Study on collecting information on substances with the view to analyse health, socio-economic and environmental impacts in connection with possible amendments of Directive 98/24/EC (Chemical Agents) and Directive 2009/148/EC (Asbestos)

Final report for diisocyanates

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September – 2021

EUROPEAN COMMISSION

Directorate-General for Employment Social Affairs and Inclusion

Directorate Employment

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Manuscript completed in September 2021

PDF ISBN 978-92-76-41922-8 doi: 10.2767/96672 KE-01-21-289-EN-N

Luxembourg: Publications Office of the European Union, 2021

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List of abbreviations and acronyms

ACGIH	American Conference for Governmental Industrial Hygienists
ACSH	Advisory Committee of Safety and Health at Work
AfA	Application for Authorisation
AGS	Committee for Hazardous Substances (Ausschuss für Gefahrstoffe)
ALIPA	European Aliphatic Isocyanates Producers Association
Anses	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (National Agency for Food Safety, Environment and Labor, France)
ASA	ASA register (of occupational exposure hazards and procedures in Finland)
AWD	Asbestos at Work Directive
BAT	Best Available Technique
BEI	Biological Exposure Indices
BGV	Biological Guidance Value
BHR20	Bronchial hyperresponsiveness using a fall in forced expiratory volume in one second (FEV1) of 20% as a cut-off level
BLV	Biological Limit Value
BOEL	Binding Occupational Exposure Limits
BREF	Best available techniques reference document
CAREX	Carcinogen Exposure
CAD	Chemical Agents Directive
CAS	Chemicals Abstracts Service
CASE	Coatings Adhesives Sealants Elastomers
CBA	Cost Benefits Analysis
CEA	Cost Effectiveness Analysis
CEFIC	European Chemical Industry Council
CEN	European Committee of Standardization

CLH	Harmonised Classification and Labelling
CLP	Classification, Labelling and Packaging
CLND	Chemiluminescent nitrogen detection
C&L	Classification and Labelling Inventory
CMD	The Carcinogens and Mutagens Directive
CMR	Carcinogenic, Mutagenic, or Reprotoxic
COLCHIC	Occupational exposure to chemical agents database
CSR	Chemical Safety Report
DAD	Diode array detector
DALY	Disability Adjusted Life Years
DEPA	Danish Environmental Protection Agency
DFR	Draft Final Report
DG	Directorate General
DRR	Dose Response Relationship
EC	European Commission
EC	Electrochemical detection
ECHA	European Chemicals Agency
EEA	European Economic Area
EEA	European Environment Agency
EPRD	Office for Economic Policy and Regional Development
EQS	Environmental Quality Standard
ERC	Environmental Release Categories
ERR	Exposure Risk Relationship
ETUI	European Trade Union Institute
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work

EWC	European Waste Catalogue
FEV	Forced expiratory volume
FL	Fluorescence detection
FoBiG	Forschungs und Beratungsinstitut Gefahrstoffe
FVC	Forced vital capacity
GDP	Gross Domestic Product
GESTIS	Internationale Grenzwerte für chemische Substanzenm (International limits for chemical substances)
HDI	Hexamethylene diisocyanate
HPLC	High pressure liquid chromatography
HSE	Health & Safety Executive, United Kingdom
HSENI	Health & Safety Executive Northern Ireland
IA	Impact Assessment
IARC	International Agency for Research of Cancer
ICA	Isocyanic Acid
IED	Industrial Emissions Directive
IFA	Institute for Occupational Safety and the German Statutory Accident Insurance (Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung)
Ige	Immunoglobulin E
ILO	International Labour Organisation
INRS	The French National Research and Safety Institute for the Prevention of Occupational Accidents and Diseases
IOM	Institute of Occupational Medicine
IPPC	Integrated Pollution Prevention and Control
ISO	The International Organization for Standardization
ISOPA	European Diisocyanate and Polyol Producers
JRC	Joint Research Centre

