantifications. Since the additional adjustment costs for companies and benefits from reduced ill health from adding a BLV to an OEL cannot be estimated with a sufficient degree of robustness, they are not included in the quantified impacts in the table below which (in addition to the preceding table) takes into account the costs of biomonitoring.

11-2 Costs and benefits to EMPLOYERS from ***combined OEL and BLV options*** *(PV over 40 years, policy options relative to the baseline)*

Costs and benefits to employers	7.3 mg/m³ and 45 mg HEAA in urine/g Creatinine	20 mg/m³ and 108 mg HEAA in urine/g Creatinine	36 mg/m³ and 188 mg HEAA in urine/g Creatinine	73 mg/m³ and 366 mg HEAA in urine/g Creatinine
Total benefits for employers (avoided disruption)	€ 1,582,097	€ 0	€ 0	€ 0
Total RMM adjustment, monitoring, and administrative costs	€ 248,070,000	€ 60,790,000	€ 12,570,000	€ 6,750,000
Number of companies minus those discontinuing	1,799	1,805	1,805	1,805
Benefits (avoided disruption) per enterprise	€ 704	€ 0	€ 0	€ 0
Adjustment, monitoring and admin costs per enterprise	€ 137,893	€ 33,679	€ 6,964	€ 3,740

Source: Study team.

11.2 SMEs

The assessment of the impact on SMEs are done following the principles of the SME test; see BR Tool #23. The SME test includes the following steps:

- Identification of affected business
- Consultation of SME stakeholders
- Assessment the impacts on SMEs
- Minimising the negative impacts on SMEs

The result of the SME test is summarised in the below table.

Table 11-3 Summary of the SME test

SME test	Summary assessment
Identification of affected businesses	
	95% of the affected companies are small companies and 3% are medium sized companies.

SME test	Summary assessment
	The share of SMEs is similar across all the most affected sectors (between 88% and >99%) with the exception of the sector that produces 1,4-dioxane.
Consultation with SME stakeholders	
	SMEs have been consulted as part of stakeholder consultation. The share of SME respondents is 100% in the stakeholder survey conducted for this study (40% of responses are from small companies, 60% of responses are from medium-sized companies). SMEs are thus well represented.
	SME stakeholders express concern that the lowest OEL option, two of the five respondents expect moderate or significant competitiveness impacts from the OEL option of 7.3 mg/m³ (2 ppm).
Assessing the impacts on SMEs	
	One indicator for assessing the impacts on SMEs is the share of first year costs in annual turnover. While there is no specific agreed benchmark for what significant impacts are, when the indicator is above 5%, then it will be considered significant in this study. The table presents how many sectors where the indicator is above 5% for small and medium companies. This indicates that it is only small companies that face more significant challenges for the lowest OEL or lowest OEL/BLV combination in the following sector: C20.1, C20.3 and C20.5 chemicals, where this indicator exceeds 14% for both lowest OEL or lowest OEL/BLV combination.

OEL	Share of sectors where first year costs exceed 5% of annual turnover	
	Small sized companies	**Medium sized companies**
7.3 mg/m3	17% (1 sector)	0%
20 mg/m3	0%	0%
36 mg/m3	0%	0%
73 mg/m3	0%	0%

SME test	Summary assessment		
	OEL	**Share of sectors where first year costs exceed 5% of annual turnover**	
		Small sized companies	**Medium sized companies**
	7.3 mg/m3 and 45 mg HEAA in urine/g Creatinine	17% (1 sector)	0%
	20 mg/m3 and 108 mg HEAA in urine/g Creatinine	0%	0%
	36 mg/m3 and 188 mg HEAA in urine/g Creatinine	0%	0%
	73 mg/m3 and 366 mg HEAA in urine/g Creatinine	0%	0%
Minimising the negative impacts on SMEs			
	None of the policy measures have special provisions for SMEs.		

Table 11-4 presents the numbers of small, medium and large enterprises likely to have workers exposed to 1,4-dioxane. The average costs of adjustment, monitoring and administrative burden by size of company is shown, together with the number of discontinuations by size of company at each of the different policy options.

The majority of enterprises that would need to comply with a new or stricter OEL would primarily consist of SMEs (see Table 3-26 showing the percentage split of enterprises with exposed workers between small, medium and large for each of the relevant sectors).

SMEs can be proportionately higher impacted by regulatory changes that introduce substantial adjustment or administrative costs. Their limited size often makes it more difficult to access capital, and most often at a higher cost of capital than large enterprises (Tool #22 of the Better Regulation Toolbox). SMEs can therefore be exposed to proportionally higher costs, as compared to the large enterprises. The table below indicates that small and medium companies have comparatively higher costs relative to turnover at the most stringent policy option (0.14% and 0.12% of turnover on average, respectively).

Table 11-4 Costs for EMPLOYERS by size of company (PV over 40 years, constant discount rate, OEL options relative to the baseline) (millions)

Sector	Small	Medium	Large
Number of companies	1,716	63	26
7.3 mg/m³			
Total RMM adjustment costs, monitoring costs, and administrative burden	€ 29	€ 52	€ 43
Average cost per company	€ 0.017	€ 0.830	€ 1.660
Average cost per company as a percentage of average turnover per company	0.14%	0.12%	0.01%
Discontinuations	5	1	0
20 mg/m³			
Total RMM adjustment costs, monitoring costs, and administrative burden	€ 0.62	€ 0.05	€ 0.06
Average cost per company	€ 0.0004	€ 0.001	€ 0.001
Average cost per company as a percentage of average turnover per company	0.003%	0.000%	0.000%
Discontinuations	0	0	0
36 mg/m³			
Total RMM adjustment costs, monitoring costs, and administrative burden	€ 0.57	€ 0 .05	€ 0 .03
Average cost per company	€ 0.000	€ 0.001	€ 0.002
Average cost per company as a percentage of average turnover per company	0.003%	0.000%	0.000%
Discontinuations	0	0	0
73 mg/m³			
Total RMM adjustment costs, monitoring costs, and administrative burden	€ 0.000	€ 0.000	€ 0.000
Average cost per company	€ 0.000	€ 0.000	€ 0.000
Average cost per company as a percentage of average turnover per company	0.000%	0.000%	0.0000%
Discontinuations	0	0	0

Source: Study team.

Adding the costs of biomonitoring to the costs in the table above, the table below presents the (partial) costs for combined OEL and BLV options. Since the additional adjustment costs for companies and benefits from reduced ill health from adding an OEL to a BLV cannot be estimated with a sufficient degree of robustness, they are not included in the quantified impacts in the table below which (in addition to the preceding table) takes into account the costs of biomonitoring.

*Table 11-5 Costs for EMPLOYERS by size of company (PV over 40 years, constant discount rate, **combined OEL and BLV options** relative to the baseline) (millions)*

Sector	Small	Medium	Large
Number of companies	1,716	63	26
7.3 mg/m³ and 45 mg HEAA in urine/g Creatinine			
Total RMM adjustment costs, air monitoring costs, air monitoring administrative burden, biomonitoring and biomonitoring administrative burden	€ 45	72.34	129.68
Average cost per company	€ 0.03	€ 1.15	€ 4.99
Average cost per company as a percentage of average turnover per company	0.22%	0.18%	0.04%
Discontinuations	5	1	0
20 mg/m³ and108 mg HEAA in urine/g Creatinine			
Total RMM adjustment costs, air monitoring costs, air monitoring administrative burden, biomonitoring and biomonitoring administrative burden	€ 11	€ 12	€ 38
Average cost per company	€ 0.01	€ 0.19	€ 1.48
Average cost per company as a percentage of average turnover per company	0.05%	0.03%	0.01%
Discontinuations	0	0	0
36 mg/m³ and 188 mg HEAA in urine/g Creatinine			
Total RMM adjustment costs, air monitoring costs, air monitoring administrative burden, biomonitoring and biomonitoring administrative burden	€ 2.9	€ 2.1	€ 7.5
Average cost per company	€ 0.00	€ 0.03	€ 0.29
Average cost per company as a percentage of average turnover per company	0.014%	0.005%	0.003%
Discontinuations	0	0	0

Sector	Small	Medium	Large
73 mg/m³ and 366 mg HEAA in urine/g Creatinine			
Total RMM adjustment costs, air monitoring costs, air monitoring administrative burden, biomonitoring and biomonitoring administrative burden	€ 1.6	€ 1.1	€ 4.1
Average cost per company	€ 0.001	€ 0.02	€ 0.16
Average cost per company as a percentage of average turnover per company	0.008%	0.003%	0.001%
Discontinuations	0	0	0

Source: Study team.

11.3 Workers

The costs and benefits for workers and their families (relative to the baseline) are summarised below for the different policy options. The benefits are the avoided costs of ill health.

At the most severe policy option it is estimated that 6 companies would close down, resulting in job losses. From the perspective of the cost to the EU, these people would, however, be available for employment elsewhere and in time, may find other equivalent employment. However, the impacts associated with the potentially temporary loss of employment can be monetised.

There are substantial benefits at the most stringent option (€ 1.86 – 3.20 million), however, there are also substantial costs related to unemployment (€ 13 million) that are higher. The other policy options would present neither costs due to unemployment nor benefits from avoided ill health.

Table 11-6 Comparison of the costs and benefits to WORKERS & THEIR FAMILIES (PV over 40 years, policy options, relative to the baseline (€ millions)

Method	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³	Baseline
Number of workers	31,150	31,150	31,150	31,150	31,150
Benefits (avoided ill health) (M1)	€1.86	€0.00	€0.00	€0.00	€0.00
Benefits (avoided ill health) (M2)	€3.20	€0.00	€0.00	€0.00	€0.00
Costs (unemployment distress)	€13	€0.00	€0.00	€0.00	€0.00
Benefits (avoided ill health) per worker (M1)	€0.0001	€0.00	€0.00	€0.00	€0.00
Benefits (avoided ill health) per worker (M2)	€0.0001	€0.00	€0.00	€0.00	€0.00
Costs (unemployment distress) per worker	€0.0004	€0.00	€0.00	€0.00	€0.00

Notes: Only additional costs and benefits (i.e. relative to the baseline) are presented in this table.
Source: Study team.

11.4 Consumers

Consumers are not likely to be affected by the implementation of any policy option, no changes in processes or substitutions that may increase the costs of products are anticipated.

11.5 Taxpayers/public authorities

The costs and benefits for the public sector (relative to the baseline) are summarised in Table 11-7 for the different policy options.

The benefits of the avoided costs of ill health relative to the baseline to the public sector are composed of cost of treatment and tax revenue, as summarised in the table below. These costs include healthcare treatment costs, which assume that the costs are borne by the public sector. There are also indirect costs due to lower tax revenues if the company's profitability is reduced or they employ fewer staff.

The table also shows costs for public authorities for transposing the OEL into national legislation. These costs are highest for the most stringent policy option (€ 0.81 million). However, these costs are almost twice as low as the avoided costs of setting a national OEL. Therefore, it would be more beneficial for Member States to transpose an EU level OEL than to set a national OEL. Nevertheless, the estimations of avoided costs of setting a national OEL are based on the assumption that all Member States without a national OEL would want to implement one and that all Member States with an existing OEL would want to revise it.

Table 11-7 Comparison of the costs and benefits to the PUBLIC SECTOR (PV over 40 years, policy options relative to the baseline) (€ millions)

Cost elements	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³	Baseline
Benefits					
Avoided costs of healthcare and avoided loss of tax revenue	€ 2	€ 0.00	€ 0.00	€ 0.00	€ 0.00
Avoided costs of revising OELs	€ 2.7	€ 1.8	€ 1.5	€ 1.4	€ 0.00
Costs					
Transposition costs	€ 0.81	€ 0.75	€ 0.66	€ 0.00	€ 0.00

Notes: Only additional costs and benefits (i.e. relative to the baseline) are presented in this table.

Source: Study team.

The BLV transposition costs, together with the avoided costs of setting national BLVs, are summarised below.

Table 11-8 Comparison of the costs and benefits to the PUBLIC SECTOR (PV over 40 years, policy options relative to the baseline) (€ millions)

Cost elements	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³	Baseline
Benefits					
Avoided costs of healthcare and avoided loss of tax revenue	Not quantified	Not quantified	Not quantified	Not quantified	€ 0.00
Avoided costs of revising BLVs	€ 2.6	€ 2.6	€ 2.6	€ 2.6	€ 0.00
Costs					
Transposition costs of BLVs	€ 1.3	€ 1.3	€ 1.3	€ 1.3	€ 0.00

Notes: Only additional costs and benefits (i.e. relative to the baseline and the OELs) are presented in this table.

Source: Study team.

11.6 Specific Member States/regions

No detailed analysis of direct impacts on Member States can be derived from this assessment. This is because the distribution of companies with workers exposed to 1,4-dioxane across EU Member States has been modelled based on Eurostat data and so may have a level of uncertainty relating to the true distribution. As such, any analysis of impacts on specific Member States would pose a level of uncertainty and may lead to inaccurate conclusions.

The table below presents Member States that would need to introduce or alter legislation at different OEL options. At the most stringent policy option, all Member States would need to change their legislation, which would affect all companies producing 1,4-dioxane in these countries, especially businesses in Italy, Germany, Spain, France and Greece as they share more than a half of all companies in the EU with workers exposed to 1,4-dioxane (see Table 3-29). There are no companies in Cyprus with workers exposed to 1,4-dioxane. The numbers of enterprises with exposed workers per Member State in Table 3-29 were derived by using Eurostat data, hence may not be an entirely accurate representation of the current situation.

Table 11-9 Member States with OELs for 1,4 - dioxane higher than the envisaged policy options

OEL	Member States who would need to introduce or alter legislation	% of MSs who would need to transpose	No of MS required to transpose
7.3 mg/m³	All	100%	27
20 mg/m³	All except Latvia and the Netherlands	93%	25
36 mg/m³	All except Denmark, Latvia, Lithuania, the Netherlands, and Sweden	81%	22
73 mg/m³	None	0%	0

Source: Study team on the basis of information in section 3.1.

*Table 11-10 Member States **with BLVs** for 1,4 - dioxane higher than the envisaged policy options*

Level (HEAA in urine/g Creatinine, at the end of exposure or shift)	Member States who would need to introduce or alter legislation	% of MSs who would need to transpose	No of MS required to transpose
45 mg	All	100%	27
108 mg	All	100%	27
188 mg	All	100%	27
366 mg	All except Germany	96%	26

Source: Study team on the basis of information in section 3.1.

11.7 Summary of distribution of the impacts

The key points on the distribution of impacts are presented below:

- A comparison of costs and benefits to employers indicates that that RMM adjustment, monitoring costs and administrative burden over a period of 40 years are significantly higher than the value of benefits returned to an enterprise for the following OEL options – 7.3 mg/m^3, 20 mg/m^3, 36 mg/m^3. No costs or benefits are expected to be incurred by employers at 73 mg/m^3. The majority of costs are attributable to adjustment costs (first year and recurrent).

- Across all sectors, 95.1% are small companies, 3.5% are medium and 1.4% are large. When measured by the number of enterprises thus, the majority of enterprises that would need to comply with a new or stricter OEL would primarily consist of SMEs.

- Small and medium companies are more disadvantaged in comparison to large companies as they have comparatively higher costs relative to turnover at the most stringent policy option (0.14% and 0.12% of turnover on average).

- There are substantial benefits from avoided ill health at the most stringent policy option (€4,87 – 6.45 million), but there are also substantial costs related to unemployment that are higher (€13 million). Other policy options have neither costs due to unemployment nor benefits from avoided ill health.

- The transposition costs and benefits (avoided costs) for the public sector (relative to the baseline) indicate that the benefits outweigh the costs, with most benefits arising under the most stringent policy option.

- The introduction of the lowest OEL will affect all Member States, whereas the introduction of the least restrictive policy option will impact no Member States. Countries that have higher number of enterprises with workers exposed to 1,4 – dioxane (e.g. Italy, Germany, Spain, France and Greece) would be more affected.

12 SUMMARY OF ECONOMIC, SOCIAL AND ENVIRONMENTAL IMPACTS

This chapter comprises the following sections:

- Section 12.1: Economic impacts
- Section 12.2: Social impacts
- Section 12.3: Environmental impacts

12.1 Economic impacts

The economic impacts relate to the direct and indirect costs that fall on companies that need to comply with the policy options are shown in Table 12-1.

Table 12-1 Aggregated PV costs and benefits for companies discounted over 40 years by policy options, € million

Cost or benefit	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Cost	€ 124.55	€ 0.73	€ 0.66	€ 0.00
Benefit (avoided cost)	€ 1.58	€ 0.00	€ 0.00	€ 0.00

Source: Study team

The annualised compliance costs expressed as proportion of turnover are expected to be 0 or negligible under OEL levels of 20 mg/m³, 36 mg/m³ and 73 mg/m³. For an OEL of 7.3 mg/m³, compliance, monitoring and administrative costs amount to 0.1% of the turnover in the most affected sector (C20.1, C20.3 and C20.5 Chemicals).

No market effects are expected at OEL levels of 20 mg/m³, 36 mg/m³ and 73 mg/m³. An OEL of and 7.3 mg/m³ would have some impacts on the market due to the required adjustment costs and discontinuations (6 enterprises).

Existing national OELs range from 20 mg/m³ to 73 mg/m³. At OEL options of 20 mg/m³ and 7.3 mg/m³, there would be an increased level playing field ensuring that all workers across the EU are protected to the same degree and all companies have to provide a similar level of protection.

Annualised costs of implementing the relevant OELs as a percentage of R&D expenditure are expected to be 0.0025% or less, suggesting that no significant impact on innovation can be expected.

OELs in selected non-EU countries range from 10 mg/m³ to 73 mg/m³ (see Table 8-24). It thus cannot be ruled out that some non-EU companies would still be bound by less stringent limit values if the following 1,4-dioxane OEL policy options were adopted in the EU: 20 mg/m³, 36 mg/m³, and 73 mg/m³, meaning that they could benefit from a comparative advantage vis-à-vis the EU.

Including the costs of biomonitoring and the associated administrative costs results in the costs and benefits to companies set out below. However, Since the additional adjustment costs for companies and benefits from reduced ill health from adding a BLV to an OEL cannot be estimated with a sufficient degree of robustness, they are not included in the quantified impacts in the table below which provides an overview for the combined OEL and BLV options, taking into account the costs of biomonitoring in addition to the costs presented above for the OEL options alone.[44]

*Table 12-2 Aggregated PV costs and benefits for companies from **combined OEL and BLV options** discounted over 40 years by policy options, € million*

Cost or benefit	7.3 mg/m³ and 45 mg HEAA in urine/g Creatinine	20 mg/m³ and 108 mg HEAA in urine/g Creatinine	36 mg/m³ and 188 mg HEAA in urine/g Creatinine	73 mg/m³ and 366 mg HEAA in urine/g Creatinine
Cost	€ 248.1	€ 60.8	€ 12.6	€ 6.8
Benefit (avoided cost)	€ 1.58	€ 0.00	€ 0.00	€ 0.00

Source: Study team

12.2 Social impacts

The social impacts relate to the benefits and costs that fall on workers and public administrations, these are shown in the table below.

*Table 12-3 Aggregated PV costs and benefits for workers and public administrations discounted over 40 years by policy options, € millions (**OEL and quantified BLV costs**)*

Cost or benefit	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Workers				
Cost	€ 13	€ 0.0	€ 0.0	€ 0.0
Benefit (avoided cost) M1	€ 1.9	€ 0.0	€ 0.0	€ 0.0
Benefit (avoided cost) M2	€ 3.2	€ 0.0	€ 0.0	€ 0.0
Public administrations				
Cost (transposition of OELs)	€ 0.8	€ 0.8	€ 0.7	€ 0.0
Benefit (avoided cost of healthcare)	€ 2.0	€ 0.0	€ 0.0	€ 0.0
Benefit (avoided cost of setting new OELs)	€ 2.7	€ 1.8	€ 1.5	€ 1.4
Cost (transposition of BLVs)	€ 1.3	€ 1.3	€ 1.3	€ 1.3

[44] Although compliance costs for achieving the different BLV levels could be estimated on the basis of the corresponding OEL levels, it cannot be excluded that this approach would underestimate the costs required for additional reductions in dermal exposure. It cannot be excluded that the equation used in RAC (2022) to relate air exposure and HEAA in urine does not take sufficiently into account dermal intake. In situations where significant dermal exposure (or ingestion due to poor hygiene) occurs, complying with an OEL of 7.3 mg/m3, for example, does not guarantee that the level of HEAA in urine/g creatinine will be below 45 mg.