LEV	Local Exhaust Ventilation
LOD	Limit of Detection
LOAEC	Lowest adverse effects concentrations
MAK	German national maximum permissible concentration
MCA	Multi-Criteria Analysis
MDI	4,4'-methylenediphenyl diisocyanate
MEGA	IFA's workplace exposure database
MS	Mass spectrometry
NACE	"nomenclature statistique des activités économiques dans la Communauté européenne" or the Statistical Classification of Economic Activities in the European Community
NCO	Isocyanates are organic compounds that contain one or more functional groups with the molecular formula -N=C=O
NIOSH	National Institute for Occupational Safety and Health
NOAEC	No observed adverse effect concentration
OEL	Occupational Exposure Limit
OEL	Occupational exposure limit
OSH	Occupational Safety and Health
OSHA	Occupational Safety and Health Administration (US)
PBT	Persistent, Bio-accumulative and Toxic
PCB	Polychlorinated biphenyls
PCM	Phase-Contrast Microscope
PGS	Process-Generated Substances
PNEC	Predicted No Effect Concentrations
POD	Point of Departure
PPB	Parts per Billion
PPE	Personal Protective Equipment
PROC	The process categories

PV	Present value
QALY	Quality-adjusted life year
R&D	Research and Development
RAC	Committee for Risk Assessment
RAR	Risk Assessment Report
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Management Measure
RPA	Risk & Policy Analysts
RPE	Respiratory Protection Equipment
SCM	Standard Cost Model
SCOEL	Scientific Committee on Occupational Exposure Limits
SEA	Socio-Economic Analysis
SEAC	Committee for Socio-Economic Analysis
SEG	Separate Exposure Group
SME	Small and Medium-sized Enterprise
STEL	Short-Term Exposure Limits
STOT RE	Specific Target Organ Toxicity, Repeat Exposure
SU	Sector of Use
SUMER	Surveillance médicale des expositions aux risques professionnels (Medical Monitoring Survey of Professional Risks)
SVC	Saturated vapour concentrations
SVHC	Substance of Very High Concern
TDI	m-tolylidene diisocyanate
TLV	Threshold Limit Value
TWA	Time Weighted Average
UK	United Kingdom
UV	Ultraviolet detection

VCM	Value of Cancer Morbidity
vPvB	Very Persistent, vey Bio-accumulative
VSL	Value of Statistical Life
VRAR	Voluntary Risk Assessment Report
WCS	Worker Contributing Scenarios
WEEE	The Waste and Electrical & Electronic Equipment Directive (2002/96/EC)
WHO	World Health Organisation
WPC	Working Party on Chemicals

Executive summary

The Chemical Agents Directive (Directive 98/24/EC) (CAD) protects workers from the risks related to chemical agents at work. The aim of this study is to support the European Commission's Impact Assessment (IA) of introducing the new limit values for diisocyanates.

The minimum requirements for protecting workers that are exposed to hazardous chemicals include occupational exposure limits (OELs), and short-term exposure limits (STELs). An OEL relates to an 8-hour time weighted average (TWA) and a STEL relates to a 15-minute short term measurement.

This study assesses the impacts of introducing an OEL/STEL for diisocyanates under the CAD. The report assumes that an OEL and STEL are introduced, together with a skin notation and notations for 'skin sensitisation' and 'respiratory sensitisation'. The study models the impact of introducing an OEL but not the STEL. Unfortunately, it is not possible to derive a dose response relationship (DRR) for the short-term exposures, and therefore it is not possible to model the impact of a STEL.

Nineteen Member States currently have an OEL or STEL for at least one diisocyanate and the median OEL is 17.5 µg NCO/m^3, which forms the baseline for the study.

Twenty-one sectors with workers diisocyanates are analysed, representing 4,226,583 exposed workers and 2,465,525 enterprises with exposed workers.

Two estimates of the cost savings (benefits) from ill health avoided under the different OEL options (Methods 1 and 2) are presented in this report. These estimates rely on two different monetisation approaches. Both monetise the same number of avoided cases and use identical methods for the monetisation of direct (healthcare, informal care, disruption for employers) and indirect (productivity/lost earnings[1]) impacts. However, they use different approaches to assign monetary values to intangible effects (reduced quality of life, pain and suffering, etc.). The results of both approaches should be considered together and treated as indicative of the general order of magnitude of the cost savings. A detailed explanation of these approaches is provided in the methodological note.

The costs and benefits (relative to the baseline) estimated in this report for the different OEL options are summarised in Table 1-1. The benefits (cost savings from reduced ill health) are shown for both calculation Method 1 and Method 2. The costs are for the present value (PV) over 40 years with a static discount rate of 4%. They assume a 5% turnover in staff.