Cost or benefit	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Benefit (avoided cost of setting new BLVs)	€ 2.6	€ 2.6	€ 2.6	€ 2.6

Source: Study team

Notes: M1= Method 1, a methodology that relies on "willingness to pay" values

M2= Method 2, a methodology that relies on monetised avoided Disability Adjusted Life Years

For workers, the benefits (avoided costs of ill health) outweigh the social cost of unemployment due to company discontinuations. For the public authorities, the benefits (avoided cost of healthcare or setting new OELs) outweigh transposition costs.

12.3 Environmental impacts

1,4-dioxane is persistent/very persistent but does not meet the criteria for classification as bio-accumulative or toxic. The environmental concerns about 1,4-dioxane are largely tied to its releases into wastewater and its presence in drinking water.

There is no evidence suggesting that introducing a new OELs would have significant direct or indirect impacts on the environment or environmental legislation/targets.

13 LIMITATIONS & SENSITIVITY ANALYSIS

This chapter presents the limitations and uncertainties of this study, and comprises the following sections:

- Section 13.1: Overview of limitations and uncertainties
- Section 13.2: Key limitations and uncertainties

13.1 Overview of limitations and uncertainties

This section sets out the key limitations and uncertainties and considers their potential impact on the conclusions. These are summarised below and their significance for the results of this study are assessed. A more detailed assessment of some of these limitations and uncertainties is provided in the next sections.

Table 13-1 Overview of the key limitations/uncertainties and their significance

Limitation or uncertainty	Explanation	Estimates in this study are U (underestimates) or O (overestimates) * *Indicates U or O likely to be significant	
		Costs	Benefits
Uncertainties that are included in the sensitivity analysis			
Exposure concentrations	Limited exposure data are available. It is possible that the measurements reflect better practices. Particularly, in the sectors where 1,4-dioxane is generated as a by-products, occupational exposure measurements are not undertaken and limited data are available. This is a significant uncertainty. Sensitivity analysis has been modelled using REACH CSR data for most sectors.	U*	U*
Contribution of dermal exposure to total uptake	There is limited evidence base to assess the contribution of dermal exposure to the total uptake. A significant dermal uptake would mean that both the costs and the benefits could be underestimated.	U*	U*
Uncertainties that are not taken any further in the sensitivity analysis			
Definition of sectors	The literature mentions other potentially relevant sectors, such as optical lens production or painting restoration.	U	U
Additional health endpoints	A number of health endpoints could not be quantified.	Not relevant	U
Slope of ERRs/DRRs	There are uncertainties in the evidence available to develop the ERR and DRR. This uncertainty could apply either way. No other ERRs or DRRs are available.	Not relevant	O or U
Staff turnover	The staff turnover is assumed to be 5%, which leads to a complete change of staff over 20 years. Although staff turnover in a company may be higher (or lower) than this, some people may	Not relevant	U

Limitation or uncertainty	Explanation	Estimates in this study are U (under-estimates) or O (overestimates) * *Indicates U or O likely to be significant	
		Costs	Benefits
	stay in the same industry and continue to experience the same exposure concentrations.		
Future trends	Exposed workforce and concentrations are assumed to remain unchanged.	O or U	O or U
Discount rate	The estimates in this report have all been modelled using a static discount rate. A declining discount rate would increase both the costs and the benefits.	U	U
'Positive bias' in reported data	It is possible that there is some self-selection among companies that provided the data collected through consultation for this study, with worse-performing companies less likely to report their exposure concentrations.	U	U
Transitional period	Not considered	-	-

Note1: A declining discount rate will increase the costs, unless the recurrent costs are negative and greater than the first year costs

13.2 Key limitations and uncertainties

Sensitivity assessments have been done to test the assumptions included in the cost and benefit estimations. The effects of alternative scenarios for costs, benefits, discount rate and transitional periods are discussed below.

The alternative exposure concentrations (8-hour TWA) reported by companies without adjusting for RPE that were taken into account in the sensitivity analysis are shown below.

Table 13-2 Summary of exposure concentrations by sectors for 1,4-dioxane used for the calculation of costs and benefits as part of the sensitivity analysis – without adjustment for the use of RPE. All values in mg/m^3 8-hour TWA

Sector		Median	P75	P90	P95	Max
Part of C20.1	Manufacture of 1,4-dioxane	Significantly <7.3	Significantly <7.3	Significantly <7.3	Significantly <7.3	Significantly <7.3
C21.1 and C21.2	Pharmaceutical production (intentional use)	16.0	18.3	20.6	22.2	29.0
C20.1, C20.3	Industrial use as a solvent and generation as by-product in the chemicals sector	13.0	14.5	16.0	16.9	21.0

Sector		Median	P75	P90	P95	Max
and C20.5						
M72.1	Laboratories	1.4	1.4	1.4	1.4	1.4
C20.4 excl. C20.42	Surfactants - presence as a minor constituent/impurity in the production of deter-gents, soaps, etc.	10.0	11.0	11.9	12.5	15.0
C20.42	Cosmetics – generation as a by-product in the produc-tion of cosmetics	10.0	11.0	11.9	12.5	15.0

Source: Study team on basis of information presented in this section.

13.2.1 Values used in the benefits and costs models - sensitivity analysis

Same as for the calculation of both the benefits and costs models under the main scenario, the exposed workers or enterprises with exposed workers are split into five groups as shown in table below. The exposure level assumed to be experienced by this group is calculated as shown in Table 13-4.

Table 13-3 Calculation of exposure levels (inhalable) used in benefits and costs models – Sensitivity analysis

Percentiles	Proportion of workers or enterprises	Calculation for exposure level assumed for modelling
0 - 50	50%	50th percentile
51 - 75	25%	Mean of 50th and 75th percentiles
76 - 90	15%	Mean of 75th and 90th percentiles
91 - 95	5%	Mean of 90th and 95th percentiles
96 - 100	5%	Geometric mean of 95th and 100th percentiles

The values used in the benefit and cost models in the sensitivity analysis for the different concentration bands are given below for each of the sectors.

Table 13-4 Calculation of exposure levels (inhalable) used in benefits and costs models – Sensitivity analysis

Band	Sector	Exposure concentration (mg/m^3)	Range – low (mg/m^3)	Range – high (mg/m^3)	Calculation method
1	Sector 1 Manufacture of 1,4-dioxane	**0.0**	0.0	0.0	Calculation method: High
2	Sector 1 Manufacture of 1,4-dioxane	**0.0**	0.0	0.0	Calculation method: Arithmetic Mean

Band	Sector	Exposure concentration (mg/m³)	Range – low (mg/m³)	Range – high (mg/m³)	Calculation method
3	Sector 1 Manufacture of 1,4-dioxane	**0.0**	0.0	0.0	Calculation method: Arithmetic Mean
4	Sector 1 Manufacture of 1,4-dioxane	**0.0**	0.0	0.0	Calculation method: Arithmetic Mean
5	Sector 1 Manufacture of 1,4-dioxane	**0.0**	0.0	0.0	Calculation method: Geometric Mean (for the highest band)
1	Sector 2 (C21.1+C21.2): Pharmaceutical industry	**16.0**	0.0	16.0	Calculation method: High
2	Sector 2 (C21.1+C21.2): Pharmaceutical industry	**17.2**	16.0	18.3	Calculation method: Arithmetic Mean
3	Sector 2 (C21.1+C21.2): Pharmaceutical industry	**19.5**	18.3	20.6	Calculation method: Arithmetic Mean
4	Sector 2 (C21.1+C21.2): Pharmaceutical industry	**21.4**	20.6	22.2	Calculation method: Arithmetic Mean
5	Sector 2 (C21.1+C21.2): Pharmaceutical industry	**25.4**	22.2	29.0	Calculation method: Geometric Mean (for the highest band)
1	Sector 3 (C20.1, C20.3 and C20.5): Chemicals	**13.0**	0.0	13.0	Calculation method: High
2	Sector 3 (C20.1, C20.3 and C20.5): Chemicals	**13.8**	13.0	14.5	Calculation method: Arithmetic Mean
3	Sector 3 (C20.1, C20.3 and C20.5): Chemicals	**15.3**	14.5	16.0	Calculation method: Arithmetic Mean
4	Sector 3 (C20.1, C20.3 and C20.5): Chemicals	**16.5**	16.0	16.9	Calculation method: Arithmetic Mean
5	Sector 3 (C20.1, C20.3 and C20.5): Chemicals	**18.8**	16.9	21.0	Calculation method: Geometric Mean (for the highest band)
1	Sector 4 (M72.1) Laboratories	**1.4**	1.4	1.4	Calculation method: High
2	Sector 4 (M72.1) Laboratories	**1.4**	1.4	1.4	Calculation method: Arithmetic Mean
3	Sector 4 (M72.1) Laboratories	**1.4**	1.4	1.4	Calculation method: Arithmetic Mean

Band	Sector	Exposure concentration (mg/m^3)	Range – low (mg/m^3)	Range – high (mg/m^3)	Calculation method
4	Sector 4 (M72.1) Laboratories	**1.4**	1.4	1.4	Calculation method: Arithmetic Mean
5	Sector 4 (M72.1) Laboratories	**1.4**	1.4	1.4	Calculation method: Geometric Mean (for the highest band)
1	Sector 5 (C20.4 excl. C20.42) Surfactants	**10.0**	0.0	10.0	Calculation method: High
2	Sector 5 (C20.4 excl. C20.42) Surfactants	**10.5**	10.0	11.0	Calculation method: Arithmetic Mean
3	Sector 5 (C20.4 excl. C20.42) Surfactants	**11.5**	11.0	11.9	Calculation method: Arithmetic Mean
4	Sector 5 (C20.4 excl. C20.42) Surfactants	**12.2**	11.9	12.5	Calculation method: Arithmetic Mean
5	Sector 5 (C20.4 excl. C20.42) Surfactants	**13.7**	12.5	15.0	Calculation method: Geometric Mean (for the highest band)
1	Sector 6 (C20.42) Cosmetics	**10.0**	0.0	10.0	Calculation method: High
2	Sector 6 (C20.42) Cosmetics	**10.5**	10.0	11.0	Calculation method: Arithmetic Mean
3	Sector 6 (C20.42) Cosmetics	**11.5**	11.0	11.9	Calculation method: Arithmetic Mean
4	Sector 6 (C20.42) Cosmetics	**12.2**	11.9	12.5	Calculation method: Arithmetic Mean
5	Sector 6 (C20.42) Cosmetics	**13.7**	12.5	15.0	Calculation method: Geometric Mean (for the highest band)

Source: Study team on the basis of the data presented in this report.

13.2.2 Cost estimates and sensitivity scenarios

The total RMM and discontinuation costs are estimated below for the different OEL options using the sensitivity scenario set out above (the values estimated using the core assumptions in Section 7 are in brackets). Please note that the assumptions about RMMs in place used for core modelling were altered for the scenario estimated below. The CSR exposure estimates are presented by PROC code, and the study team derived a distribution of exposure concentrations based on each PROC code being an exposure concentration data point (e.g. median, maximum concentrations were taken from the data for the different PROC codes, averaged across all registrants). However, only three of the up to 11 PROC codes relate to fully or partially closed systems. As a result, the RMMs currently in place were modelled differently to the core scenario: in the core scenario presented in Section 7, 55% of companies in the pharmaceutical and chemical industries are expected to have a closed system in place, with a further 20% having a partial enclosure in place. However, in the sensitivity analysis modelling, these percentages have been reversed, with 55% of companies modelled to have a partial enclosure in place and 20% companies having a closed system in place.

Table 13-5 Adjustment costs for the different OEL options by sector (PV sum of total RMM and discontinuation costs over 40 years) – SENSITIVITY ANALYSIS USING REACH CSR DATA FOR MOST SECTORS

Sector		**Total PV cost by OEL option in PV40 €**			
		73 mg/m³	**36 mg/m³**	**20 mg/m³**	**7.3 mg/m³**
Part of C20.1	Manufacture of 1,4-dioxane	0 (0)	0 (0)	0 (0)	0 (0)
C21.1 and C21.2	Pharmaceutical production (intentional use)	0 (0)	0 (0)	-€1 million (0)	€784.5 million (€0.9 million)
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	0 (0)	0 (0)	0 (0)	€109.5 million (€120.8 million)
M72.1	Laboratories	0 (0)	0 (0)	0 (0)	€0 (-€1.1 million)
C20.4 excl. C20.42	Surfactants – generation as a by-product in the production of detergents, soaps, etc.	0 (0)	0 (0)	0 (0)	€7.6 million (€0.4 million)
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	0 (0)	0 (0)	0 (0)	€10.8 million (€0.5 million)
Total		**0 (0)**	**0 (0)**	**-€1 million (0)**	**€912 million (€121 million)**

Source: Study team.

The total costs in the sensitivity scenario are higher than in the scenario modelled in Section 7 (€912 million compared with €121 million over 40 years), with the vast majority of the cost difference relating to the pharmaceutical sector. Although the CSRs do not provide data for the two downstream sectors considered in this study where 1,4-dioxane is generated as a by-product, there are some data for a sector in which 1,4-dioxane has no technical function. These data have been used for modelling the impacts in the surfactants and cosmetics sectors. Given the uncertainty about the impacts in these sectors, the (higher) estimates in the table above should be carefully considered.

13.2.3 Benefit assessment and sensitivity scenarios

The benefits from avoided ill health estimated using the sensitivity assumptions set out above are presented for the three relevant endpoints below. The values estimated under the core assumptions in Section 6 are presented in brackets. As no benefits are likely to arise from avoided ill health under the two least stringent policy options, only the results for the two most stringent policy options – i.e. 7.3 mg/m³ and 20 mg/m³, are included the tables below.

Table 13-6 METHOD 1: Benefits from avoided ill health (OEL options, relative to the baseline) SENSITIVITY ANALYSIS USING REACH CSR DATA FOR MOST SECTORS

OEL option	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
20 mg/m³ (5.5 ppm)	€613,027 (€0)	€583,408 (€0)	€5,120,886 (€0)	**€6,317,320 (€0)**
7.3 mg/m³ (2 ppm)	€4,684,694 (€631,096)	€4,458,056 (€600,517)	€35,552,009 (€4,195,687)	**€44,694,758 (€5,427,300)**

Source: Study team.

The Method 1 benefits at different OEL options, split by sector are presented in table below.

Table 13-7 METHOD 1: Benefits from avoided ill health by sector by OEL options, relative to the baseline SENSITIVITY ANALYSIS USING REACH CSR DATA FOR MOST SECTORS

Sector	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
20 mg/m³ (5.5 ppm)				
Part of C20.1	€0 (€0)	€0 (€0)	€0 (€0)	**€0 (€0)**
C21.1 and C21.2	€613,027 (€0)	€583,408 (€0)	€5,120,886 (€0)	**€6,317,320 (€0)**
C20.1, C20.3 and C20.5	€0 (€0)	€0 (€0)	€0 (€0)	**€0 (€0)**
M72.1	€0 (€0)	€0 (€0)	€0 (€0)	**€0 (€0)**
C20.4 excl. C20.42	€0 (€0)	€0 (€0)	€0 (€0)	**€0 (€0)**
C20.42	€0 (€0)	€0 (€0)	€0 (€0)	**€0 (€0)**
7.3 mg/m³ (2 ppm)				
Part of C20.1	€0 (€0)	€0 (€0)	€0 (€0)	**€0 (€0)**
C21.1 and C21.2	€3,592,020 (€21,447)	€3,418,282 (€20,401)	€27,729,479 (€51,687)	**€34,739,781 (€93,535)**
C20.1, C20.3 and C20.5	€849,757 (€595,458)	€808,633 (€566,612)	€6,271,356 (€4,047,838)	**€7,929,746 (€5,209,910)**

Sector	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
M72.1	€0 (€0)	€0 (€0)	€0 (€0)	**€0 (€0)**
C20.4 excl. C20.42	€88,684 (€6,120)	€84,385 (€5,823)	€566,302 (€41,348)	**€739,370 (€53,252)**
C20.42	€154,233 (€10,643)	€146,756 (€10,127)	€984,872 (€71,911)	**€1,285,861 (€92,681)**

Source: Study team.

Method 2 relies on monetised DALYs, with the results presented in table below. The workforce turnover is 5% per year and a static discount rate of 3% is used.

Table 13-8 METHOD 2: Benefits from avoided ill health (OEL options, relative to the baseline) SENSITIVITY ANALYSIS USING REACH CSR DATA FOR MOST SECTORS

OEL option (Inhalable)	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
20 mg/m^3 (5.5 ppm)	€435,460 (€0)	€832,944 (€0)	€7,189322 (€0)	**€8,457,727 (€0)**
7.3 mg/m^3 (2 ppm)	€3,327,748 (€421,991)	€6,364,868 (€807,062)	€49,912,232 (€5,544,768)	**€59,604,848 (€6,773,820)**

Source: Study team.

The Method 2 benefits at different OEL options, split by sector are presented below.

Table 13-9 METHOD 2: Benefits from avoided ill health by sector by OEL options, relative to the baseline SENSITIVITY ANALYSIS USING REACH CSR DATA FOR MOST SECTORS

Sector	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
20 mg/m^3 (5.5 ppm)				
Part of C20.1	€ 0 (€ 0)	€ 0 (€ 0)	€ 0 (€ 0)	**€ 0 (€ 0)**
C21.1 and C21.2	€ 435,460 (€ 0)	€ 832,944 (€ 0)	€ 7,189,322 (€ 0)	**€ 8,457,727 (€ 0)**
C20.1, C20.3 and C20.5	€ 0 (€ 0)	€ 0 (€ 0)	€ 0 (€ 0)	**€ 0 (€ 0)**
M72.1	€ 0 (€ 0)	€ 0 (€ 0)	€ 0 (€ 0)	**€ 0 (€ 0)**
C20.4 excl. C20.42	€ 0 (€ 0)	€ 0 (€ 0)	€ 0 (€ 0)	**€ 0 (€ 0)**
C20.42	€ 0	€ 0	€ 0	**€ 0**

Sector	Kidney effects	Liver effects	Local irritation in the nasal cavity	Total
	(€ 0)	(€ 0)	(€ 0)	**(€ 0)**
7.3 mg/m³ (2 ppm)				
Part of C20.1	€0 (€0)	€0 (€0)	€0 (€0)	**€0 (€0)**
C21.1 and C21.2	€2,551,573 (€14,283)	€4,880,359 (€27,306)	€38,930,013 (€68,030)	**€46,361,946 (€109,618)**
C20.1, C20.3 and C20.5	€603,621 (€396,544)	€1,154,503 (€758,406)	€8,804,492 (€5,327,670)	**€10,562,616 (€6,482,619)**
M72.1	€0 (€0)	€0 (€0)	€0 (€0)	**€0 (€0)**
C20.4 excl. C20.42	€62,996 (€4,075)	€120,478 (€7,794)	€795,043 (€54,423)	**€978,517 (€66,292)**
C20.42	€109,558 (€7,088)	€209,527 (€13,556)	€1,382,683 (€94,647)	**€1,701,769 (€115,291)**

Source: Study team.

The total benefits split between the avoided costs for workers & families (M1 & M2), avoided costs for employers and avoided costs for public authorities are presented below for the different OEL options using the sensitivity assumptions set out in Section 13.2.1 (the values estimated using the core assumptions in Section 6 are in brackets).

The total benefits in the sensitivity scenario are higher than in the scenario modelled in Section 6 (€44.7 - €59.6 million compared with € 4.9 - €6.5 million over 40 years at 7.3 mg/m³ and € 6.3-€8.5 million compared with €0 million over 40 years at 20 mg/m³). The vast majority of the benefit difference relates to the pharmaceutical sector.