For the benefits, these do not occur until the OEL is reduced to 3 µg NCO/m^3 and they are low at this level. This is because the exposure concentrations gathered were below 3 µg NCO/m^3. The benefits start to increase as the OEL decreases to and below 1 µg NCO/m^3.

For the costs, there is a substantial increase at and below 1 µg NCO/m^3. However, there are also significant costs at the highest OEL options due to the cost of monitoring and administrative burden, even though there is no anticipated cost of risk management measures at these higher OEL options. At the lowest OEL options at and below 0.5 µg NCO/m^3, the costs are significant, primarily due to the number of discontinuations that would occur as companies could not comply with the OELs.

The multi-criteria analysis summarising both the monetised and qualitative impacts is shown in Table 1-2.

[1] This is not the case where lost earnings are already taken into account in the Willingness to Pay estimate in published literature.

The Committee for Risk Assessment (RAC) recommended a maximum STEL value of 6 µg NCO /m^3, which should not be more than double the OEL.

The most important issue is the degree of uncertainty particularly regarding the benefits, but also regarding the costs. There are five factors contributing to this uncertainty surrounding the benefits:

- **STEL modelling** – The impact of introducing a STEL upon the cases/benefits could not be modelled. This probably means that cases at the higher OEL options are missing and therefore that there should be benefits as the OEL options reduce to 10 or 6 µg NCO/m^3.
- **Limit of quantification (LOQ)** – Many exposure measurements are below the limit of quantification (LOQ) and with agreement of the steering group, are set to default to half the LOQ for all exposures below the LOQ. This probably means that the exposure levels are higher at the lower percentiles than they should be, which implies that the number of cases and the potential benefits at the lower OEL options are overestimated. This issue was addressed in the sensitivity analysis.
- **REACH Restriction** – The impact of the REACH Restriction on exposure concentrations is unknown. ECHA estimated a reduction in the number of cases of between 50 and 70% but this appears to be based on little evidence. To run the cost model, the exposure concentrations after the REACH Restriction had to be estimated, and the assumption of a 50% reduction to all levels agreed between the study team and the steering group could be incorrect. In addition, some reduction in cases is likely to be related to reduced dermal contact, but the likely proportion of the reduction is unknown. This issue was addressed in the sensitivity analysis.
- **DRRs relevance to all diisocyanates uses** – The RAC opinion and the derivation of the DRRs for asthma are based upon two reports: one based entirely on a TDI production facility (Collins *et al.*, 2017) and another report based entirely on HDI used in spray painting (Pronk *et al.*, 2009). TDI is known to be more hazardous than the other diisocyanates and spray painting is a hazardous use because, by definition, the diisocyanate is in aerosol form and thus more likely to be inhaled. Therefore, it seems possible that the DRR may overestimate the risk in sectors using other diisocyanates like MDI, particularly the construction sectors and G45.2 vehicle repair, and/or those sectors not involved in spray painting. However, the study team has no evidence that the data in these two reports is not representative of all diisocyanates and sought to consider all possible reasons for the apparent discrepancy between the expected and modelled number of cases occurring at low exposure levels.
- **Member States with OELs** – The benefits are overestimated by approximately 10% because the effect of the Member States that have already implemented OELs or STELs has not been taken into consideration.

The uncertainty regarding the costs is primarily due to three factors:

- **Cost of compliance with STELs** – The impact of introducing a STEL upon the costs could not be modelled, and the costs associated with achieving STELs at higher exposure values cannot be estimated. Therefore, the costs are an underestimate.
- **Risk management costs** – These may be underestimated as estimates from several other sources tend to be higher.

- **Member States with OELs** – The benefits are overestimated by approximately 10% because the effect of the Member States that have already implemented OELs or STELs has not been taken into consideration.

Further issues relating to the EU strategic goals and EU Green Deal:

- **Non-EU competition** – In nearly all EU's major competitors, the OELs for diisocyanates are 17 µg NCO/m^3 or higher (China has 15 µg NCO/m^3 for HDI, but 48 µg NCO/m^3 for TDI). In many sectors, particularly C13 Textiles, C14 Apparel, C22.21 Rigid foams, C22.29 Flexible foams, C20 Chemicals and C31 Furniture, the products are price sensitive and competition from nearby countries such as Turkey, Belarus, UK, Ukraine and Russia is fierce. Saudi Arabia, China, Japan and South Korea are also competitive countries that manufacture products using diisocyanates in many sectors.

- **Small and medium sized companies** – The cost of compliance consisting of risk management measures, monitoring and administrative burden falls relatively heavily on small and medium sized companies at all OEL options. There is a cost of compliance at all options due to the cost of monitoring and administrative burden: the cost per company steps up considerably as the OEL reduces to 6 µg NCO/m^3 and increases again as the OEL reduces to 1 µg NCO/m^3.

- **EU Green Deal** – Several sectors play a significant role in achieving the EU's Green Deal. All construction sectors and C16 Wood are important because considerable renovation of buildings is anticipated: wood is a favoured material due to its sustainability. Energy efficient insulation and an extensive range of building techniques depend upon polyurethane, adhesives, sealants and coatings that use diisocyanates. In addition, in C29 Motor vehicles, manufacturers of electric vehicles are increasingly considering replacing heavier materials in cars with polyurethane to offset the weight of batteries. Finally, sophisticated polyurethane coatings are used in many applications including the rotor surfaces of wind turbines.

Technical and regulatory issues that will affect companies implementing an OEL or STEL:

- **Lowest limit of quantification** – The ISO 17734-1 sampling and analysis method in Table 4-63 appears to be incorrect following conversations with the ISO. This implies that the lowest STEL that could currently be monitored is 3 µg NCO/m^3 and the lowest OEL is 0.2 µg NCO/m^3.

- **Continuous monitoring** – This is important for identifying peaks quickly and evacuating, if necessary, but there are limits of detection of about 1ppb or about 3.5 µg NCO/m^3. Companies tend to set the warning at 1ppb and evacuation at 5ppb or about 17.5 µg NCO/m^3 or the OEL of many Member States. There are concerns that an OEL below 10 µg NCO/m^3 could lead some companies to remove continuous monitoring, which is expensive, because the warnings cannot be set sufficiently lower than the OEL.

- **Alternatives** – These are often more toxic than diisocyanates. Formaldehyde users in several sectors are waiting for details of a new REACH Restriction which, if it requires a new low limit, may cause them to switch to MDI. Epoxy resins are another alternative that are known to be able to cause skin sensitisation. The alternatives often have a lower performance with issues ranging from being more reactive, not as strong, requiring much greater volumes, and taking longer to install. There are also issues with the market availability of some alternatives.

- **Other regulations being considered** – Polyurethane manufacturers are particularly concerned about two potential changes in next year's REACH revision: Mixture Assessment Factor (MAF) and REACH registration of polymers.

Other issues for DG EMPL and the Working Party on Chemicals to consider are:

- **Standard identification and recording of asthma caused by diisocyanates** – It is difficult to identify cases of occupational asthma caused by diisocyanates accurately as there are many causes of asthma, and there is no consistency in registering cases in the EU. Ideally, there would be a common EU approach to defining and registering cases.
- **Approach to analysing occupational asthmagens** – Sensitising substances present specific challenges as it is hard to model how sensitisation and occupational asthma occurs. Further consideration of the best approach to use when analysing occupational asthmagens is required.
- **Medical surveillance** – According to several stakeholders, industry had expected medical surveillance for workers to be introduced as part of the REACH Restriction. In addition to limit values, the Chemicals Agents Directive (CAD) contains provisions for appropriate medical surveillance of workers at a national level. Medical surveillance can also be mandated at an EU level under the CAD: it is already mandated for lead. Further work is beyond the scope of this study, but it is an option that could be considered.

Table 1-1 Cost-benefit ratios of the OEL options (all impacts over 40 years and additional to the baseline)

Impact	**OEL options (µg NCO/m^3)**							
	0.025	**0.1**	**0.5**	**1**	**3**	**6**	**10**	**17.5**
Total benefits M1	€3,400 million	€2,600 million	€320 million	€93 million	€2 million	-	-	-
Total benefits M2	€6,300 million	€4,700 million	€590 million	€170 million	€4 million	-	-	-
Total costs	€340,000 million	€110,000 million	€35,000 million	€30,000 million	€15,000 million	€14,000 million	€5,600 million	€5,600 million
Cost benefit ratio M1	99	43	109	329	7,221	∞	∞	∞
Cost benefit ratio M2	54	24	60	183	4,036	∞	∞	∞