Table 13-10 Overview of benefits (total for all provisions) over 40 years (without transition measures) SENSITIVITY ANALYSIS USING REACH CSR DATA FOR MOST SECTORS (€ millions)

Description		7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Health and safety	Avoided costs for workers & families M1	€16.9 (€1.9)	€2.4 (€0)	€0 (€0)	€0 (€0)
	Avoided costs for workers & families M2	€29.5 (€3.2)	€4.2 (€0)	€0 (€0)	€0 (€0)
	Avoided costs for employers	12.0 (€1.6)	€1.7 (€0)	€0 (€0)	€0 (€0)

Description		7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
	Avoided costs for public administrations	18.2 (€2.0)	€2.6 (€0)	€0 (€0)	€0 (€0)
TOTAL		**€44.7 – €59.6 (M1 – M2)**	**€6.3 – €8.5 (M1 – M2)**	**€0**	**€0**

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together). Totals may not add up due to rounding.

Source: Study team.

13.2.4 Discount rate

None of the effects modelled in this report associated with 1,4-dioxane have a latency and hence the sensitivity analysis does not include variations in the discount rate.

13.2.5 Transitional periods

A transitional period has not been proposed by ACSH.

13.2.6 Combined effect of alternative assumptions

Using alternative exposure data results in an increase in the estimated costs for an OEL of 7.3 mg/m³. However, the majority of the cost increase relates to the pharmaceutical sector and this section discusses the reasons why the cost increase in the pharmaceutical sector may be an over-estimate.

13.2.7 Contribution of dermal exposure to combined uptake

The BLV policy options were chosen as corresponding to the OEL policy options, calculated using a function[45] derived by Eckert, Hartwig and Drexler (2020) reported in RAC (2022). However, the function developed by Eckert, Hartwig and Drexler (2020) relates air exposure and HEAA in urine[46] and, consequently, in situations where significant dermal exposure (or ingestion due to poor hygiene) occurs, complying with an OEL of 7.3 mg/m³ does not guarantee that the level of HEAA in urine/g creatinine will be below 45 mg.

REACH registration CSRs provide modelled values for 'dermal exposure' and 'combined routes' which appear to provide an indication of the contribution of the dermal route to the total burden. This differs by CSR and PROC within a range between 2% and 97% (the average of all values across all PROCs and CSRs is 40%). However, it can be argued that modelled estimates produced by common modelling tools under REACH should not be taken as estimates of real exposure since they start from high conservative estimates and which are then refined in a stepwise approach until a point where exposure is below the Derived No-Effect Level (DNEL). Consequently, using the quantitative outcome from such a modelling exercise may not be suitable for the purposes of the cost-benefit analysis in this study. However, two illustrative scenarios are provided below.

After excluding PROC 1 'Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions' and PROCs 8a, 8b and 9 (transfer

[45] Based on a total of 27 subjects across 3 studies.

[46] In one of the three studies underlying this function (Young 1976), workers at a chemical plant were tested. The extent of dermal exposure is not clear. The other two studies involved exposure by inhalation of volunteers.

tasks)[47], the average contribution of dermal to combined exposure across all the remaining PROCs across all REACH registration CSRs is 22%. Although, as noted above, using REACH registration data for the purposes of cost-benefit calculation in this study is problematic, several illustrative scenarios are provided below.
The cost model used in this study focuses on inhalation and does not include the cost of PPE for reducing dermal exposure but includes costs for additional Occupational Hygiene (OH) measures. Combining an assumption that dermal exposure contributes 22% to the total burden with the exposure concentrations in the core scenario suggests that 181 small, 15 medium and 6 large companies may currently be exceeding a BLV of 45 mg HEAA in urine/g creatinine. Applying the OH unit costs in the model to these companies, and assuming that these costs would be required to reduce dermal exposure in addition to the cost of reducing exposure by inhalation, suggests an additional PV40 cost **of €209 million** (in addition to the €121 million for reducing air exposure).

In a theoretical scenario where air concentrations are reduced below the levels required to comply with an OEL of 7.3 mg/m^3 by another 22% results in a total cost of €535 million (PV40) (less the €121 million for 7.3 mg/m^3 so the additional PV40 cost is about **€ 414 million**).

In a theoretical scenario where air concentrations are reduced below the levels required to comply with an OEL of 7.3 mg/m^3 by another 10% results in a total cost of €270 million (PV40) (less the €121 million for 7.3 mg/m^3 so the additional PV40 cost is about **€ 149 million**).

[47] PROC 8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
PROC 8b Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
PROC 9Transfer of substance or mixture into small containers (dedicated filling line, including weighing)

14 IMPACTS OF THE POLICY OPTIONS

The impacts of the policy options are summarised in the following sections:

- Section 14.1: Cost-benefit assessment (CBA)
- Section 14.2: Multi-criteria analysis (MCA)
- Section 14.3: Practical implications of establishing an OEL
- Section 14.4: Compliance with the subsidiarity and proportionality principles
- Section 14.5: Highlighted issues
- Section 14.6: Summary for the option suggested by the ACSH

This chapter summarises the estimates presented in the previous chapters by means of a Cost-benefit assessment (CBA) and a Multi-criteria (MCA) analyses. All the costs and benefits presented in this chapter are Present value (PV) over 40 years and additional to the baseline scenario.

14.1 Cost-benefit assessment (CBA)

14.1.1 Overview of the benefits for the policy options

The benefits (relative to the baseline) estimated in this report for the different policy options are summarised in the tables below. The benefits include the direct, the indirect and the intangible benefits as described in Section 6.

Table 14-1 Overview of the benefits (PV cost savings due to reduced ill health and avoided costs) per OEL option

Impact	Stakeholders affected	Policy options			
		7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Direct benefits – improved well-being – health					
Reduced cases of ill health (kidney effects)	Workers & families	500	0	0	0
Reduced cases of ill health (liver effects)	Workers & families	630	0	0	0
Reduced cases of ill health (local irritation in the nasal cavity)	Workers & families	4,400	0	0	0
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€ 2 - 3 million	€ 0 - 0 million	€ 0 - 0 million	€ 0 - 0 million
Avoided costs	Companies	€ 1.6	€ 0	€ 0	€ 0
Avoided costs	Public sector	€ 2	€ 0	€ 0	€ 0
EU policy agenda	All	Improvements in workers fundamental rights and contribution towards Green Deal: Chemical Strategy towards a toxic-free environment			
Direct benefits – improved well-being - environmental					
Environmental releases	All	Potential for reduced air emissions, unclear whether emissions into wastewater would increase or decrease			
Direct benefits – market efficiency					
Level playing field	Companies	The ratio between the maximum and minimum national OEL is currently 3.65. The ratio between the maximum/minimum STEL is 2.08. A reduction in the OEL and STEL is likely to improve the level playing field in the internal market.			

Impact	Stakeholders affected	Policy options			
		7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Indirect benefits					
Administrative simplification	Companies	Should all Member States have a harmonised OEL this would reduce the administrative burden for enterprises with operations across multiple Member States. However, the majority of enterprises under review are small and are unlikely to have multinational operations and be unaffected by this simplification.			
Synergy	Companies	Synergies in terms of exposure reduction for other chemical substances used in production sectors may occur. The specific substances will vary between the sectors. The level of synergy to be harnessed will also depend on the RMMs applied in each enterprise.			
Corporate Social Responsibility	Companies	A limit value may make work with 1,4-dioxane to be perceived as a less risky line of work. This is particularly significant given the profile given to 1,4-dioxane by the recent reclassification of 1,4-dioxane as Carcinogenic 1B. As a result of such an improvement in the public image, companies may find it easier to recruit and retain staff, reducing the cost of recruitment and increasing the productivity of workers.			
Avoided cost of setting OEL	Public sector	€ 2.7	€ 1.8	€ 1.5	€ 1.4

Source: Study team. Note: Totals may not sum due to rounding.

14.1.2 Overview of the costs for the policy options

The estimated direct and indirect costs are presented in Table 14-2. The costs are for the present value (PV) over 40 years with a static discount rate of 3%.

Table 14-2 Overview of the costs of OEL options (incremental to the baseline, PV in € million over 40 years)

Impact	Stakeholders affected	Policy options			
		7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Direct costs – adjustment					

Impact	Stakeholders affected	Policy options			
		7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Risk management measures (first year and recurrent) and discontinuation costs	Companies	€ 120	€ 0	€ 0	€ 0
Monitoring (sampling and analysis)	Companies	€ 2.4	€ 0.55	€ 0.49	€ 0
Direct costs – administrative					
Administrative burden	Companies	€ 0.74	€ 0.21	€ 0.19	€ 0
Direct compliance costs – total					
Adjustment, monitoring and administrative burden costs per company	Companies	€ 6.2	€ 0.84	€ 0.76	€ 0
Direct costs - enforcement costs					
Transposition costs	Public sector	€ 0.81	€ 0.78	€ 0.66	€ 0
Enforcement costs except transposition	Public sector				
Indirect costs – other					
Firms exiting the market - No. of company closures	Companies	6	-	-	-
Employment – Jobs lost	Workers & families	140	-	-	-
Employment – Social cost	Workers & families	€ 13	€ 0	€ 0	€ 0
International competitiveness	Companies	Some non-EU countries would have less stringent OELs			
Consumers	Consumers	No significant impacts expected			

Impact	Stakeholders affected	Policy options			
		7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Internal market Lowest to highest OEL	Companies	7.3 mg/m³-7.3 mg/m³	20 mg/m³-20 mg/m³	20 mg/m³-36 mg/m³	20 mg/m³-73 mg/m³
Specific MSs/regions - MSs that would have to change OELs	Public sector	27	25	22	
Regulation	Companies	A REACH restriction on use of 1,4-dioxane in surfactants is currently under consideration			

Source: Study team. Note: Totals may not sum due to rounding.

14.1.3 Impact of different timescales for costs and benefits

An EU-wide OEL or BLV will not produce benefits or costs until it enters into force. Prior to this date, benefits cannot be actualised as there will be no changes to the regulation, however during this period some companies may opt to implement lower OELs/BLVs pre-emptively. These companies are not considered in this section as it is not possible to identify or quantify them.

The benefits of the proposed OEL/BLV start to occur as soon as compliance is made mandatory with benefits continuing annually as outlined in section 6. However, some RMMs require substantial upfront implementation costs which are modelled on a first- and twenty-year basis. For example, the implementation of local extraction ventilation has an anticipated lifespan of 20 years requiring upfront costs at the first year (year of regulatory change), and, on average, twenty years later. This is also true for all extraction and ventilation RMMs. These RMMs also incur a continued operational cost each year (due to, for example, energy, filters, maintenance, etc.).

In contrast RPE and occupation health measures do not require upfront capital expenditure, however, they have a substantial recurring annual cost in terms of RPE parts (filters), upkeep and staff training.

Due to the fact that none of the benefits from reduced ill health estimated in this study have a latency, the savings from avoided ill health are expected to be distributed equally over the assessment period.

Given that some costs will be up-front, whilst the benefits are distributed equally over the assessment period, the benefit-cost ratio is likely to increase over the assessment period. Truncating the assessment period at less than 20 years would result in the benefit-cost ratio underestimating the full benefits.

14.1.4 CBA for the policy options

The overall costs and benefits of the OEL policy options are shown in Table 14-3.

Table 14-3 Summary of monetised costs and benefits of the OEL options (static discount rate, additional to the baseline)

Policy option	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Total benefits M1	€ 5.4	€ 0	€ 0	€ 0
Total benefits M2	€ 6.8	€ 0	€ 0	€ 0
Total costs	€ 140	-€ 0.3	-€ 0.1	-€ 1.4
Cost benefit ratio M1	25	n/a	n/a	n/a
Cost benefit ratio M2	20	n/a	n/a	n/a

*Notes: *Values relate to method 1 - method 2. n/a = not applicable, division by zero. Totals may not sum due to rounding.*

Source: Study team.

The overall costs and benefits of the combined OEL and BLV policy options are shown in Table 14-4. Since the additional adjustment costs for companies and benefits from reduced ill health from adding a BLV to an OEL cannot be estimated with a sufficient degree of robustness, they are not included in the quantified impacts in the table below which provides a CBA for combined OEL and BLV options, taking into account the costs of biomonitoring in addition to the costs presented above in the CBA for the OEL options.[48]

*Table 14-4 Summary of monetised costs and benefits of **combined OELs and BLVs** (static discount rate, additional to the baseline)*

Policy option	7.3 mg/m³ and 45 mg HEAA in urine/g Creatinine	20 mg/m³ and 108 mg HEAA in urine/g Creatinine	36 mg/m³ and 188 mg HEAA in urine/g Creatinine	73 mg/m³ and 366 mg HEAA in urine/g Creatinine
Total benefits M1	€ 5.4*	€ 0*	€ 0*	€ 0*
Total benefits M2	€ 6.8*	€ 0*	€ 0*	€ 0*
Total costs	€ 260*	€ 58*	€ 10*	€ 4*
Cost benefit ratio M1	47*	n/a	n/a	n/a
Cost benefit ratio M2	38*	n/a	n/a	n/a

*Notes: Values relate to method 1 - method 2. n/a = not applicable, division by zero. * For the BLV component, only partial costs and benefits have been included in the calculation and the totals do not include the adjustment costs and potential health savings additional to the OEL. Totals may not sum due to rounding.*

Source: Study team

[48] Although compliance costs for achieving the different BLV levels could be estimated on the basis of the corresponding OEL levels, it cannot be excluded that this approach would underestimate the costs required for additional reductions in dermal exposure. It cannot be excluded that the equation used in RAC (2022) to relate air exposure and HEAA in urine does not take sufficiently into account dermal intake. In situations where significant dermal exposure (or ingestion due to poor hygiene) occurs, complying with an OEL of 7.3 mg/m3, for example, does not guarantee that the level of HEAA in urine/g creatinine will be below 45 mg.

14.2 Multi-criteria analysis (MCA)

Table 14-5 summarises both the monetised and qualitative impacts.

The MCA includes the monetised health benefits and the quantifying compliance costs. Other effects including market effects are described only qualitatively.

The sensitivity assessment presented in the previous section indicates the uncertainty related to the monetised and quantified values. The sensitivity assessment points to the fact that benefits and costs could be of the same order of magnitude, the number presented below suggests that costs exceed benefits.

Table 14-5 Multi-criteria analysis (all impacts over 40 years and additional to the baseline) per OEL option (millions)

Impact	Stakeholders affected	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Direct costs – adjustment					
Risk management measures - first year	Companies	€ 53	€ 0	€ 0	€ 0
Risk management measures – recurrent	Companies	-€ 34	€ 0	€ 0	€ 0
Risk management measures - discontin-uation	Companies	€ 102	€ 0	€ 0	€ 0
Risk management measures total	Companies	€ 120	€ 0	€ 0	€ 0
Risk management measures total per company	Companies	€ 0.067	€ 0	€ 0	€ 0
Monitoring (sampling and analysis)	Companies	€ 2.4	€ 0.55	€ 0.49	€ 0
Direct costs - administrative					
Administration burden	Companies	€ 0.74	€ 0.21	€ 0.19	€ 0
Direct costs – total compliance					
Adjustment, monitoring and administra-tion burden costs	Companies	€ 130	€0.76	€ 0.68	€ 0
Adjustment, monitoring and administra-tion burden costs per company	Companies	€ 0.07	€ 0.0004	€ 0.0004	€ 0
Direct costs - enforcement costs					

Impact	Stakeholders affected	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Transposition costs	Public sector	€ 0.81	€ 0.78	€ 0.66	€ 0
Enforcement costs except transposition	Public sector	Enforcement costs may arise as a result of ensuring compliance with new OELs however these costs are not estimated as they are specific to Member States individual inspection regime.			
Indirect costs – other					
Firms discontinuing at least a part of their business - No. of company closures	Companies	6.3	0	0	0
Firms discontinuing at least a part of their business - %	Companies	0.4%	0%	0%	0%
Total compliance costs as % of turnover over 40 years (including discontinuations)	Companies	0.8%	0.01%	0%	0%
First year compliance costs as % of annual turnover (excluding discontinuations)	Companies	Up to 14.3% (C20.1, C20.3 and C20.5 chemicals - small enterprises)	Up to 0.06% (M72.1 laboratories - small enterprises)	Up to 0.06% (M72.1 laboratories - small enterprises)	0%
Employment – Jobs lost	Workers & families	140	0	0	0
Employment – Social cost	Workers & families	€ 13	€ 0	€ 0	€ 0
International competitiveness	Companies	Some non-EU countries would have less stringent OELs		No impact expected	
Consumers	Consumers	No significant impact	No significant impact	No impact	No impact
Internal market Lowest to highest OEL	Companies	7.3 mg/m³-7.3 mg/m³	20 mg/m³-20 mg/m³	20 mg/m³-36 mg/m³	20 mg/m³-73 mg/m³

Impact	Stakeholders affected	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Specific MSs/regions - MSs that would have to change OELs	Public sector	27	25	22	0
Regulation	Companies	A REACH restriction on use of 1,4-dioxane in surfactants is currently under consideration			
Direct benefits – improved well-being - health					
Reduced cases of ill health (kidney effects)	Workers & families	500	0	0	0
Reduced cases of ill health (liver effects)	Workers & families	630	0	0	0
Reduced cases of ill health (local irritation in the nasal cavity)	Workers & families	4,400	0	0	0
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€ 2 - 3 million	€ 0 - 0 million	€ 0 - 0 million	€ 0 - 0 million
Direct benefits – improved well-being - safety					
Avoided costs	Companies	€ 1.6	€ 0	€ 0	€ 0
Avoided costs	Public sector	€ 2	€ 0	€ 0	€ 0
EU policy agenda	All	Improvements in workers fundamental rights and contribution towards Green Deal: Chemical Strategy towards a toxic-free environment			
Direct benefits – improved well-being - environmental					
Environmental releases	All	Potentially, a reduction in emissions into the air but unclear impact on emissions to water		No impact	No impact

Impact	Stakeholders affected	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Direct benefits – market efficiency					
Level playing field	Companies	The ratio between the maximum and minimum national OEL is currently 3.65. The ratio between the maximum/minimum STEL is 2.08. A reduction in the OEL and STEL is likely to improve the level playing field in the internal market.			No impact
Indirect benefits					
Administrative simplification	Companies	Should all Member States have a harmonised OEL this would reduce the administrative burden for enterprises with operations across multiple Member States. However, the majority of enterprises under review are small and are unlikely to have multinational operations and be unaffected by this simplification.			
Synergy	Companies	Synergies in terms of exposure reduction for other chemical substances used in production sectors may occur. The specific substances will vary between the sectors. The level of synergy to be harnessed will also depend on the RMMs applied in each enterprise.			
Corporate Social Responsibility	Companies	Work with 1,4-dioxane may be less perceived as a risky line of work associated with health issues, in particular given the recent reclassification of 1,4-dioxane as Carcinogenic 1B. As a result of such an improvement in the public image, companies may find it easier to recruit and retain staff, reducing the cost of recruitment and increasing the productivity of workers.			
Avoided cost of setting OEL	Public sector	€ 2.7	€ 1.8	€ 1.5	€ 1.4
Other impacts					
Recycling – loss of business	Recycling companies	No impacts expected			
Impacts on fundamental rights	All	Improved occupational health			
Impacts on digitalisation	Companies	No impact expected.			

Impact	Stakeholders affected	7.3 mg/m³	20 mg/m³	36 mg/m³	73 mg/m³
Contributions to the UN sustainable development goals	All	Potential for reduced emissions into the air but it is unclear whether this would not increase emissions into wastewater.			

Source: Study team. Note: Totals may not sum due to rounding.

No data are available for the costs of compliance with the STEL options. In the absence of such data, it can be assumed that compliance with the OEL option would also mean that the relevant companies would comply with a STEL at a higher level. The ratios between the STELs and OELs currently in place in the Member States that have both an OEL and a STEL are summarised below.