Source: Study team

Notes: ∞ or infinity is given because the costs are high, and the benefits are zero

Table 1-2 Multi-criteria analysis (all impacts over 40 years and additional to the baseline)

Impact	Stakeholders affected	OEL options (µg NCO/m³)							
		0.025	0.1	0.5	1	3	6	10	17.5
Direct costs – compliance									
Risk management measures and discontinuation costs (one-off and recurrent)	Companies	€320,000 million	€88,000 million	€12,000 million	€8,700 million	€830 million	€10 million	€0 million	€0 million
Monitoring (sampling and analysis)	Companies	€19,000 million	€19,000 million	€19,000 million	€18,000 million	€11,000 million	€11,000 million	€4,600 million	€4,600 million
Direct costs – administrative burdens									
Company cost of administration burden	Companies	€3,800 million	€3,800 million	€3,800 million	€3,800 million	€2,400 million	€2,400 million	€1,000 million	€1,000 million
Direct costs – total									
Compliance, monitoring and administration burden costs per company	Companies	€140,000	€45,000	€14,000	€12,000	€5,900	€5,600	€2,300	€2,300
Direct costs – enforcement costs									

Impact	Stakeholders affected	OEL options (µg NCO/m³)							
		0.025	0.1	0.5	1	3	6	10	17.5
Transposition costs	Public sector	€970,000	€970,000	€970,000	€970,000	€970,000	€970,000	€970,000	€970,000
Enforcement costs	Public sector	€0	€0	€0	€0	€0	€0	€0	€0
Monitoring costs	Public sector	€0	€0	€0	€0	€0	€0	€0	€0
Adjudication costs	Public sector	€0	€0	€0	€0	€0	€0	€0	€0
Indirect costs – other									
Firms exiting the market - No. of company closures	Companies	57,000	12,000	1,300	830	53	0	0	0
Employment – Jobs lost	Workers & families	420,000	64,000	16,000	14,000	100	0	0	0
Employment – Social cost	Workers & families	€34 billion	€5 billion	€1.3 million	€1.1 million	€8.5 million	0	0	0
International competitiveness	Companies	Several sectors are in price sensitive competitive markets with many competitors outside the EU							
Consumers	Consumers	Limited impacts expected							
Internal market	Companies	0.025 - 0.025	0.1 - 0.1	0.5 - 0.5	1 - 1	3 - 3	3 - 6	3 - 10	3 - 17.5

Impact	Stakeholders affected	OEL options (µg NCO/m³)							
		0.025	0.1	0.5	1	3	6	10	17.5
Lowest to highest OEL									
Specific MSs/regions - MSs that would have to change OELs	Public sector	All MS	All MS	All MS	All MS	All MS except SE	All MS except SE	All MS except IE, SE, PL	18 EU MS
Regulation	Companies	Cumulative impact of many changes in regulations, implemented or awaited							
Direct benefits – improved well-being - health									
Reduced cases of ill health (asthma)	Workers & families	94,000	70,000	8,600	2,300	50	0	0	0
Reduced cases of ill health (irritation)	Workers & families	10,000	10,000	10,000	10,000	260	0	0	0
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€1,400 - 4,000 million	€1,000 - 3,000 million	€130 - 370 million	€38 - 100 million	€1 - 2 million	€0	€0	€0
Direct benefits – improved well-being - safety									
Avoided costs	Companies	€610 million	€460 million	€59 million	€18 million	€0.4 million	€0	€0	€0
Avoided costs	Public sector	€1,670 million	€1,250 million	€160 million	€44 million	€1 million	€0	€0	€0
Social policy agenda	All	Contribution to Green Deal: Chemicals Strategy towards a toxic-free environment							

Impact	Stakeholders affected	OEL options (µg NCO/m³)							
		0.025	0.1	0.5	1	3	6	10	17.5
Direct benefits – improved well-being - environmental									
Environmental releases	All	No impact/limited impact							
Direct benefits – market efficiency									
Level playing field	Companies	A harmonisation of the OEL and STEL leads to a level playing field, as all companies across all Member States follow a more symmetric requirement. The level-playing field increases slightly with the stringency of OEL and STEL							
Indirect benefits									
Administrative simplification	Companies	For large, and to lesser extent medium, companies with facilities in different Member States will experience administrative simplification, owing to a more harmonious set of compliance requirements. The sectors expected to benefit most are C20 Chemicals, C29 Motor vehicles and C30 Transport.							
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 diisocyanates may be less perceived as a risky line of work associated with health issues. 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	€1,750,000	€1,750,000	€1,750,000	€1,750,000	€1,750,000	€1,750,000	€1,750,000	€1,750,000

Source: Study team

Notes: All costs/benefits are incremental to the baseline (PV over 40 years)

1. Introduction

This section comprises the following subsections:

- 1.1 The Chemical Agents Directive
- 1.2 The study
- 1.3 Study scope
- 1.4 Structure of the report

1.1 The Chemical Agents Directive

The Chemicals Agents Directive (Directive 98/24/EC) or CAD, protects workers from exposure to hazardous chemicals at work. The minimum requirements for protecting workers that are exposed to hazardous chemicals include occupational exposure limits (OELs), and short-term exposure limits (STELs). An OEL relates to an 8 hr TWA and a STEL relates to a 15-minute short term measurement. For each OEL/STEL, Member States are required to establish a corresponding national limit value (OEL/STEL), from which they can only deviate to a lower but not to a higher value.

In addition to limit values, the CAD also contains provisions to have arrangements in place to deal with accidents, incidents and emergencies, to provide information to workers along with appropriate training, and carrying out appropriate medical surveillance of workers. These provisions are important and help to protect workers, the training required as part of the CAD compliments the REACH restriction training.

Di-isocyanates are respiratory sensitisers, also called asthmagens, potentially causing occupational asthma, which is an allergic reaction that can occur in some workers when they are exposed to such substances. They can cause a change in people's airways, known as the 'hypersensitive state'. Not everyone who becomes sensitised goes on to get asthma. But once the lungs become hypersensitive, further exposure to the substance, even at quite low levels, may trigger an attack.

1.2 The study

This report is one of four reports elaborated within the framework of a study undertaken for the European Commission by a consortium comprising RPA Risk & Policy Analysts (United Kingdom), COWI A/S (Denmark), FoBiG (Forschungs- und Beratungsinstitut Gefahrstoffe) (Germany), and EPRD (Office for Economic Policy and Regional Development) (Poland). The four reports are:

- Methodological note;
- Report for asbestos;
- Report for diisocyanates;
- Report for lead and its 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 chemical agents with the view to support the European Commission in the preparation of an Impact Assessment report to accompany a potential proposal to amend Directive 98/24/EC.

The specific objective of this report is to assess the impacts of introducing an OEL and STEL for diisocyanates under the scope of the CAD.

1.2.1 Methodology

The methodology used for study and a summary of the stakeholder consultation are described in detail in the methodological note.

Throughout the report, there are references to information sources. If no specific sources are provided for tables or figures, the study team derived the results based upon information collected for the study and the models developed.

1.3 Study scope

1.3.1 Diisocyanates

Diisocyanates are industrial chemicals used as raw materials for all polyurethane products, surface coatings, adhesives, sealants, elastomers and textiles. Diisocyanates are widely used in Europe in many different products, including many relevant to the EU Green Deal (*The European Green Deal*, no date) such as energy efficient insulation and building techniques, and many that support essential services such as insulation throughout the cool chain distribution network (such as appliances, warehouses, trucks).

According to ISOPA/ALIPA:

> *"The polyurethane industry generates a substantial contribution to European wealth and job creation. Close to 245,000 companies throughout Europe are creating a value of €255 billion every year" (ISOPA-ALIPA, 2019).*

The diisocyanate substance with the highest volume on the market is polymeric MDI (pMDI), as indicated in Table 4-5, however, pMDI is not REACH registered. pMDI uses are similar to MDI and apply to manufacturing rigid and semi-rigid polyurethane foam for construction panels, spray foam insulation, appliance insultation, refrigeration and cool chain insulation applications, and the automotive sector.

Although there are at least 25 different diisocyanates substances, as indicated by ECHA (2019) there are 11 registered diisocyanates, which account for > 99.9 % of the registered tonnage. ECHA (2019) indicates that of the REACH registered substances:

- the most common commercial TDI (m-tolylidene diisocyanate) is a mixture of 2,4'-TDI and 2,6'-TDI (80/20 TDI or 65/35 TDI). TDI represents 48% of the overall amount of REACH registered diisocyanates used;
- the second highest volume is for 4,4'-MDI (29%);
- the third highest is 2,4'-TDI (12%); and
- the fourth highest is HDI (4.3%).