Table 14-6 STEL/OEL factors (rounded)

Member State(s) or source	STEL/OEL ratio
AT, CZ, DE, DK, FR, SI	2
LT, SE	3
FI	4
RAC opinion	10

Source: Calculated from information in Table 3-1

Although peak exposures may be significantly higher than the 8-hour TWA, the fact that several Member States have STELs at 2 to 4 times the value of the OEL lends some support to the contention that compliance with an OEL of 7.3 mg/m^3 is likely to ensure compliance with a STEL at ten times this value, i.e. 73 mg/m^3. This would mean that no additional costs would be expected from complementing an OEL of 7.3 mg/m^3 with one of the STELs considered in this study, with the exception of additional measurement costs in cases where companies are particularly concerned about specific high-exposure activities.

Although adjustment costs for achieving the different BLV levels could be estimated on the basis of the corresponding OEL levels, it is likely that the equation used in RAC (2022) takes no (or limited) dermal intake into account. Should there be no dermal uptake of 1,4-dioxane, the costs of RMMs required to comply with a BLV would be the same as those of the corresponding OEL levels as determined by the equation in RAC (2022).

Any kind of direct contact may lead to dermal exposure: splashes, touching contaminated objects or surfaces. High vapour pressure of 1,4-dioxane leads to reduced potential to come into contact with contaminated surfaces/objects and also leads to reduced potential for skin exposure during removal of gloves. Where a BLV is exceeded, it may be because of inhalation and/or dermal exposure. Gloves plus potentially other protective PPE such as clothing, aprons, has the potential to reduce dermal exposure to negligible levels, if properly used. These additional costs cannot be quantified.

As a result, it is expected that costs in addition to the costs of reducing air concentrations to comply with the OEL may not be sufficient to comply with a corresponding BLV and additional costs may be incurred. In addition, the costs of biomonitoring are estimated to reach €122.87 million over 40 years for the policy option of 45 mg HEAA in urine /g creatinine and €60.09 million, €11.88 million, and €6.75 million for the policy options of 108, 188 and 366 mg HEAA in urine /g creatinine, respectively.

If a worker complies with a BLV of 45 mg HEAA in urine/g creatinine, then the reduction in ill health will be greater than for an OEL of 7.3 mg/m^3. For irritation in the nasal cavity, it is possible that there would be no additional reduction but an additional reduction can be expected for kidney and liver effects. However, there is insufficient information to quantify these additional reductions.

Since the additional adjustment costs for companies and benefits from reduced ill health from adding a BLV to an OEL cannot be estimated with a sufficient degree of robustness, they are not included in the quantified impacts in the table below which provides an MCA for combined OEL and BLV options, taking into account the costs of biomonitoring in addition to the costs presented above in the MCA for the OEL options.[49]

[49] Although compliance costs for achieving the different BLV levels could be estimated on the basis of the corresponding OEL levels, it cannot be excluded that this approach would underestimate the costs required for additional reductions in dermal exposure. It cannot be excluded that the equation used in RAC (2022) to relate air exposure and HEAA in urine does not take sufficiently into account dermal intake. In situations where significant dermal exposure (or ingestion due to poor hygiene) occurs, complying with an OEL of 7.3 mg/m3, for example, does not guarantee that the level of HEAA in urine/g creatinine will be below 45 mg.

Table 14-7 Multi-criteria analysis (all impacts over 40 years and additional to the baseline) per ***combined OEL and BLV option*** *(millions). Note: * For the BLV component, only partial costs and benefits have been included in the calculation and the totals do not include the adjustment costs and potential health savings additional to the OEL.*

Impact	Stakeholders affected	7.3 mg/m³ and 45 mg HEAA in urine/g Creatinine	20 mg/m³ and 108 mg HEAA in urine/g Creatinine	36 mg/m³ and 188 mg HEAA in urine/g Creatinine	73 mg/m³ and 366 mg HEAA in urine/g Creatinine
Direct costs – adjustment					
Risk management measures - first year*	Companies	€ 53	€ 0	€ 0	€ 0
Risk management measures – recurrent*	Companies	-€ 34	€ 0	€ 0	€ 0
Risk management measures - discontinuation	Companies	€ 102	€ 0	€ 0	€ 0
Risk management measures total*	Companies	€ 120	€ 0	€ 0	€ 0
Risk management measures total per company*	Companies	€ 0.067	€ 0	€ 0	€ 0
Monitoring (sampling and analysis – air and biomonitoring)	Companies	€ 120	€ 57	€ 11	€ 5.7
Direct costs - administrative					
Administration burden	Companies	€ 7.9	€ 4	€ 1.3	€ 1
Direct costs – total compliance					
Adjustment, monitoring and administration burden costs	Companies	€ 250	€ 61	€ 13	€ 6.8

Impact	Stakeholders affected	7.3 mg/m³ and 45 mg HEAA in urine/g Creatinine	20 mg/m³ and 108 mg HEAA in urine/g Creatinine	36 mg/m³ and 188 mg HEAA in urine/g Creatinine	73 mg/m³ and 366 mg HEAA in urine/g Creatinine
Adjustment, monitoring and administration burden costs per company	Companies	€ 0.14	€ 0.034	€ 0.007	€ 0.004
Direct costs - enforcement costs					
Transposition costs – OEL and BLV	Public sector	€ 2.1	€ 2.1	€ 2	€ 1.3
Enforcement costs except transposition	Public sector	Enforcement costs may arise as a result of ensuring compliance with new OELs and BLVs however these costs are not estimated as they are specific to Member States individual inspection regime.			
Indirect costs – other					
Firms discontinuing at least a part of their business - No. of company closures	Companies	6.3	0	0	0
Firms discontinuing at least a part of their business - %	Companies	0.4%	0%	0%	0%
Total compliance costs as % of turnover over 40 years (including discontinuations)	Companies	0.38%	0.09%	0.02%	0.01%
First year compliance costs as % of annual turnover (excluding discontinuations)	Companies	Average: 0.4% Up to 14.6% (C20.1, C20.3 and C20.5 chemicals - small enterprises)	Average: 0.1% Up to 0.51% (C20.1, C20.3 and C20.5 chemicals - small enterprises)	Average: 0.1% Up to 0.33% (M72.1 laboratories - small enterprises)	Average: 0.04% Up to 0.26% (M72.1 laboratories - small enterprises)
Employment – Jobs lost	Workers & families	140	0	0	0
Employment – Social cost	Workers & families	€ 13	€ 0	€ 0	€ 0
International competitiveness	Companies	Some non-EU countries would have less stringent OELs and BLVs			

Impact	Stakeholders affected	7.3 mg/m³ and 45 mg HEAA in urine/g Creatinine	20 mg/m³ and 108 mg HEAA in urine/g Creatinine	36 mg/m³ and 188 mg HEAA in urine/g Creatinine	73 mg/m³ and 366 mg HEAA in urine/g Creatinine
Consumers	Consumers	No significant impact	No significant impact	No impact	No impact
Internal market Lowest to highest OEL	Companies	7.3 mg/m³-7.3 mg/m³	20 mg/m³-20 mg/m³	20 mg/m³-36 mg/m³	20 mg/m³-73 mg/m³
Internal market Lowest to highest BLV	Companies	45 - 45 mg HEAA/g creatinine	108 - 108 mg HEAA/g creatinine	188 - 188 mg HEAA/g creatinine	200 - 400 mg HEAA/g creatinine
Specific MSs/regions - MSs that would have to change OELs	Public sector	27	25	22	0
Specific MSs/regions - MSs that would have to change BLVs	Public sector	27	27	27	26
Regulation	Companies	A REACH restriction on use of 1,4-dioxane in surfactants is currently under consideration			
Direct benefits – improved well-being – health					
Reduced cases of ill health (kidney effects)*	Workers & families	500	0	0	0
Reduced cases of ill health (liver effects)*	Workers & families	630	0	0	0
Reduced cases of ill health (local irritation in the nasal cavity)*	Workers & families	4,400	0	0	0
Ill health avoided, incl. intangible costs (M1 to M2)*	Workers & families	€ 2 - 3 million	€ 0 - 0 million	€ 0 - 0 million	€ 0 - 0 million
Direct benefits – improved well-being – safety					
Avoided costs	Companies	€ 1.6	€ 0	€ 0	€ 0

Impact	Stakeholders affected	7.3 mg/m³ and 45 mg HEAA in urine/g Creatinine	20 mg/m³ and 108 mg HEAA in urine/g Creatinine	36 mg/m³ and 188 mg HEAA in urine/g Creatinine	73 mg/m³ and 366 mg HEAA in urine/g Creatinine
Avoided costs	Public sector	€ 2	€ 0	€ 0	€ 0
EU policy agenda	All	Improvements in workers fundamental rights and contribution towards Green Deal: Chemical Strategy towards a toxic-free environment			
Direct benefits – improved well-being – environmental					
Environmental releases	All	Potentially, a reduction in emissions into the air but unclear impact on emissions to water		Limited or no impact	Limited or no impact
Direct benefits – market efficiency					
Level playing field	Companies	The ratio between the maximum and minimum national OEL is currently 3.65. The ratio between the maximum/minimum STEL is 2.08. A reduction in the OEL and STEL is likely to improve the level playing field in the internal market. Two Member States currently have a BLV, both at levels above the relevant BLV options.			No impact for the OEL. Only two Member States currently have a BLV, one of which is at a level above and one below this option..
Indirect benefits					
Administrative simplification	Companies	Should all Member States have a harmonised OEL and BLV this would reduce the administrative burden for enterprises with operations across multiple Member States. However, the majority of enterprises under review are small and are unlikely to have multinational operations and be unaffected by this simplification.			
Synergy	Companies	Synergies in terms of exposure reduction for other chemical substances used in production sectors may occur. The specific substances will vary between the sectors. The level of synergy to be harnessed will also depend on the RMMs applied in each enterprise.			
Corporate Social Responsibility	Companies	Work with 1,4-dioxane may be less perceived as a risky line of work associated with health issues, in particular given the recent reclassification of 1,4-dioxane as Carcinogenic 1B. As a result of such			

Impact	Stakeholders affected	7.3 mg/m³ and 45 mg HEAA in urine/g Creatinine	20 mg/m³ and 108 mg HEAA in urine/g Creatinine	36 mg/m³ and 188 mg HEAA in urine/g Creatinine	73 mg/m³ and 366 mg HEAA in urine/g Creatinine
		an improvement in the public image, companies may find it easier to recruit and retain staff, reducing the cost of recruitment and increasing the productivity of workers.			
Avoided cost of setting OEL and BLVs	Public sector	€ 5.3	€ 4.4	€ 4.1	€ 4
Other impacts					
Recycling – loss of business	Recycling companies	No impacts expected			
Impacts on fundamental rights	All	Improved occupational health			
Impacts on digitalisation	Companies	No impact expected.			
Contributions to the UN sustainable development goals	All	Potential for reduced emissions into the air but it is unclear whether this would not increase emissions into wastewater.			

Source: Study team. Note: Totals may not sum due to rounding.

14.3 Practical implications of establishing an OEL

The following table highlights practical considerations for citizens/consumers, businesses and administrations which should be considered under the introduction of an EU OEL.

Table 14-8 Practical implications of establishing an OEL/BLV for 1,4 - dioxane

Citizens/Consumers	Businesses	Administrations
- Employees have a duty to comply with requirements of their employers regarding the use of preventative and protective equipment and measures necessary to comply with the OSH legislation.	Businesses must comply with OSH legilsated provisions (e.g. an OEL) which would have the following practical implications: - installation and continued operation of necessary risk management measures (RMMs) (such as forms of local exhaust ventilation and enclosed cabinets, personal protective equipment (PPE), respiratory protective equipment (RPE), organisational hygiene measures, general ventilation etc.) required to meet the OEL/BLV. - implementation of a sampling strategy for airborne concentration measurements as part of business risk assessment processes and effectiveness checks of existing measures to meet the OEL. - implementation of a sampling strategy for urine testing of exposed employees as part of the business risk assessment processes and effectiveness checks of existing measures to meet the BLV. - ensure compliance with other provisions in the legislation (specific information and training to workers as regards the new working methods if such is the need in order to comply with the new OEL/BLV, collection of records, information to competent authorities, etc.).	Member States must transpose the amended Directive into national legislation: - assessment of the national scenario and potential impacts; - tripartite consultation of the proposal (workers, employers, authorities); - facilitate implementation of the national legislation by providing, among other measures, technical guidance to employers. These costs are minor in comparison to the overall costs of functioning incurred by the enforcement. Member States must also comply with the whole set of OSH national legislation provisions related to an OEL/BLV. For firefighting personnel this would require: - Implementation and continued operation of necessary RMMs suitable for this sector. For example, RPE, PPE, and organisational hygiene measures. - implementation of a sampling strategy for airborne concentration measurements as part of risk assessment processes and effectiveness checks of existing measures to meet the OEL. - implementation of a sampling strategy for urine testing of exposed firefighters as part of the risk assessment processes and effectiveness checks of existing measures to meet the BLV.

Citizens/Consumers	Businesses	Administrations
		- ensure that 1,4-dioxane is managed in line with the provisions of the carcinogens and mutagens national legislation. - ensure compliance with other provisions in the legislation (specific information and training to workers as regards the new working methods if such is the need in order to comply with the new OEL/BLV, collection of records, information to competent authorities, etc.).

Source: Study team.

14.4 Compliance with subsidiarity and proportionality principles

Article 5.3 of the Treaty of Europe says "*Under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level.*"

Whilst Member States can and do set their own limit values, the analysis and decision making are more efficient and effective if the process of setting limit values is undertaken at the Union level. The introduction of limit values at Union level also ensures that there is not divergence of risk within industry operating across the Union. For these reasons the introduction of EU wide limit values can be seen as compliant with the principle of subsidiary.

Article 5.3 of the Treaty of Europe says "*Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.*" It is often described as "not using a sledgehammer to crack a nut".

For control of exposure to CMR substances it has been established that the inclusion in the CMRD and the subsequent introduction of limit values is an appropriate method of controlling exposure. 1,4-dioxane is already covered by the CMRD, therefore the Member States have already agreed that setting limit values through the process managed by the Advisory Committee for Safety and Health at Work (ACSH), Working Party on Chemicals (WPC) and DG EMPL is the appropriate and proportionate manner. By definition, Member States are obliged under the CMRD to continually work to reduce the exposure to PAH and this study provides all of the impacts, including the costs and benefits to the ACSH, WPC and DG EMPL enabling them to specify acceptable limit values. Given the structure and previous establishment of the above process, the introduction of EU wide limit values can be seen as compliant with the principle of proportionality.

14.5 Highlighted issues

Other issues to be considered in the decision-making process include:

- The modelling for the core scenario typically (but not always) relies on measured exposure data – these data tend to be quite old and limited. As an alternative scenario, the sensitivity analysis relies on modelled exposure data in REACH registration CSRs to estimate an alternative scenario. The greatest difference between the sectors is in C21.1 and 21.2 Pharmaceutical production (intentional use), where the impacts estimated using the CSR data are significantly greater (PV costs over 40 years of €784.5 million compared with €0.9 million in the core scenario). In the pharmaceutical sector, the core scenario relies on two datasets providing personal and fixed measurements in pharmaceutical production in 1996/97.

- Whilst the estimates in the core scenario for the chemical sector (C20.1, C20.3 and C20.5) are largely driven by a single modelled value, modelled exposure data for this sector in the CSRs suggest similar levels of exposure to the core scenario. It should be noted that the chemicals sector is the only industrial sector (other than the pharmaceutical sector) with intentional use of 1,4-dioxane. There are indications that some use to 1,4-dioxane occurs in the absence of fully closed systems and as a result, it can be expected that some workers are exposed to concentrations above 7.3 mg/m^3 and 20 mg/m^3.

- As regards unintentional generation as a by-product, the sensitivity scenario estimates greater costs than the core scenario. These should be related to the numbers of potentially affected companies in the two sectors (53 and 70).

- There is uncertainty about the contribution of dermal exposure to the overall uptake of 1,4-dioxane. However, given the potential contribution of dermal exposure to the total uptake of 1,4-dioxane, a skin notation could have a positive effect.

14.6 Summary for the option agreed by the ACSH

The ACSH Opinion on an EU Binding Occupational Exposure Limit Value (BOEL), Short Term Exposure Limit (STEL), Biological Limit Value (BLV) and skin notation for 1,4-dioxane (Doc. 007/23) was adopted on 22nd September 2023. The ACSH recommended that an OEL of 7.3 mg/m^3 (2 ppm), a STEL of 73 mg/m^3 (20 ppm) and a BLV of 45 g HEAA in urine/g Creatinine, at the end of exposure or shift, as well as a skin notation, are adopted.

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16 ANNEXES

16.1 Annex 1: Summary of Consultation

A summary of consultations for the study is provided in the Methodological Note annex called Summary of the Consultation Exercise.

This section provides a summary of the stakeholder consultation exercises undertaken as part of this study ('Study on collecting the most recent information on substances to analyse 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, mutagens or reprotoxic substances at work').

16.1.1 Outline of consultation strategy

The primary aim of the consultation activities is to identify information not available via desk-based research. For example, although information on current OELs, STELs, BLVs and notations is available, there is limited information on the specific concrete risk management measures already in place, as well as those that would need to be implemented, should the proposed measures be introduced into the CMRD. There may also, for example, be complications regarding the specificities of different sites and environments in which workers may be exposed. Consultation activities therefore formed a valuable part of this study.

The consultation activities conducted to date have included:

- Targeted questionnaires, these included: substance specific questionnaires, Member State Authorities, OSH Experts, Trade Unions and a further short questionnaire for welding50;
- Interviews;
- Site visits; and
- Conversations (these consisted of email exchanges and online calls).

The study team have consulted a range of organisations whose activities are relevant to the five substances[51] being analysed as part of this study. Information collected via consultation included the sectors and processes in which the relevant substances are used, the size of companies that would be impacted, estimates of numbers of workers exposed currently, current air concentrations of substances concerned (both 8-hour time weighted averages (8-h TWA) and 15-minute reference periods), current biological limit values, as well as risk management measures currently in place, and risk management measures that would need to be implemented should the limits be introduced and the associated costs.

Consultation activities have been conducted by those with expertise; substance experts (those writing the substance-specific reports) and national experts (with knowledge of the situation in their Member State and native language competence) conducted the interviews with stakeholders.

[50] Questionnaires for MSA, Trade Unions and the further welding questionnaire were often accompanied by interviews. The aim of these interviews was to fill in the questionnaire and this formed the basis of the interview questions.

[51] Cobalt and inorganic cobalt compounds, isoprene, polycyclic aromatic hydrocarbons, welding fume and 1,4-dioxane

The substance and national experts in turn were also supported by experts in cost-benefit analysis and consultation via a consortium led by RPA which has worked on all five previous OELs studies.

Any contact made with stakeholders was logged so that progress can be monitored, and interview guides have been prepared for those conducting interviews to ensure that the approach to collecting data was thorough and consistent. These guides include information clarifying the objectives of the study, the study approach and provide detailed information on the measures being assessed. They also include information on the role of the national experts and the specific data that needs to be collected via consultation, as well as the privacy statement and the confidentiality options.

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

- There has been no public consultation conducted as part of this work, although the survey has – through its submission strategy – aimed to reach out widely.
- The consultation focused on generating *evidence* to directly support the analyses. Views and opinions have also been provided and are presented here as well, but the approach towards this has not been as systematic.
- Much of the evidence gathered is of a confidential nature and is thus not presented here, however it has been used to support the calculations and assessments that result from the analyses.