Together, these four substances account for around 94% of all REACH registered manufactured/imported diisocyanates in Europe.

ECHA (2019) indicates that the three most produced diisocyanates (TDI, 4,4'-MDI and 2,4'-TDI) are typically used in the manufacture of flexible and rigid foams, adhesives and sealants. HDI and IPDI are often present in coatings and paints but are not used in flexible and rigid foams or composites or in cleaning products. It is also indicated the use of diisocyanates in the automotive industry is widespread throughout the supply chain including several uses of MDI, IPDI and HDI. The aerospace sector is also indicated for several uses of diisocyanates including the use of DDI, HDI and TDI.

The general aspects of occupational exposure and the potential for exposure in the production of diisocyanates and their industrial use are discussed in ECHA (2019). The current and proposed harmonised sensitisation classifications for diisocyanates are given in Table 1-1.

Table 1-1 Diisocyanates harmonised sensitisation classifications and proposed harmonised sensitisation classifications

Substance	EC number	CAS number	C&L Inventory - Sensitisation
m-tolylidene diisocyanate	247-722-4	26471-62-5	Skin Sens. 1 H317 Resp. Sens. 1 H334
4,4'-methylenediphenyl diisocyanate	202-966-0	101-68-8	Skin Sens. 1 H317 Resp. Sens. 1 H334
4-methyl-m-phenylene diisocyanate	209-544-5	584-84-9	Skin Sens. 1 H317 Resp. Sens. 1 H334
Hexamethylene diisocyanate	212-485-8	822-06-0	Skin Sens. 1 H317 Resp. Sens. 1 H334
o-(p-isocyanatobenzyl)phenyl isocyanate	227-534-9	5873-54-1	Skin Sens. 1 H317 Resp. Sens. 1 H334
3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate	223-861-6	4098-71-9	Skin Sens. 1 H317 Resp. Sens. 1 H334
4,4'-methylenedicyclohexyl diisocyanate	225-863-2	5124-30-1	Skin Sens. 1 H317 Resp. Sens. 1 H334
1,5-naphthylene diisocyanate	221-641-4	3173-72-6	Resp. Sens. 1 H334
2,2'-methylenediphenyl diisocyanate	219-799-4	2536-05-2	Skin Sens. 1 H317 Resp. Sens. 1 H334
1,3-bis(isocyanatomethyl)benzene	222-852-4	3634-83-1	Proposed classification: Skin Sens. 1A H317 Resp. Sens. 1 H334
1,3-bis(1-isocyanato-1-methylethyl)benzene	220-474-4	2778-42-9	Proposed classification: Skin Sens. 1A H317 Resp. Sens. 1 H334
2,2,4(or 2,4,4)- Trimethylhexane-1,6-diisocyanate	915-277-1	32052-51-0	Proposed classification: Skin Sens. 1A H317 Resp. Sens. 1 H334
2,5-bisisocyanatomethylbicyclo[2.2.1]heptane	411-280-2	74091-64-8	Skin Sens. 1 H317 Resp. Sens. 1 H334
2,4-dioxo-1,3- diazetidine-1,3-bis(methyl-m-phenylene) diisocyanate	247-953-0	26747-90-0	Harmonised classification by most dossier