The table below summarises the stakeholder groups targeted and the tools, interests and strategies applied:

Table 16-1 Consultation tools and strategies

Stakeholder type	Interests represented	Main consultation tools	Strategy
EU Associations and REACH Consortia	Industry	Online interviews Email requests	Our previous work demonstrated that EU Associations are the best instrument for reaching out to manufacturers/users. Upon our request, the EU associations thus forwarded the questionnaires to national associations and companies. Supplementary information e.g. on number of companies, numbers of workers exposed, market situation, etc. was collected through email requests and online interviews with the associations and REACH consortia and statistics from Eurostat.
Member State Authorities	Member State authorities	Questionnaires Online interviews	Member State authorities were contacted with a questionnaire and responses were followed up with online interviews, where possible. Experience from supporting the OELs 3, OELs 4 and OELs 5 studies demonstrated that this is the most effective way of collecting the specific information across all Member States.
Manufacturers/users	Industry	Questionnaires Online interviews	Based on the experience from OELs 3, OELs 4 and OELs 5, questionnaires for manufacturers/users were mainly distributed via EU associations. The EU associations forwarded the

Stake-holder type	Interests represented	Main consul-tation tools	Strategy
		Email requests	questionnaire directly to companies or forwarded it to national industry associations which then forwarded it to their member companies. This strategy was deemed the most sensible as experience from the previous OELs studies shows that only a few companies answer the questionnaire unless encouraged to do so by either their relevant EU association or their national industry associations. To increase the number of responses, questionnaires were refined and kept as short as possible, and focused on providing data on existing RMMs as well as RMMs (and costs) needed to comply with the various reference limits (options) Questionnaire responses were then, where possible/ necessary, followed up by interviews and site visits. Some companies have been also contacted directly (i.e. not via the associations) by phone by national experts who encouraged and assisted the companies in filling out the questionnaire and/or undertook telephone interviews. This additional approach was selected to ensure that answers are provided by companies situated in as many Member States as possible.
National industry associations	Industry	Online interviews Email requests	National industry associations were primarily contacted via the EU associations. Some national associations were contacted directly by phone by national experts and interviewed to collect information supplementary to the information from EU associations, and identify relevant national companies to be approached by the national experts.
Trade Unions	Workers	Online interviews Email requests WPC	Based on previous experience, this study focused on obtaining a few more targeted telephone interviews and email correspondence, as well as collecting information from worker association representatives of the WPC.
Occupational Health & Safety Professionals	Contacted to obtain scientific information	Questionnaire Online interviews	Occupational health and safety professionals were contacted with a questionnaire. This is considered the most efficient way to collect specific information across all Member States.
Working Party on Chemicals (WPC)	Industry Workers Member State Authorities	Participation in workshop	The study team presented draft results to the Working Party on Chemicals in May 2023. Previously, this has proved to be an effective means of receiving feedback from

Stake-holder type	Interests represented	Main consul-tation tools	Strategy
			representatives of industry, employers' associa-tions, workers' organisations and Member State authorities.
Laboratories	In communica-tion to obtain information on sampling and analysis	Online interviews Email requests	In the study supporting OELs 3, a large number of laboratories were contacted via email re-quests. Limited information was obtained, and it was only obtained when the email requests were combined with telephone contact. For previous OELs studies and this study, the approach has been to contact a small number of laboratories by phone and email using direct contacts, and to dedicate efforts to following-up on these, to ob-tain detailed information on methods applied, standards, limits of quantification and prices.

Source: Analysis by RPA Ltd and COWI

Some stakeholders could not be reached. Substance experts wanted to contact specific national welding institutes, companies and trade unions. Efforts were made to contact these stakeholders but there was no response.

16.1.2 Documentation of formal consultation activity

The questionnaires for each substance and stakeholder group can be found in the appendices.

- 1,4 Dioxane Questionnaire: 1,4 Dioxane Annex 3
- MSA Questionnaire: Annex 2 (Methodological Note);
- OSH Questionnaire: Annex 3 (Methodological Note); and
- Trade union questionnaire: Annex 4 (Methodological Note)

16.1.3 Methodologies and tools to process data

The online questionnaires for this report were gathered using EU Survey. EU Survey allows for full control over the creation and design of the questionnaire and allows translations to be edited through the website tools. Once completed, the survey data was exported from EU Survey into Excel and cleaned to ensure that only genuine responses were analysed. Any test answers or irrelevant responses were removed[52]. This was then provided to substance experts for their analysis to combine with information that had been obtained through internet research, interviews and other means.

A stakeholder log was also created to monitor and record contact with stakeholders. This included contact information, contact method, and survey completion.

Experts responsible for each substance were provided with all the information relevant for their substance (questionnaire responses, interview minutes, site visit reports, position papers, etc.). All

[52] One response for PAH and two responses for welding fumes were removed as these were completed by industry associations rather than companies and were analysed separately.

information was analysed by the specific substance expert and, where considered robust and relevant, used as the basis for the substance-specific analyses in conjunction with information obtained via desk-based research.

16.1.4 Results of consultation activities

The consultation activities being conducted as part of this study are explained in greater detail in the subsections below.

16.1.5 Targeted online survey

The online targeted survey opened on 23 January 2023 and ran until 27 March 2023. The deadline was extended twice to allow for a broader range of stakeholders to respond and address low response rates for certain substances.

Stakeholders were initially contacted via email. The email provided an overview of the study and a link to the RPA webpage explaining the consultation activities, with links to each of the questionnaires, the privacy statement, and an introductory letter from the Commission. A link rather than an attachment was used to decrease the size of the email and reduce the number of emails automatically directed to junk folders. Five separate questionnaires were created for each of the substances for companies, three for the different stakeholder groups and an additional welding questionnaire:

- Companies - cobalt;
- Companies - PAH;
- Companies - isoprene;
- Companies -1,4 – dioxane;
- Companies - welding fume;
- Member State Authorities;
- Occupational Safety and Health Experts;
- Trade Unions; and
- Welding short interview guide.

The questionnaires for companies were available as a link to EU Survey. The questionnaire for Member State authorities and occupational safety and health experts was available as a Word document which could be downloaded and sent to the study team using the designated OELs 6 email address. Trade Unions and specific welding stakeholders were also contacted by national experts and invited to interview for the questionnaire.

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

Translations of each of the substance questionnaires were available in German, French, Italian, Polish and Spanish and respondents also had the option to ask the study team for the questionnaire in a language of their choice. Translations were initially requested through EU Survey and were then checked and edited by the National Experts.

At the end of the questionnaire, respondents were given the opportunity to add any further comments and were asked if they were willing for a substance expert to ask potential follow-up questions and whether they would be willing to host a site visit. Follow-up interviews were useful when there were gaps in a stakeholder's response and questions could be asked further to fill in missing information. Other consultation methods were used to probe further into respondents' answers and gain a more in-depth understanding of the topic and potential impacts.

National experts were used to contact MSAs for countries where there was no response from that country.

The Commission and the WPC were provided the opportunity to comment on the drafts of each questionnaire before they were launched, to ensure that they were relevant and user-friendly.

Some stakeholders however expressed difficulty in responding to the questionnaire due to the complexity of the study – this was particularly the case for welding fume. Discussions were held with key industry associations and these stakeholders were provided with the opportunity to respond to the questionnaire via interview, where explanation could be provided for each question. Responses were also received from industry organisations.

It should also be noted that some industry associations had already carried out their own surveys or had contributed to discussions on the relevant occupational exposure limits prior to this study, which may have resulted in consultation fatigue for some substances.

Around **691** stakeholders were invited to take part in the questionnaire. Many of the stakeholders contacted were relevant for multiple substances. However, the true number of stakeholders that were contacted is likely to be higher as many industry and EU associations were contacted and asked to distribute the survey to their members. Based on experience from previous studies, this has been a useful method to ensure a high response rate from companies. Efforts were also made during calls with industry associations to encourage their members to respond. Stakeholders were selected from the sectors that were identified as being relevant for each of the substances. The tables below provide a summary of the responses according to stakeholder type.

Table 16-2 Summary of numbers of stakeholders directly contacted by questionnaire type

Stakeholder type		Number contacted
Companies	Companies	15.91% (110 out of 691)
	Industry associations	61.07% (422 out of 691)
Member State Authorities		20.69% (143 out of 691)
Occupational Health and Safety Experts		2.32% (16 out of 691)
Trade Unions*		3 contacted
Welding (short interviews)*		20 contacted

*Source: Consultation. *These were accompanied by an interview and were undertaken in addition to the main questionnaires and thus are not included in the total number.*

Four reminders were sent out to stakeholders to prompt them to respond and update them on the extension to the survey deadline. Stakeholders that had completed the survey or indicated to the study team that the substance was not relevant to them were removed from the mailing list.

Table 16-3 Breakdown of number of stakeholders directly contacted by questionnaire type

Stakeholder type	Number contacted
Company	15.63% (108 out of 691)
Education and Training	0.14% (1 out 691)
Industry associations	59.62% (412 out of 691)
Laboratories	0.14% (1 out of 691)
Public authority	20.69% (143 out of 691)
NGO	1.45% (10 out of 691)
OSH Professional	2.32% (16 out of 691)
Trade Unions	0% (0 out of 691)

Source: Consultation.

The table below provides an overview of the number of responses received to the questionnaires from those contacted. This number includes the number of responses that were able to be analysed after the initial cleaning process. Most responses came from companies as this was the stakeholder group where there was the most engagement and requests for responses. At least one contact was approached for each Member State, however not all Member States provided a response to the targeted questionnaire. The study team used the national experts to conduct interviews with the member state authorities that have not responded to the questionnaire, these were often accompanied by an interview based on the questions in the survey. National experts were also tasked with contacting and getting responses from trade unions.

Table 16-4 Responses per questionnaire

Stakeholder type	Number of responses
Companies	16.67% (5 out of 30)
Member State Authorities	83.33% (25 out of 30)
Occupational Health and Safety Experts	0% (0 out of 30)
Trade Unions	2 responses
Total	**30**

Source: Consultation.

A large number of responses were received for substances that are used in a wide variety of industries. Five responses were received to the 1,4 dioxane questionnaire. A breakdown of the questionnaire responses per substance and by company size is presented in the tables below.

Table 16-5 Number of responses submitted by companies, by substance questionnaire, and size of company

Company size (employees)	1,4 Dioxane
Micro (<10)	0
Small (10-49)	2
Medium (50-249)	3
Large (250<)	0
Total	**5**

Source: Consultation.

16.1.5.1 Online interviews

Online interviews were conducted with stakeholders whose activities are relevant to the five substances. The aim of these interviews was to build upon the information provided in response to the questionnaires, to fill any information gaps. The study team aimed to obtain detailed information on processes, to pinpoint exactly where exposure is likely to occur, to investigate what types of risk management measures are already in place and how effective they are, as well as what risk management measures would be required if limits were lowered and other potential ramifications for the company, etc.

Interviews were obtained a variety of ways. At the end of the questionnaire, respondents were asked if they would be willing to take part in an interview. However, some online interviews were arranged through making direct contact with key industry associations.

Consultees were given the opportunity to respond in their native language. In cases where this was required, the interview was carried out by the national expert.

Each online interview lasted approximately one hour. At the end of the telephone interview, we ensured that the organisations/individuals are satisfied with the minutes of the interview. This either involves sending them the minutes by email and receiving confirmation or, if the interviewee was happy with this, a sign-off process at the end of the interview.

National experts and substance specific experts conducted interviews with relevant stakeholders. Some of the interviews were based on the responses to the questionnaire. The meeting notes were shared with the company after the interview, and that occasion was also used to ensure mutual agreement on the level of confidentiality required.

Three interviews[53] were conducted relating to the use of 1,4-dioxane in the EU. A summary of the number of interviews carried out is presented in the table below.

[53] Two of these interviews were extended email exchanges.

Table 16-6 Breakdown of interviews per stakeholder type

Stakeholder type	Interviews conducted
Laboratories	0% (0 out of 3)
EU industry association	0% (0 out of 3)
Companies	0% (0 out of 3)
Member State Authorities	0% (0 out of 3)
Trade Unions	0% (0 out of 3)
Occupational health and safety experts	0% (0 out of 3)
Other	100% (3 out of 3)
Total	3

Source: Consultation

16.1.5.2 Conversations

Email requests have also been used to collect information for the study. The purpose of email requests is similar to the interviews, with stakeholders being asked for further detail on their answers to the questionnaire, as well as making requests for additional information such as industry statistics.

1,4 - Dioxane. For 1,4 - dioxane, constructive conversations have been carried out via email with the following stakeholders:

- Company, Spain.

16.1.5.3 Site visits

Companies whose activities are likely to be affected by the potential modifications to the CMRD were also asked whether they would be willing to welcome members of the study team for a site visit. Companies to be visited were identified via the questionnaire or via contact established via industry associations.

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

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

Site visits were undertaken during Spring and Summer 2023, once significant progress had been made with data collection. This ensured that site visits added more nuance to the data already collected and helped to fill remaining information gaps.

For 1,4-dioxane no site visits were conducted.

16.1.5.4 Consultation results by substance

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

16.1.5.5 Summary of consultation statistics

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

The breakdown of questionnaire responses, interviews and site visits by company size are provided below. They show that the majority of the responses were received from large or medium-sized enterprises, with fewer responses from small and small enterprises.

Table 16-7 Breakdown of questionnaire responses, interviews and site visits per company size (only for consulted companies and laboratories)

Company size (employees)	Questionnaire responses	Interviews	Site visits
Micro (<10)	0% (0 out of 5)	Interviews were labelled as other.	No site visits were conducted.
Small (10-49)	40% (2 out of 5)		
Medium (50-249)	60% (3 out of 5)		
Large (250<)	0% (0 out of 5)		

Source: Consultation

The breakdown of questionnaire responses, interviews and site visits per substance are provided below. These results show that most questionnaire responses and site visits were provided in relation to PAH, welding fume and cobalt, with relatively fewer responses for isoprene and 1,4-dioxane.

Table 16-8 Breakdown of questionnaire responses, interviews and site visits per substance (all stakeholders; companies, Member State authorities, trade associations, OSH (Occupational Safety and Health) specialists)

Substance	Questionnaire responses[54]	Interviews	Site visits
1,4 Dioxane	9.93% (30 out of 302)	5.17% (3 out of 58)	0% (0 out of 9)
Trade Unions	2 responses	n/a	n/a
Other	0% (0 out of 302)	3.45% (2 out of 58)	0% (0 out of 9)

Source: Consultation

The breakdown of questionnaire responses, interviews and site visits per Member State are provided below. These results show a high number of questionnaire responses were received from Germany and a high number of interviews were from Belgium. It is not clear why these countries received high responses but the high responses from these countries occurred across all substances.

In the substance reports, the potential impact of the high number of responses from Belgium and Germany is referred to if the study team thinks that the results could be biased by this. Germany in particular has already implemented regulations relating to welding and has relatively low existing OELs for PAH, cobalt and isoprene. Overall, the unbalanced breakdown of responses by Member States is taken into account by the study team, and the information is balanced by data from other stakeholders and sources, to ensure that the conclusions are not believed to be unduly influenced by the responses from Belgium and Germany.

Table 16-9 Breakdown of questionnaire responses, interviews and site visits per Member State (all stakeholders; companies, Member State authorities, trade associations, OSH (Occupational Safety and Health) specialists)

Country	Questionnaire responses	Interviews	Site visits
Inside the EU			
Austria	0% (0 out of 30)	0% (0 out of 3)	-
Belgium	3.33% (1 out of 30)	0% (0 out of 3)	-
Bulgaria	6.67% (2 out of 30)	0% (0 out of 3)	-
Croatia	3.33% (1 out of 30)	0% (0 out of 3)	-
Cyprus	3.33% (1 out of 30)	0% (0 out of 3)	-
Czechia	3.33% (1 out of 30)	0% (0 out of 3)	-
Denmark	3.33% (1 out of 30)	0% (0 out of 3)	-
Estonia	0% (0 out of 30)	0% (0 out of 3)	-

[54] The questionnaire responses are higher here as the MSA and OSH questionnaire had substance specific sections. Where these have been completed, they have been added as one response.

Country	Questionnaire responses	Interviews	Site visits
Finland	3.33% (1 out of 30)	0% (0 out of 3)	-
France	3.33% (1 out of 30)	0% (0 out of 3)	-
Germany	10% (3 out of 30)	0% (0 out of 3)	-
Greece	0% (0 out of 30)	0% (0 out of 3)	-
Hungary	0% (0 out of 30)	0% (0 out of 3)	-
Ireland	3.33% (1 out of 30)	0% (0 out of 3)	-
Italy	13.33% (4 out of 30)	0% (0 out of 3)	-
Latvia	3.33% (1 out of 30)	0% (0 out of 3)	-
Lithuania	3.33% (1 out of 30)	0% (0 out of 3)	-
Luxembourg	0% (0 out of 30)	0% (0 out of 3)	-
Malta	0% (0 out of 30)	0% (0 out of 3)	-
Netherlands	3.33% (1 out of 30)	0% (0 out of 3)	-
Poland	3.33% (1 out of 30)	0% (0 out of 3)	-
Portugal	3.33% (1 out of 30)	0% (0 out of 3)	-
Romania	3.33% (1 out of 30)	0% (0 out of 3)	-
Slovakia	3.33% (1 out of 30)	0% (0 out of 3)	-
Slovenia	3.33% (1 out of 30)	0% (0 out of 3)	-
Spain	3.33% (1 out of 30)	0% (0 out of 3)	-
Sweden	3.33% (1 out of 30)	0% (0 out of 3)	-
Multiple Member States	0% (0 out of 30)	0% (0 out of 3)	-
Other	-	100% (3 out of 3)	-
Outside the EU			
Iceland	0% (0 out of 30)	0% (0 out of 3)	-
Norway	3.33% (1 out of 30)	0% (0 out of 3)	-
South Korea	0% (0 out of 30)	0% (0 out of 3)	-
Switzerland	0% (0 out of 30)	0% (0 out of 3)	-

Country	Questionnaire responses	Interviews	Site visits
UK	0% (0 out of 30)	0% (0 out of 3)	-
US	0% (0 out of 30)	0% (0 out of 3)	-
Total	**30**	**3**	**0**

Source: Consultation

Notes: In some cases, the input for location was given as several Member States or a list of companies for the same response. In order to not inflate the numbers presented, if this was given as an answer, it is recorded this under 'multiple Member States'.

Site visits have been carried out, but the location cannot be disclosed due to confidentiality and the small sample size.

16.1.5.6 How the information gathered has been taken into account

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

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

The table below summarises how the responses in each questionnaire section are used in each report. The majority of the analysis is undertaken and discussed in each of the substance specific reports.

Table 16-10 Questionnaire sections mapped to relevant section in each substance report

Questionnaires and sections	Report section
Companies	
B	Exposure concentrations Exposed workforce Current risk management measures (RMMs)
C	Lowest technically possible and economically feasible option
D	RMMs needed to achieve compliance
E	Voluntary industry initiatives
F	Other benefits
G	Impact of the implementation of other OELs

Questionnaires and sections	Report section
H	Other comments
Member State Authority	Existing national limits Costs for public administrations Costs Market effects Environmental impacts Indirect benefits Employment
Occupational Health & Safety Experts	Current risk management measures (RMMs) Existing national limits RMMs needed to achieve compliance
Trade Unions	Voluntary industry initiatives Exposed workforce Benefits
Welding	(Welding only- short interviews) Definition of the problem Benefits

Source: Study team

16.2 Annex 2 : Who is affected and how?

The benefits of an OEL of 7.3 mg/m^3 are summarised below, showing a reduction in the three effects considered in the study.

Table 16-11 Overview of benefits (total for all provisions) – OEL 7.3 mg/m^3 in € millions

Description	Amount € millions
Direct benefits	
Workers & families - Reduced cases of ill health (kidney effects)	497
Workers & families - Reduced cases of ill health (liver effects)	633
Workers & families - Reduced cases of ill health (local irritation in the nasal cavity)	4,382
Workers & families - Ill health avoided, incl. intangible costs (M1 to M2)	€ 1.9 – € 3.2
Companies - Avoided costs	€ 1.6
Public sector - Avoided costs	€ 2.0
Indirect benefits	
Public sector - Avoided cost of setting an OEL	€ 1.4

Source: Study team

Notes: Benefits are PV discounted over 40 years

Table 16-12 and Table 16-13 give an overview of costs and apply the "one in, one out" approach for the preferred option. The costs are presented as present value costs discounted over 40 years and are not split between one-off and recurrent costs. In the study, adjustment costs are presented as first year and recurrent costs. First year costs include recurrent costs incurred in the first year: this also applies to first year compliance (adjustment plus monitoring and administrative burden) costs.

Please note that for reasons of consistency with the preceding table, only the costs associated with an OEL are set out below. A simultaneous implementation of a BLV at 45 mg HEAA in urine/g Creatinine would entail significant additional costs not included in the table below.

Table 16-12 Overview of costs – OEL of 7.3 mg/m³ in € millions

	Businesses	Administration
Direct adjustment costs	€ 121	€ 0.8
Direct administrative costs	€1.5	NA
Direct regulatory fees and charges	NA	NA
Direct enforcement costs		Not estimated
Indirect costs	NA	€2

Source: Study team

Notes: Costs are PV discounted over 40 years

Enforcement costs are not estimated as they are specific to Member States individual inspection regime.

Table 16-13 Application of the 'one in, one out' approach – OEL of 7.3 mg/m³ in € millions

	Total
Businesses	
New administrative burdens (INs)	€1.5

	Total
Removed administrative burdens (OUTs)	€0
Net administrative burdens	€ 1.5
Adjustment costs	€ 121.5
Total administrative burdens	€ 123

Source: Study team

Notes: recurrent costs are PV discounted over 40 years

The impact on Sustainable Development Goals is summarised below.

Table 16-14 Overview of relevant Sustainable Development Goals – OEL of 7.3 mg/m^3 in € millions

Relevant SDG	Expected progress towards the Goal
SDG 8 Decent work & economic growth”	The preferred policy option achieves improved worker and family health outcomes.
SDG 3 Good health and wellbeing	The preferred policy option achieves improved worker and family health outcomes. T
SDG 14 and 15 Life below water and Life on land	Potential for improved health and reduced emissions into the air but it is unclear whether this would not increase emissions into wastewater

Source: Study team

16.3 Annex 3: Questionnaire for companies – 1,4-dioxane

Questionnaire for companies: 1,4 - Dioxane

Fields marked with * are mandatory.

Questionnaire for companies: 1,4-dioxane

This survey is part of a study to support a possible amendment of Directive 2004/37/EC on the protection of workers from exposure to carcinogens, mutagens or reprotoxic substances at work (the Carcinogens, Mutagens or Reprotoxic substances Directive, **CMRD**). Specifically, the study assesses the impacts of establishing new limit values for some substances or introducing a substance into Annex I.

The substances being considered are:

- **Polycyclic aromatic hydrocarbons (PAH)**
- **Cobalt and inorganic cobalt compounds**
- **Isoprene**
- **1,4-dioxane**
- **Welding fume**

New OELs are proposed for the first four substances above, under the CMRD. In addition, biological limit values (BLV) are proposed for PAH and 1,4-dioxane, and a 15-minute short-term exposure limit value (STEL) is proposed for 1,4-dioxane. ‘Skin sensitisation’ and ‘respiratory sensitisation’ notations are also proposed for cobalt and inorganic cobalt compounds, and ‘skin’ notations are proposed for isoprene, PAHs and 1,4-dioxane.

An amendment to include welding fume in Annex I of the CMRD is also being considered.

This questionnaire is intended for all companies where exposure to **1,4 dioxane** takes place.

The study is being undertaken by a consortium comprising RPA Risk & Policy Analysts (United Kingdom), RPA Europe (Italy), RPA Europe Prague (Czech Republic) COWI (Denmark), FoBiG Forschungs- und Beratungsinstitut Gefahrstoffe (Germany), EPRD (Poland) and Force Technology (Denmark) under a contract for the European Commission's Directorate-General for Employment, Social Affairs and Inclusion.

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

This questionnaire is intended for a **single facility.** If workers are exposed at multiple facilities, please complete the questionnaire several times or contact the study team.

It will take approximately 15–45 minutes to answer the questionnaire depending on data availability and detail.

The deadline for completion of the questionnaire is 3 March 2023.

This questionnaire is available in English, French, German, Italian, Polish and Spanish. However, you are welcome to answer the questions in an official language of the European Union of your choice. If you prefer to be interviewed in your language or if you have questions about the survey, please contact: OELs6@rpaltd.co.uk

Abbreviations used in the questionnaire:

8 hour TWA - 8 hour Time-Weighted Average, measured in parts per million (ppm) or milligrams per cubic metre (mg/m^3). The 8 hour TWA is an expression for the average exposure for a typical working day. It is calculated by summing up the concentrations (in ppm or mg/m^3) during different periods of a day (usually 8 hours). Each concentration is multiplied by its relevant duration and the total is divided by the entire length of the working day (usually 8 hours) such as in this example:

8h-TWA = (2 hours * 500 ppm + 5 hours * 100 ppm + 1 hours * 700 ppm) / (2 + 5 + 1 hours).

BLV - Biological Limit Value

CMRD - Carcinogens, Mutagens or Reprotoxic substances Directive 2004/37/EC

HEAA - β-Hydroxyethoxyacetic acid

LOAEL - Lowest Observed Adverse Effect Level is the lowest tested exposure concentration which is observed to produce an adverse effect in a living organism.

NACE - NACE Revision 2, statistical classification of economic activities in the European Community. See https://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF, page 61 ff.

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

RAC - The Committee for Risk Assessment (RAC) is a scientific committee of ECHA that prepares the opinions related to the risks of substances to human health and the environment. It also assisted DG Employment with the evaluation of MOCA and inorganic arsenic compounds.

RMM - Risk Management Measure

RPE - Respiratory protective equipment

SMEs - Small and Medium-sized Enterprises. Companies with between 50 and 249 employees are usually referred to as medium-sized. Companies with between 10 and 49 employees are usually referred to as small (and with less than 10 employees as micro enterprises). Companies with more than 250 employees are referred to as large companies. For further definitions, please refer to http://ec.europa.eu/growth/smes

/business-friendly-environment/sme-definition/index_en.htm

STEL - A short-term exposure limit is like an OEL but involves a shorter reference period (usually 15 minutes). The aim of this value is to prevent adverse health effects caused by peaks in exposure that will not be controlled by the application of an 8-hour TWA limit.

Publication privacy settings

☐ By checking this box, I confirm that I have read the Privacy Statement and agree with the processing of my personal data for the purposes stated therein. I acknowledge that my views could be shared with the European Commission and published with information concerning the type of the organisation for which I submit information, to which I hereby give my consent.

A) About your company

A1) Please provide the following details about your company

* **Name of contact person**

* **Company**

* **Email address of contact person**

Telephone number of contact person

* **Country of facility**

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czechia
- Denmark
- Estonia
- Finland

- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Slovak Republic
- Slovenia
- Spain
- Sweden
- Other

If other, please specify

A2) Please define the sector in which your company is active (if possible, using a NACE code)

- C20.1 Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms
- C20.12 Manufacture of dyes and pigments
- C20.17 Manufacture of synthetic rubber in primary forms
- C20.4 Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations
- C20.42 Manufacture of perfumes and toilet preparations
- C20.5 Manufacture of other chemical products
- C20.52 Manufacture of glues
- C20.59 Manufacture of other chemical products n.e.c.
- C21.1 Manufacture of pharmaceutical products
- C21.2 Manufacture of pharmaceutical preparations
- C22 Manufacture of rubber and plastic products
- C22.1 Manufacture of rubber products
- C28.96 Manufacture of plastics and other rubber machinery
- Other

If other, please specify

A3) Please describe your company's overall application of 1,4-dioxane within the scope of the study. If exposure to 1,4-dioxane at your facility occurs as a result of unintentional generation of 1,4-dioxane, e.g. as a result of ethoxylation, please describe the process(es) that result in worker exposure.

A4) How many workers are employed in your company at the facility for which you are filling out this questionnaire?

A5) Have you any experience of workers having health issues resulting from occupational exposure to 1,4 - dioxane at the workplace?

A6) Have any workers left the company due to health issues associated with exposure to 1,4 - dioxane?

A7) What is the annual turnover in EUR at the facility for which you are filling out this questionnaire?

- < €2 million
- €2–10 million
- €10–50 million
- €50–100 million
- > €100 million

Please complete a separate questionnaire for each facility.

A8) Please give the name and address (incl. country) of the facility for which you are completing this questionnaire

B) Information about current exposure at your facility

B1) Please specify the most important processes during which exposure to 1,4-dioxane can occur. You can specify a maximum of four processes.

Process 1

- PROC 1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
- PROC 4 Chemical production where opportunity for exposure arises
- PROC 5 Mixing or blending in batch processes
- PROC 6 Calendering operations
- PROC 7 Industrial spraying
- PROC 8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b Transfer of substance or mixture (charging and discharging) at dedicated facilities
- PROC 9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10 Roller application or brushing
- PROC 11 Non-industrial spraying
- PROC 12Use of blowing agents in manufacture of foam
- PROC 13 Treatment of articles by dipping and pouring
- PROC 14 Tabletting, compression, extrusion, pelletisation, granulation
- PROC 15 Use as laboratory reagent
- PROC 16 Use of fuels
- PROC 17 Lubrication at high energy conditions in metal working operations
- PROC 18 General greasing/lubrication at high kinetic energy conditions
- PROC 19 Manual activities involving hand contact
- PROC 20 Use of functional fluids in small devices
- PROC 21 Low energy manipulation of substances bound in materials and/or articles
- PROC 22 Manufacturing and processing of minerals and/or metals at substantially elevated temperature
- PROC 23 Open processing and transfer operations with minerals/metals at elevated temperature
- PROC 24 High (mechanical) energy work-up of substances bound in materials and/or articles
- PROC 25 Other hot work operations with metals
- PROC 26 Handling of solid inorganic substances at ambient temperature
- PROC 27a Production of metal powders (hot processes)
- PROC 27b Production of metal powders (wet processes)
- PROC 28 Manual maintenance (cleaning and repair) of machinery
- Other

Please specify the process

Process 2

- PROC 1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition

- PROC 4 Chemical production where opportunity for exposure arises
- PROC 5 Mixing or blending in batch processes
- PROC 6 Calendering operations
- PROC 7 Industrial spraying
- PROC 8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b Transfer of substance or mixture (charging and discharging) at dedicated facilities
- PROC 9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10 Roller application or brushing
- PROC 11 Non-industrial spraying
- PROC 12Use of blowing agents in manufacture of foam
- PROC 13 Treatment of articles by dipping and pouring
- PROC 14 Tabletting, compression, extrusion, pelletisation, granulation
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- PROC 16 Use of fuels
- PROC 17 Lubrication at high energy conditions in metal working operations
- PROC 18 General greasing/lubrication at high kinetic energy conditions
- PROC 19 Manual activities involving hand contact
- PROC 20 Use of functional fluids in small devices
- PROC 21 Low energy manipulation of substances bound in materials and/or articles
- PROC 22 Manufacturing and processing of minerals and/or metals at substantially elevated temperature
- PROC 23 Open processing and transfer operations with minerals/metals at elevated temperature
- PROC 24 High (mechanical) energy work-up of substances bound in materials and/or articles
- PROC 25 Other hot work operations with metals
- PROC 26 Handling of solid inorganic substances at ambient temperature
- PROC 27a Production of metal powders (hot processes)
- PROC 27b Production of metal powders (wet processes)
- PROC 28 Manual maintenance (cleaning and repair) of machinery
- Other

Please specify the process

Process 3

- PROC 1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
- PROC 4 Chemical production where opportunity for exposure arises
- PROC 5 Mixing or blending in batch processes
- PROC 6 Calendering operations
- PROC 7 Industrial spraying
- PROC 8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b Transfer of substance or mixture (charging and discharging) at dedicated facilities
- PROC 9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)

- PROC 10 Roller application or brushing
- PROC 11 Non-industrial spraying
- PROC 12Use of blowing agents in manufacture of foam
- PROC 13 Treatment of articles by dipping and pouring
- PROC 14 Tabletting, compression, extrusion, pelletisation, granulation
- PROC 15 Use as laboratory reagent
- PROC 16 Use of fuels
- PROC 17 Lubrication at high energy conditions in metal working operations
- PROC 18 General greasing/lubrication at high kinetic energy conditions
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- PROC 22 Manufacturing and processing of minerals and/or metals at substantially elevated temperature
- PROC 23 Open processing and transfer operations with minerals/metals at elevated temperature
- PROC 24 High (mechanical) energy work-up of substances bound in materials and/or articles
- PROC 25 Other hot work operations with metals
- PROC 26 Handling of solid inorganic substances at ambient temperature
- PROC 27a Production of metal powders (hot processes)
- PROC 27b Production of metal powders (wet processes)
- PROC 28 Manual maintenance (cleaning and repair) of machinery
- Other

Please specify the process

Process 4

- PROC 1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
- PROC 4 Chemical production where opportunity for exposure arises
- PROC 5 Mixing or blending in batch processes
- PROC 6 Calendering operations
- PROC 7 Industrial spraying
- PROC 8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b Transfer of substance or mixture (charging and discharging) at dedicated facilities
- PROC 9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10 Roller application or brushing
- PROC 11 Non-industrial spraying
- PROC 12Use of blowing agents in manufacture of foam
- PROC 13 Treatment of articles by dipping and pouring
- PROC 14 Tabletting, compression, extrusion, pelletisation, granulation
- PROC 15 Use as laboratory reagent
- PROC 16 Use of fuels

- PROC 17 Lubrication at high energy conditions in metal working operations
- PROC 18 General greasing/lubrication at high kinetic energy conditions
- PROC 19 Manual activities involving hand contact
- PROC 20 Use of functional fluids in small devices
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- PROC 22 Manufacturing and processing of minerals and/or metals at substantially elevated temperature
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- PROC 24 High (mechanical) energy work-up of substances bound in materials and/or articles
- PROC 25 Other hot work operations with metals
- PROC 26 Handling of solid inorganic substances at ambient temperature
- PROC 27a Production of metal powders (hot processes)
- PROC 27b Production of metal powders (wet processes)
- PROC 28 Manual maintenance (cleaning and repair) of machinery
- Other

Please specify the process

B2) Please provide the number of workers exposed at all exposure levels during a typical working day.

	Number of workers exposed
Process 1	
Process 2	
Process 3	
Process 4	

B3) Please provide data for inhalation exposure over 8 hours (8-hour Time Weighted Averages) from your most recent measurements of air exposure concentration and include the unit of measurement. The 8 hour TWA should ideally be expressed in ppm (parts per million) or milligram per cubic metre (mg/m^3).

	Process 1	Process 2	Process 3	Process 4
Lowest exposure level (value, unit)				
Highest exposure level (value, unit)				
Mean exposure level (Arithmetic mean; value, unit)				
Median exposure level (value, unit)				
95th percentile exposure level (value, unit)				
Number of samples (n)				
Year of monitoring				
B4) Please select the sampling method followed	○ Stationary sampling ○ Personal sampling ○ Personal sampling of inhalation air inside the RPE	○ Stationary sampling ○ Personal sampling ○ Personal sampling of inhalation air inside the RPE	○ Stationary sampling ○ Personal sampling ○ Personal sampling of inhalation air inside the RPE	○ Stationary sampling ○ Personal sampling ○ Personal sampling of inhalation air inside the RPE
B5) Are the workers wearing respiratory protective equipment (RPE)	○ Yes	○ Yes	○ Yes	○ Yes

during the activity?	No	No	No	No
B6) Please indicate the standard/analytical method followed	Air - DFG (German Research Foundation) Air - NIOSH 1602 Other	Air - DFG (German Research Foundation) Air - NIOSH 1602 Other	Air - DFG (German Research Foundation) Air - NIOSH 1602 Other	Air - DFG (German Research Foundation) Air - NIOSH 1602 Other
B7) If you answered ‘other’ to B6, please specify				
B8) If you have exposure data other than 8 hour Time Weighted Averages, please specify type of value and air exposure concentration	Type of value (value, unit)	Type of value (value, unit)	Type of value (value, unit)	Type of value (value, unit)

B9) If you have indicated below limit of quantification (LoQ) and/or limit of detection (LoD) in the responses above, what was the LOQ or LOD?

	Value	Unit
Limit of quantification		
Limit of detection		

B10) Could actions related to covid-19 have artificially reduced exposure levels?

- Yes, reduced exposure
- Yes, increased exposure
- No change
- Don't know

B11) Please provide a short explanation for your answer to B10

Short-term exposure (15 minutes)

Please specify short term exposure peaks for the same processes as above. If you cannot provide these peaks for the same processes as above please provide the data to OELs6@rpaltd.co.uk

B12) Please provide data for maximum inhalation exposure over 15 minutes from your most recent measurements of air exposure concentration and include the unit of measurement. The 15 minute maximum value should ideally be expressed in ppm (parts per million) or milligram per cubic metre (mg/m^3).

	Process 1	Process 2	Process 3	Process 4
Lowest exposure level (value, unit)				
Highest exposure level (value, unit)				
Mean exposure level (Arithmetic mean; value, unit)				
Median exposure level (value, unit)				
95th percentile exposure level (value, unit)				
Number of samples (n)				
Year of monitoring				
B13) Please select the sampling method followed	◯ Stationary sampling ◯ Personal sampling ◯ Personal sampling of inhalation air inside the RPE	◯ Stationary sampling ◯ Personal sampling ◯ Personal sampling of inhalation air inside the RPE	◯ Stationary sampling ◯ Personal sampling ◯ Personal sampling of inhalation air inside the RPE	◯ Stationary sampling ◯ Personal sampling ◯ Personal sampling of inhalation air inside the RPE
B14) Are the workers wearing respiratory protective equipment (RPE) during the activity?	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No

B15) Please indicate the standard/analytical method followed	Air - DFG (German Research Foundation) Air - NIOSH 1602 Other	Air - DFG (German Research Foundation) Air - NIOSH 1602 Other	Air - DFG (German Research Foundation) Air - NIOSH 1602 Other	Air - DFG (German Research Foundation) Air - NIOSH 1602 Other
B16) If you answered ‘other’ to B15, please specify				
B17) If you have other exposure data for short term peak exposures other than for a 15 minute period, please specify type of value and the air exposure concentration	Type of value (value, unit)	Type of value (value, unit)	Type of value (value, unit)	Type of value (value, unit)

B18) Please provide information about any activities that lead to high short term exposure?

Biomonitoring

B19) Please provide data for HEAA in urine/g Creatinine at the end of exposure or shift from your most recent measurements

	Process 1	Process 2	Process 3	Process 4
Lowest exposure level (value, unit)				
Highest exposure level (value, unit)				
Mean exposure level (Arithmetic mean; value, unit)				
Median exposure level (value, unit)				
95th percentile exposure level (value, unit)				
Number of samples (n)				
Year of monitoring				

B20) Please provide more detail on monitoring campaign

B21) If you have any data relevant to biomonitoring other than HEAA in urine/g Creatinine at the end of the exposure or shift, please provide it below.

Type of value (value, unit):

B22) Do you have any other information on exposure to this substance at your facility?

If you are happy to provide more detailed information about numbers of workers exposed, exposure levels and/or further processes, please email this to OELs6@rpaltd.co.uk

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B23) Which Risk Management Measures are in place to control exposure of 1,4-dioxane in the different processes at this facility? Please tick all that you use.

	Process 1	Process 2	Process 3	Process 4
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐
Closed systems	☐	☐	☐	☐
Partial hood enclosures	☐	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐

Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐	☐
Half and full facemasks (negative pressure respirators)	☐	☐	☐	☐
Disposable respirators (FFP masks)	☐	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐	☐
Goggles	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐
Training and education	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement of air concentrations to detect unusual exposures	☐	☐	☐	☐
Creating a culture of safety	☐	☐	☐	☐
Partial substitution of 1,4-dioxane used in this activity in the past	☐	☐	☐	☐
Discontinuation of part of the activity using 1,4-dioxane	☐	☐	☐	☐
PPE is essential regardless of the OEL	☐	☐	☐	☐
Other	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

B24) Could there be co-exposure from 1,4-dioxane and any of these substances or processes at this facility? Please tick all that apply.

	Select
Polycyclic aromatic hydrocarbons	☐
Cobalt substances under the CMRD	☐
Isoprene	☐
Perform welding	☐

B25) Is your company making any investments not directly related to exposure to 1,4-dioxane that are likely to lead to a reduction in exposure to 1,4-dioxane?

at most 1 answered row(s)

	Select
Investments are being made that will significantly reduce exposure to 1,4-dioxane	☐
Investments are being made that may reduce exposure to 1,4-dioxane	☐
No investments are planned that will reduce exposure to 1,4-dioxane	☐
Don’t know	☐

B26) If any investments are being made in question B25, what are the investments for? Please tick all that apply.

	Select
Compliance with other OELs (please specify which)	☐
Improved risk management measures being implemented alongside other improvements to production facilities	☐
New or improved production facilities that will remove from or reduce exposure to worker	☐
Other, please specify	☐

Compliance with other OELs, please specify

Other, please specify

B27) When will the reduction in worker exposure take effect?

at most 1 answered row(s)

	Select

By the end of 2024	☐
By the end of 2029	☐
By the end of 2034	☐

C) What are the lowest exposure levels that you could achieve

8 - Hour TWA

	Value	Unit
C1) What do you think is the *lowest technically possible* 8 hour TWA air concentration that can be achieved in this facility? (Please specify the units, preferably in mg/m³)		
C2) What do you think is the *lowest economically* feasible 8 hour TWA air concentration that can be achieved in this facility? (Please specify the units, preferably in mg/m³)		

C3) Any comments on above answers?

C4) Do you have to comply with the European Workplace exposure standard EN 689?

- Yes
- No
- Don't know

15 minute peaks

	Value	Unit
C5) What do you think is the *lowest technically possible* 15 minute air concentration that can be achieved in this facility? (Please specify the units, preferably in mg/m³)		
C6) What do you think is the *lowest economically feasible* 15 minute air concentration that can be achieved in this facility? (Please specify the units, preferably in mg/m³)		

C7) Any comments on above answers?

Biological Limit Values

	Value	Unit
C8) What do you think is the *lowest technically* possible HEAA in urine/g Creatinine at the end of exposure or shift for all your workers that can be achieved in this facility?		
C9) What do you think is the *lowest economically* feasible HEAA in urine/g Creatinine at the end of exposure or shift for all your workers that can be achieved in this facility?		

C10) Any comments on above answers?

D) Compliance with a potential new OEL under the CMRD

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

The following limit values and air concentrations given below are used as policy options for this questionnaire.

Policy Options	**1,4-dioxane**
Policy option 1 (current IOELV in the CAD)	73 mg/m³ (20 ppm)
Policy option 2 (Median of national OELs)	36 mg/m³ (10 ppm)
Policy option 3 (Lowest national OEL)	20 mg/m³ (5.5 ppm)
Policy option 4 (based on RAC)	7.3 mg/m³ (2 ppm)

D1) If the OEL was 73 mg/m³ (20 ppm), which *additional* RMMs would be the most important in helping you to achieve this?

	Process 1	Process 2	Process 3	Process 4
No action required as OEL already achieved	☐	☐	☐	☐
Substitution of substance	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐
Closed systems	☐	☐	☐	☐
Partial hood enclosures	☐	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐	☐
Half and full facemasks (negative pressure respirators)	☐	☐	☐	☐
Disposable respirators (FFP masks)	☐	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐	☐
Goggles	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐
Training and education	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐

Continuous measurement of air concentrations to detect unusual exposures				
Creating a culture of safety				
Other				

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

D2) What is your estimated range of initial investment costs for additional RMMs required at this facility to achieve an OEL of 73 mg/m³ (20 ppm)?

- < €10,000
- €10,000 - €100,000
- €100,000 - €1 million
- > €1 million

D3) What is your estimated range of annual recurrent costs for additional RMMs required at this facility to achieve an OEL of 73 mg/m³ (20 ppm)?

- < €1,000
- €1,000 - €10,000
- €10,000 - €100,000
- > €100,000

D4) If the OEL was 36 mg/m³ (10 ppm), which additional RMMs would be the most important in helping you to achieve this?

	Process 1	Process 2	Process 3	Process 4
No action required as OEL already achieved	☐	☐	☐	☐
Substitution of substance	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐
Closed systems	☐	☐	☐	☐
Partial hood enclosures	☐	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐	☐
Half and full facemasks (negative pressure respirators)	☐	☐	☐	☐

Disposable respirators (FFP masks)	☐	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐	☐
Goggles	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐
Training and education	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement of air concentrations to detect unusual exposures	☐	☐	☐	☐
Creating a culture of safety	☐	☐	☐	☐
Other	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

D5) What is your estimated range of <u>initial investment costs</u> for additional RMMs required at this facility to achieve an OEL of 36 mg/m³ (10 ppm)?

- < €10,000
- €10,000 - €100,000
- €100,000 - €1 million
- > €1 million

D6) What is your estimated range of <u>annual recurrent costs</u> for additional RMMs required at this facility to achieve an OEL of 36 mg/m³ (10 ppm)?

- < €1,000
- €1,000 - €10,000
- €10,000 - €100,000
- > €100,000

D7) If the OEL was 20 mg/m³ (5.5 ppm), which additional RMMs would be the most important in helping you to achieve this?

	Process 1	Process 2	Process 3	Process 4
No action required as OEL already achieved	☐	☐	☐	☐
Substitution of substance	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐
Closed systems	☐	☐	☐	☐
Partial hood enclosures	☐	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐	☐
Half and full facemasks (negative pressure respirators)	☐	☐	☐	☐

Disposable respirators (FFP masks)	☐	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐	☐
Goggles	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐
Training and education	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Measures for workers’ personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement of air concentrations to detect unusual exposures	☐	☐	☐	☐
Creating a culture of safety	☐	☐	☐	☐
Other	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

D8) What is your estimated range of initial investment costs for additional RMMs required at this facility to achieve an OEL of 20 mg/m³ (5.5 ppm)?

- < €10,000
- €10,000 - €100,000
- €100,000 - €1 million
- > €1 million

D9) What is your estimated range of annual recurrent costs for additional RMMs required at this facility to achieve an OEL of 20 mg/m³ (5.5 ppm)?

- < €1,000
- €1,000 - €10,000
- €10,000 - €100,000
- > €100,000

D10) If the OEL was 7.3 mg/m³ (2 ppm), which additional RMMs would be the most important in helping you to achieve this?

	Process 1	Process 2	Process 3	Process 4
No action required as OEL already achieved	☐	☐	☐	☐
Substitution of substance	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐
Closed systems	☐	☐	☐	☐
Partial hood enclosures	☐	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐	☐
Half and full facemasks (negative pressure respirators)	☐	☐	☐	☐

Disposable respirators (FFP masks)	☐	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐	☐
Goggles	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐
Training and education	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement of air concentrations to detect unusual exposures	☐	☐	☐	☐
Creating a culture of safety	☐	☐	☐	☐
Other	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

D11) What is your estimated range of <u>initial investment costs</u> for additional RMMs required at this facility to achieve an OEL of 7.3 mg/m³ (2 ppm)?

- < €10,000
- €10,000 - €100,000
- €100,000 - €1 million
- > €1 million

D12) What is your estimated range of <u>annual recurrent costs</u> for additional RMMs required at this facility to achieve an OEL of 7.3 mg/m³ (2 ppm)?

- < €1,000
- €1,000 - €10,000
- €10,000 - €100,000
- > €100,000

D13) Would the level of costs as incurred by the lowest policy option of OEL of 7.3 mg/m³ (2 ppm) affect the competitiveness of your company?

Competitors in EU	Significant positive impact Moderate positive impact Limited/no impact Moderate negative impact Significant negative impact
Competitors outside of EU	Significant positive impact Moderate positive impact Limited/no impact Moderate negative impact Significant negative impact

D14) Any other comments on this section?

E) Compliance with a potential new STEL under the CMRD

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

The following limit values and air concentrations given below are used as policy options for this questionnaire.

Policy Options	**1,4-dioxane**

Policy Option 1 Highest STEL in an EU Member State (Finland), also 146 mg/m³ in Austria, Germany, Slovenia and 140 mg/m³ in the Czech Republic and France	150 mg/m³ (40 ppm)
Policy Option 2 Intermediate level at the mid point between 90 mg/m³ and 150 mg/m³	120 mg/m³ (33 ppm)
Policy Option 3 Intermediate value, selected due to the fact that two Member States (Lithuania and Sweden) have a STEL of 90 mg/m³	90 mg/m³ (25 ppm)
Policy Option 4 RAC recommendation, also close to the lowest national STEL (72 mg/m³ in Denmark)	73 mg/m³ (20 ppm)

E1) If the STEL was 150 mg/m³ (40 ppm), which *additional* RMMs would be the most important in helping you to achieve this?

	Process 1	Process 2	Process 3	Process 4
No action required as STEL already achieved	☐	☐	☐	☐
Substitution of substance	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐
Closed systems	☐	☐	☐	☐
Partial hood enclosures	☐	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐	☐
Half and full facemasks (negative pressure respirators)	☐	☐	☐	☐
Disposable respirators (FFP masks)	☐	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐	☐
Goggles	☐	☐	☐	☐

Gloves	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐
Training and education	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement of air concentrations to detect unusual exposures	☐	☐	☐	☐
Creating a culture of safety	☐	☐	☐	☐
Other	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

E2) What is your estimated range of initial investment costs for additional RMMs required at this facility to achieve an STEL with 150 mg/m³ (40 ppm)?

- < €10,000
- €10,000 - €100,000
- €100,000 - €1 million
- > €1 million

E3) If the STEL was 120 mg/m³ (33 ppm), which *additional* RMMs would be the most important in helping you to achieve this?

	Process 1	Process 2	Process 3	Process 4
No action required as STEL already achieved	☐	☐	☐	☐
Substitution of substance	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐
Closed systems	☐	☐	☐	☐
Partial hood enclosures	☐	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐	☐
Half and full facemasks (negative pressure respirators)	☐	☐	☐	☐
Disposable respirators (FFP masks)	☐	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐	☐
Goggles	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐

Training and education	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement of air concentrations to detect unusual exposures	☐	☐	☐	☐
Creating a culture of safety	☐	☐	☐	☐
Other	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

E4) What is your estimated range of initial investment costs for additional RMMs required at this facility to achieve an STEL with 120 mg/m³ (33 ppm)?

- ○ < €10,000
- ○ €10,000 - €100,000
- ○ €100,000 - €1 million
- ○ > €1 million

E5) If the STEL was 90 mg/m³ (25 ppm), which *additional* RMMs would be the most important in helping you to achieve this?

	Process 1	Process 2	Process 3	Process 4
No action required as STEL already achieved	☐	☐	☐	☐
Substitution of substance	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐
Closed systems	☐	☐	☐	☐
Partial hood enclosures	☐	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐	☐
Half and full facemasks (negative pressure respirators)	☐	☐	☐	☐
Disposable respirators (FFP masks)	☐	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐	☐
Goggles	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐

Training and education	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement of air concentrations to detect unusual exposures	☐	☐	☐	☐
Creating a culture of safety	☐	☐	☐	☐
Other	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

E6) What is your estimated range of initial investment costs for additional RMMs required at this facility to achieve a STEL with 90 mg/m³ (25 ppm)?

- < €10,000
- €10,000 - €100,000
- €100,000 - €1 million
- > €1 million

E7) If the STEL was 73 mg/m³ (20 ppm), which *additional* RMMs would be the most important in helping you to achieve this?

	Process 1	Process 2	Process 3	Process 4
No action required as STEL already achieved	☐	☐	☐	☐
Substitution of substance	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐
Closed systems	☐	☐	☐	☐
Partial hood enclosures	☐	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐	☐
Half and full facemasks (negative pressure respirators)	☐	☐	☐	☐
Disposable respirators (FFP masks)	☐	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐	☐
Goggles	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐

Training and education	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement of air concentrations to detect unusual exposures	☐	☐	☐	☐
Creating a culture of safety	☐	☐	☐	☐
Other	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

E8) What is your estimated range of initial investment costs for additional RMMs required at this facility to achieve a STEL with 73 mg/m³ (20 ppm)?

- < €10,000
- €10,000 - €100,000
- €100,000 - €1 million
- > €1 million

E9) Would the level of costs as incurred by the lowest policy option of STEL with 73 mg/m³ (20 ppm) affect the competitiveness of your company?

Competitors in EU	Significant positive impact Moderate positive impact Limited/no impact Moderate negative impact Significant negative impact
Competitors outside of EU	Significant positive impact Moderate positive impact Limited/no impact Moderate negative impact Significant negative impact

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E10) Any other comments on this section?

F) Compliance with a potential new BLV under the CMRD

This section considers the Risk Management Measures (RMMs) that would have to be put in place to comply with a new BLV under the CMRD.

If your answers are the same as for the corresponding OEL policy options, please tick this box and skip to section G.

- Answers are the same

The following limit values and air concentrations given below are used as policy options for this questionnaire.

Policy Options	**HEAA in urine/g Creatinine, at the end of exposure or shift**
Policy Option 1	366 mg

(Corresponds to an OEL of 73 mg/m³)	
Policy Option 2 (Corresponds to an OEL of 36 mg/m³)	188 mg
Policy Option 3 (Corresponds to an OEL of 20 mg/m³)	108 mg
Policy Option 4 (Corresponds to an OEL of 7.3 mg/m³ and is the RAC's recommendation)	45 mg

F1) If the BLV was 366 mg , which *additional* RMMs would be the most important in helping you to achieve this?

	Process 1	Process 2	Process 3	Process 4
No action required as BLV already achieved	☐	☐	☐	☐
Substitution of substance	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐
Closed systems	☐	☐	☐	☐
Partial hood enclosures	☐	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐	☐
Half and full facemasks (negative pressure respirators)	☐	☐	☐	☐
Disposable respirators (FFP masks)	☐	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐	☐
Goggles	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐

Training and education	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement of air concentrations to detect unusual exposures	☐	☐	☐	☐
Creating a culture of safety	☐	☐	☐	☐
Other	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

F2) What is your estimated range of initial investment costs for additional RMMs required at this facility to achieve a BLV of 366mg?

- < €10,000
- €10,000 - €100,000
- €100,000 - €1 million
- > €1 million

F3) If the BLV was 188 mg, which *additional* RMMs would be the most important in helping you to achieve this?

	Process 1	Process 2	Process 3	Process 4
No action required as STEL already achieved	☐	☐	☐	☐
Substitution of substance	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐
Closed systems	☐	☐	☐	☐
Partial hood enclosures	☐	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐	☐
Half and full facemasks (negative pressure respirators)	☐	☐	☐	☐
Disposable respirators (FFP masks)	☐	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐	☐
Goggles	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐

Training and education	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement of air concentrations to detect unusual exposures	☐	☐	☐	☐
Creating a culture of safety	☐	☐	☐	☐
Other	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

F4) What is your estimated range of <u>initial investment costs</u> for additional RMMs required at this facility to achieve a BLV of 188mg?

- < €10,000
- €10,000 - €100,000
- €100,000 - €1 million
- > €1 million

F5) If the BLV was 108 mg, which *additional* RMMs would be the most important in helping you to achieve this?

	Process 1	Process 2	Process 3	Process 4
No action required as STEL already achieved	☐	☐	☐	☐
Substitution of substance	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐
Closed systems	☐	☐	☐	☐
Partial hood enclosures	☐	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐	☐
Half and full facemasks (negative pressure respirators)	☐	☐	☐	☐
Disposable respirators (FFP masks)	☐	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐	☐
Goggles	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐

Training and education	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement of air concentrations to detect unusual exposures	☐	☐	☐	☐
Creating a culture of safety	☐	☐	☐	☐
Other	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

F6) What is your estimated range of initial investment costs for additional RMMs required at this facility to achieve a BLV of 108mg?

- ◯ < €10,000
- ◯ €10,000 - €100,000
- ◯ €100,000 - €1 million
- ◯ > €1 million

F7) If the BLV was 45 mg, which *additional* RMMs would be the most important in helping you to achieve this?

	Process 1	Process 2	Process 3	Process 4
No action required as STEL already achieved	☐	☐	☐	☐
Substitution of substance	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐
Closed systems	☐	☐	☐	☐
Partial hood enclosures	☐	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐	☐
Half and full facemasks (negative pressure respirators)	☐	☐	☐	☐
Disposable respirators (FFP masks)	☐	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐	☐
Goggles	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐

Training and education	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement of air concentrations to detect unusual exposures	☐	☐	☐	☐
Creating a culture of safety	☐	☐	☐	☐
Other	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

F8) What is your estimated range of *initial investment costs* for additional RMMs required at this facility to achieve a BLV of 45mg?

- < €10,000
- €10,000 - €100,000
- €100,000 - €1 million
- > €1 million

F9) Would the level of costs as incurred by the lowest policy option of BLV of 45mg affect the competitiveness of your company?

Competitors in EU	Significant positive impact Moderate positive impact Limited/no impact Moderate negative impact Significant negative impact
Competitors outside of EU	Significant positive impact Moderate positive impact Limited/no impact Moderate negative impact Significant negative impact

F10) Any other comments on this section?

G) Compliance with a potential skin notation under CMRD

This section considers the Risk Management Measures (RMMs) that would have to be put in place to comply with a new skin notation under the CMRD.

G1) If a skin notation were introduced under the CMRD, which *additional* RMMs would be the most important in helping you to reduce dermal exposure?

	Process 1	Process 2	Process 3	Process 4
No action required	☐	☐	☐	☐
Substitution of substance	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐

Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐
Closed systems	☐	☐	☐	☐
Control cabs	☐	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Training and education	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Creating a culture of safety	☐	☐	☐	☐
Other	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

G2) What is your estimated range of initial investment costs for additional RMMs required at this facility to reduce dermal exposure?

- < €10,000
- €10,000 - €100,000
- €100,000 - €1 million
- > €1 million

G3) Any other comments on this section?

H) Indirect benefits

This question aims to capture indirect benefits that may arise for your company, should an EU-wide OEL be introduced for 1,4-dioxane.

H1) Do you think your company will benefit from any of these indirect benefits if an EU-wide OEL for 1,4 -dioxane is introduced? Please tick all that apply.

	Select
Healthier staff	
Increased productivity of workers	
Improved public image	
Easier to recruit staff	
Easier to retain staff	
Reduced cost of recruitment	
Easier monitoring of exposure	
Savings because company currently has multiple locations in different Member States with different regulations or OELs	
Level playing field with EU competitors	
Other indirect benefits, please specify	
There will be no indirect benefits	

If other, please specify

l) Is your company working towards voluntary industry targets?

Voluntary Industry Targets

	Response
I1) Is your company trying to meet voluntary industry targets? If yes, please specify the targets (concentration, units)	
I2) What are the main challenges in meeting the voluntary targets?	
I3) Have you made any assessment of the possible costs of meeting the voluntary targets? If yes, please provide information on costs and cost structure.	

J) Any other comments

J1) Do you have any other comments relevant to this study that you would like to make?

K) Further communication

K1) Please tick if you are happy for the study team to contact you for further clarification or discussion about your responses?

- Yes
- No

K2) Please tick if you would be willing to host a site visit for the study team at this facility. This can be carried out under a non-disclosure agreement.

- Yes
- No

K3) If you prefer this contact to be via a different email or phone number from those you provided at the start of the questionnaire, please provide the details here.

Thank you for your answers!

16.4 Annex 4: Overview of limit values in Member States

The existing limit values for 1,4-dioxane are shown in the tables below.

Table 16-15 OELs and STELs in EU Member States and selected non-EU countries for 1,4-dioxane

Country	OEL (mg/m³)	Specification of OEL	STEL (mg/m³)	Specification of STEL
Austria [1,2,3]	73 *	- Carc, Sk	146 *	- Momentary value, Carc, Sk
Belgium [1,2,4]	73 **	- Sk	-	
Bulgaria [5]	73 **		20 **	
Croatia [6]	73 **		-	
Cyprus [7]	73 **		-	
Czechia [8]	70 *	- Sk	140 *	- Sk
Denmark [1,2,9]	36 (T) [&] **	- Carc, Sk	72 (T) [&] **	- 15 min average value, Carc, Sk
Estonia [10]	73 *		-	
Finland [1,2,11]	36 (I) [&] ^^	- Sk	150 (I) [&] ^^	- 15 min average value, Sk
France [1,2,12]	73 *	- Restrictive statutory limit values, Carc	140 ^	- Carc
Germany [1,2,13]	73 *	- Sk	146 *	- 15 min average value, Sk
Greece [14]	73 *		-	
Hungary [1,15]	73 *	- Sk	-	
Ireland [1,2,16]	73 ^^	- Sk	-	
Italy [1,17]	73 **	- Sk	-	
Latvia [1,2,18]	20 **		-	
Lithuania [19]	35 **	- Carc	90 **	- Carc
Luxembourg [20]	73 ***		-	
Malta [21]	73 [%]		-	
Netherlands [1,22]	20 (T) [&] **		-	

Country	OEL (mg/m³)	Specification of OEL	STEL (mg/m³)	Specification of STEL
Poland [1,2,23]	50 (V) & **		-	
Portugal [24]	73 ^		-	
Romania [1,2,25]	73 *	- Carc, Sk	-	
Slovakia [27]	73 **		-	
Slovenia [27]	73 **	- Sk	146 **	- Sk
Spain [1,2,28]	73 **	- Carc, Sk	-	
Sweden [1,2,29]	35 **	- Carc	90 ^^	- 15 min average value, Carc
European Union [1,2,30]	73	- IOELV	-	
RAC [2]	7.3	- Sk	73	- Sk
EU candidate counties				
Albania [46]	73 ^	- Sk	20 ^	- Sk
Bosnia and Her-zegovina [47]	-		-	
Georgia [48]	-		-	
Moldova [49]	73 *		10 *	
Montenegro [50]	-		-	
North Macedonia [51]	73 *	- Carc, Sk	-	
Serbia [52]	73 *		-	
Turkey [1,41]	73 %		-	
Ukraine [53]	-		-	
Other countries				
Australia [1,31]	36 ***	- Carc, Sk	-	
Brazil [32]	-		-	

Country	OEL (mg/m³)	Specification of OEL	STEL (mg/m³)	Specification of STEL
Canada, Ontario [1,33]	20 ***	- value only given in ppm	-	
Canada, Québec [1,34]	72 ***	- Carc, Sk	-	
China	-		-	
India [35]	-		-	
Japan, MHLW [1,36]	10 ***	- value only given in ppm	-	
Japan, JOSH [1,37]	3.6 ^^^	- Carc, Sk	-	
Norway [1,2,38]	18 (T) [&] ^^	- Carc, Sk	36 (T) [&] ^^	- 15 min average value, Sk
Russia [39]	10 (V) [%]		-	
South Korea [1]	20 [%]	- value only given in ppm, Sk	-	
Switzerland [1,2,40]	72 *	- Carc, Sk	144 *	- Carc, Sk
United Kingdom [1,2,42]	73 *	- Sk	-	
USA, ACGIH [43]	20 ^	- value only given in ppm, Carc, Sk	-	
USA, NIOSH [1,2,44]	-		3.6	- ceiling limit value (30 min), Carc
USA, OSHA [1,2,45]	360 *	- Sk	-	

Notes:
RAC = Committee for Risk Assessment
MHLW = Ministry of Health, Labour and Welfare
JSOH = Japan Society for Occupational Health
ACGIH = American Conference of Governmental Industrial Hygienists
NIOSH = National Institute for Occupational Safety and Health
OSHA = Occupational Safety and Health Administration
(V) = vapour
** Binding value according to country-specific source*
*** Binding value according to reply of member state authority on questionnaire*

Country	OEL (mg/m³)	Specification of OEL	STEL (mg/m³)	Specification of STEL

**** Binding value according to the Final report for OEL/STEL deriving systems from 2018 (Available at: https://bit.ly/3PKDhbS, accessed on 05.07.2023). Status was not checked since 2018.*
^ Indicative value according to country-specific source
^^ Indicative value according to reply of member state authority on questionnaire
^^^ Indicative value according to the Final report for OEL/STEL deriving systems from 2018 (Available at: https://bit.ly/3PKDhbS, accessed on 05.07.2023). Status was not checked since 2018.
% According to (country-specific source) unclear if value is binding or indicative
& Information according to reply of member state authority on questionnaire
Carc = notation for carcinogenicity
Sk = skin notation assigned or danger of skin absorption
- no value available

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Country	OEL (mg/m³)	Specification of OEL	STEL (mg/m³)	Specification of STEL

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18: Latvia (2022) List of limit values. Available at: https://likumi.lv/doc.php?id=157382&from=off, accessed on 06.12.2022
19: Lithuania (2022) List of limit values. Available at: https://www.e-tar.lt/portal/lt/legalAct/TAR.8012ED3EA143/asr, accessed on 06.12.2022
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21: Malta (2021) List of limit values. Available at: https://legislation.mt/eli/sl/424.24/eng/pdf, accessed on 06.12.2022
22: Netherlands (2022) List of limit values. Available at: https://wetten.overheid.nl/BWBR0008587/2022-07-01#BijlageXIII, accessed on 06.12.2022
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Country	OEL (mg/m³)	Specification of OEL	STEL (mg/m³)	Specification of STEL

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Country	OEL (mg/m³)	Specification of OEL	STEL (mg/m³)	Specification of STEL
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Table 16-16 BLVs in EU Member States and selected non-EU countries for 1,4-dioxane

Country	1,4-Dioxane in urine	Specification
Germany [1,2]	200 mg/g creatinine	"Biologischer Grenzwert" biological limit value at workplace; Parameter analysed 2-Hydroxyethoxyacetic acid; Sampling time for long-term exposure: at the end of the shift after several shifts
Slovenia [3]	400 mg 2-Hydroxyethoxyacetic acid/g creatinine	Parameter analysed 2-Hydroxyethoxyacetic acid; Sampling time: at the end of the work shift
RAC [1]	45 mg 2-hydroxyethoxyacetic acid/g creatinine	Parameter analysed 2-Hydroxyethoxyacetic acid; Sampling time: at the end of exposure or end of shift
Non-EU countries		
Switzerland [4]	400 mg 2-Hydroxyethoxyacetic acid/g creatinine	Parameter analysed 2-Hydroxyethoxyacetic acid; Sampling time: at the end of the work shift or end of exposure
RAC = Committee for Risk Assessment Sources: 1: RAC, Committee for Risk Assessment (2022) ANNEX 1 in support of the Committee for Risk Assessment (RAC) for evaluation of limit values for 1,4-dioxane at the workplace. European Chemicals Agency (ECHA), Helsinki, Finland. Available at: https://echa.europa.eu/documents/10162/073d44ca-5ad2-8128-fd15-8c74a4bdb126, accessed on 05.01.2023		

Country	1,4-Dioxane in urine	Specification
2: Germany (2022) TRGS 903. Available at: https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/TRGS-903.html, accessed on 15.02.2023 *3: Slovenia (2021) List of limit values. Available at: http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV14252, accessed on 07.12.2022* *4: Switzerland (2022) List of limit values. Available at: https://www.suva.ch/de-ch/services/grenzwerte#gnw-location=%2F, accessed on 10.12.2022*		

16.5 Annex 5: Relevant sectors

Table 16-17 Analysed sectors with risk of exposure to 1,4-dioxane

NACE code	Short name for sector	NACE full name
N/A	Manufacture of 1,4-dioxane	Part of C20.1 Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms
C21.1 and C21.2	Pharmaceutical production (intentional use)	C21.1 Manufacture of basic pharmaceutical products C21.2 Manufacture of pharmaceutical preparations
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as a by-product in the chemicals sector	C20.1Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics C20.5 Manufacture of other chemical products
M72.1	Laboratories (intentional use as a solvent)	M72.1 Research and experimental development on natural sciences and engineering
C20.4 excl. C20.42	Surfactants – presence as a minor constituent/impurity in the production of detergents, soaps, etc.	C20.4 Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations, excluding C20.42 Manufacture of perfumes and toilet preparations
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	C20.42 Manufacture of perfumes and toilet preparations

Source: Study team.

16.6 Annex 6: Consistency and synergies of establishing OELs under the CMRD

In addition to the CMRD, 1,4-dioxane is also subject to other EU legislation, including Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1223/2009 (Cosmetic Products Regulation).

In 2021, 1,4-dioxane was included in the Substances of Very High Concern (SVHC) Candidate List for Authorisation1 according to REACH Art. 57 (a) and 57 (f),2 with this triggering substitution and information requirements. In addition, a recent call for evidence by the German Federal Institute for Occupational Safety and Health (BAuA) (open until 20 July 2023) suggests that a potential Annex XV restriction on the manufacture, placing on the market and use of 1,4-dioxane in surfactants is under consideration; this appears to be motivated by the need to prevent environmental emissions of 1,4-dioxane.

1,4-dioxane is listed in Annex II of Regulation (EC) No 1223/2009 on cosmetic products (substances prohibited in cosmetic products).

An OEL under the CMRD for 1,4-dioxane has the potential to complement existing and potential future measures under REACH and the Cosmetics Regulation that target environmental and consumer exposure by establishing a high level of worker protection.

16.7 Annex 7: 1,4-dioxane – kidney effects

Analysis name: BMDL10-Kidney_Kasai,2009
This report was generated by **Anonymous** on **2/26/2023 12:04:14 PM (CET)**. PROAST version 70.1

Input values

Removed data
No

Type of response data
Quantal

Dose column(s)
Concentration [ppm]

Response column(s)
Response kidney

Group size column(s)
n

Covariate column
none

Litter effect
No

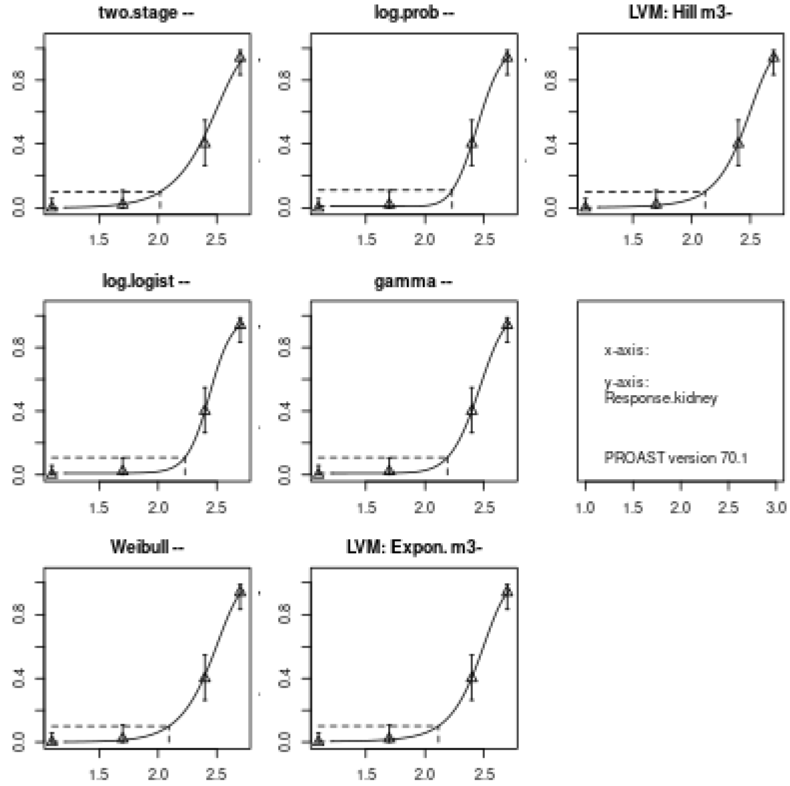
BMR (CES)
0.1

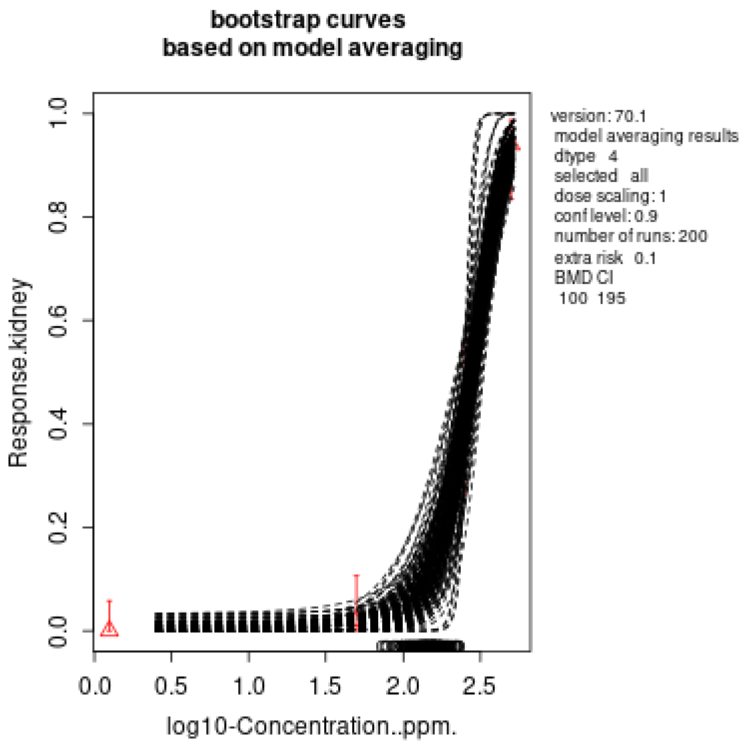
Model averaging
Yes

Number of bootstrap runs
200

AIC criterion
2

Graphical output





Fitted models

model	No.par	loglik	AIC	accepted	BMDL	BMDU	BMD	conv
null	1	-128.21	258.42	NA	NA	NA	NA	NA
full	4	-49.9	107.8	NA	NA	NA	NA	NA
two.stage	3	-50.5	107	yes	79.1	117	104	yes
log.logist	3	-50.58	107.16	yes	122	200	169	yes
Weibull	3	-50.04	106.08	yes	88.7	166	124	yes
log.prob	3	-50.6	107.2	yes	128	200	170	yes
gamma	3	-50.57	107.14	yes	93.1	192	155	yes
LVM: Expon.m3 -	3	-49.99	105.98	yes	92.7	166	130	yes
LVM: Hill m3 -	3	-49.99	105.98	yes	92.8	166	130	yes

Model weights

model	weight
two.stage	0.1153
log.logist	0.1064
Weibull	0.1826
log.prob	0.1043
gamma	0.1075
EXP	0.192
HILL	0.192

BMD confidence interval based on model averaging

BMDL	BMDU
101	195

16.8 Annex 8: 1,4-dioxane – liver effects

Analysis name: BMDL10-Liver_Kasai,2009
This report was generated by **Anonymous** on **2/23/2023 2:00:16 PM (CET)**. PROAST version 70.1

Input values
Removed data

No

Type of response data

Quantal

Dose column(s)

Concentration [ppm]

Response column(s)

Response liver

Group size column(s)

n

Covariate column

none

Litter effect

No

BMR (CES)

0.1

Model averaging

Yes

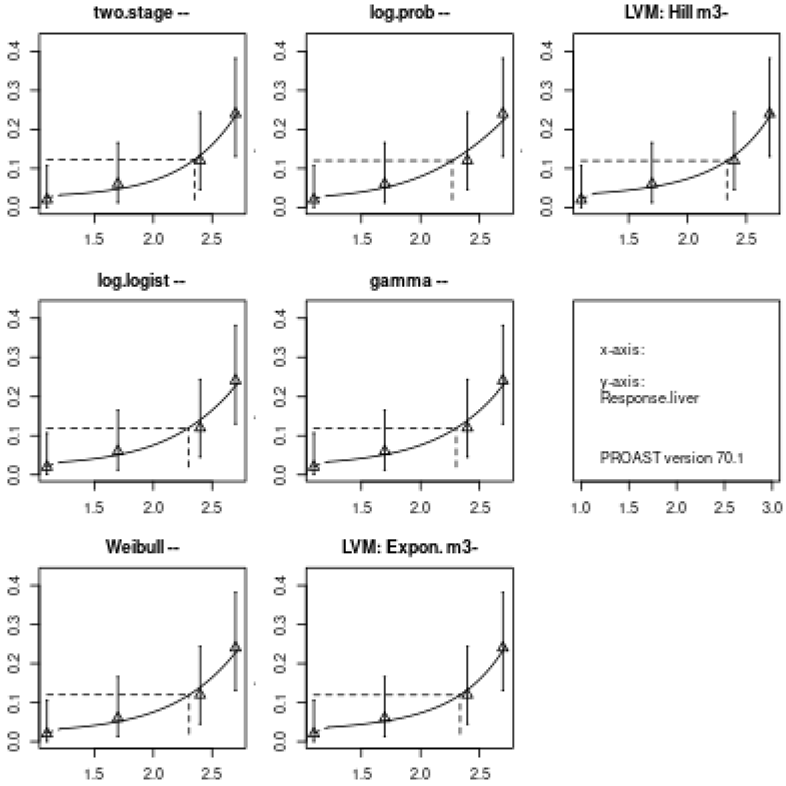
Number of bootstrap runs

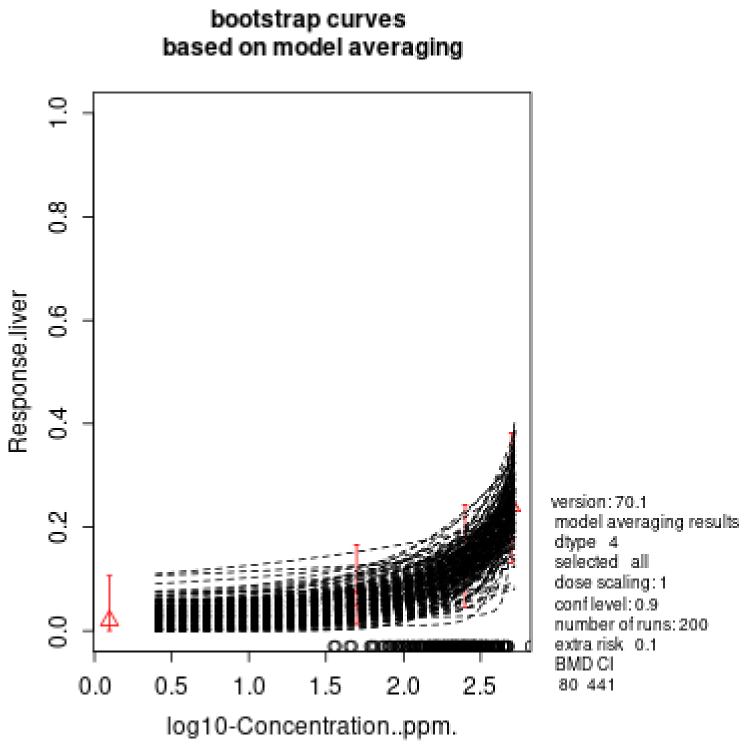
200

AIC criterion

2

Graphical output





Fitted models

model	No.par	loglik	AIC	accepted	BMDL	BMDU	BMD	conv
null	1	-69.3	140.6	NA	NA	NA	NA	NA
full	4	-62.15	132.3	NA	NA	NA	NA	NA
two.stage	3	-62.31	130.62	yes	143	423	225	yes
log.logist	3	-62.31	130.62	yes	52.6	421	199	yes
Weibull	3	-62.29	130.58	yes	52.8	421	202	yes
log.prob	3	-62.38	130.76	yes	50	421	186	yes
gamma	3	-62.29	130.58	yes	52.5	418	201	yes
LVM: Expon. m3-	3	-62.22	130.44	yes	62.6	424	217	yes
LVM: Hill m3-	3	-62.23	130.46	yes	55.1	425	217	yes

Model weights

model	weight
two.stage	0.1399
log.logist	0.1399
Weibull	0.1427
log.prob	0.1304
gamma	0.1427
EXP	0.153
HILL	0.1515

BMD confidence interval based on model averaging

BMDL	BMDU
80	441

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