Substance	EC number	CAS number	C&L Inventory - Sensitisation
			notifiers: Skin Sens. 1A H317
2,4,6-triisopropyl-mphenylene diisocyanate	218-485-4	2162-73-4	Proposed classification: Skin Sens. 2 H315 Resp. Sens. 1 H334
3,3'-dimethylbiphenyl4,4'-diyl diisocyanate	202-112-7	91-97-4	Proposed classification: Skin Sens. 1 H317 Resp. Sens. 1 H334
p-phenylene diisocyanate	203-207-6	104-49-4	Proposed harmonised classification by the dossier submitter: Skin Sens. 1 H317 Resp. Sens. 1 H334
1,5-Diisocyanatopentane	807-040-5	4538-42-5	Harmonised classification by most dossier notifiers: Skin Sens. 1 H317 Resp. Sens. 1 H334
1,3-diethyl-2,4-diisocyanato-5-methylbenzene	813-050-0	2162-70-1	Harmonised classification by most dossier notifiers: Skin Sens. 1 H317 Resp. Sens. 1 H334
1,3- bis(isocyanatomethyl) cyclohexane	609-567-4	38661-72-2	-
2-methyl-m-phenylene diisocyanate	202-039-0	91-08-7	Skin Sens. 1 H317 Resp. Sens. 1 H334
A mixture of: S-(3-trimethoxysilyl) propyl 19-siocyanato-11-(6-isocyanatohexyl)-10,12-dioxo-2,9,11,13-tetraazanonadecanthioate; S-(3-(trimethoxysilyl) propyl 17-isocyanato-9-(isocyanatohexyl-aminocarbonyl)-10-oxo-2,9,11-triazaheptadecanethioate	402-290-8	85702-90-5	Skin Sens. 1 H317 Resp. Sens. 1 H334
1,8-diisocyanato-4-isocyanatomethyloctane	429-140-4	79371-37-2	-
2,4,4-trimethylhexa-1,6-diyl diisodiisocyanate	239-714-4	15646-96-5	Resp. Sens. 1 H334
2,2,4-trimethylhexa-1,6-diyl diisodiisocyanate	241-001-8	16938-22-0	Resp. Sens. 1 H334

Source: ECHA Registration Dossiers (2020)

Particularly important factors for the potential for occupational exposure to diisocyanates are:

- Volatility: due to their lower molecular weight, diisocyanates have significant vapour pressures at room temperature and therefore may vaporise more easily and become significantly concentrated within the workplace.
- Hot processes: higher temperatures will increase vapour pressure and therefore the tendency of diisocyanates to vaporise and become significantly concentrated within the workplace. Hot processes involving diisocyanates or products containing them may lead to thermal degradation and exposure to diisocyanates.
- Aerosolisation: the use of diisocyanates as part of spraying operations, especially on surfaces with a greater surface area, may lead to aerosol release and inhalation exposure including from the dust of finished products or articles.
- Dermal exposure: skin contact with uncured diisocyanates products may be a significant exposure route.

The main process to produce diisocyanates is the phosgenation of corresponding diamines. The entire manufacturing processes involved in this process take places in a closed system due to the hazardous properties of phosgene (carbonyl dichloride). Therefore, occupational exposure from the manufacturing of diisocyanates may be low, however, some exposure may occur from loading/unloading operations.

One of the main uses of diisocyanates is within the polyurethane industry, the manufacturing involves a highly exothermic process. As significant volumes of diisocyanates are used and a significant temperature may be reached, vapour pressure may increase significantly along with the potential for occupational exposure. Several studies have investigated the levels of diisocyanates within occupational settings of the polyurethane industry along with biomonitoring of its workforce.

Within the construction and building industry, MDI is one of the diisocyanates that are used. This includes use within boat building where occupational exposure monitoring found a powered hood with an appropriate filter and appropriate Respiratory protection equipment (RPE) significantly reduced occupational exposure.

As part of autobody shop operations, HDI and IPDI are among diisocyanates that are used. The diisocyanates are used as part of industrial spraying operations and concentrations from aerosolisation in these areas have been recorded as being higher than in car body repair shops. In addition to aerosolisation, mixing and other paint related tasks, for example sanding and compounding, contribute to exposure.

This study assesses the impacts of introducing an OEL/STEL for diisocyanates under the CAD. The report assumes that an OEL and STEL are introduced, together with a skin notation and notations for ‘skin sensitisation’ and ‘respiratory sensitisation’.

1.3.2 Existing OELs and STELs

Some diisocyanates are already the subject to national OELs and STELs in EU Member States. These are described in section 4.

1.3.3 Selection of relevant substances

1.3.3.1 Introduction

All diisocyanates are covered within the scope of the study. However, there are 28 diisocyanates either registered or with harmonised classification and labelling (CLH) very many of which are barely, if ever, used. To focus respondents' attention during the consultation, it was important to identify the most relevant and heavily used diisocyanates. A total of 13 diisocyanates were selected and the process of defining them is described below.

1.3.3.2 Criteria for the determination of the relevant compounds

Of the 28 diisocyanates either registered or with harmonised classification, 11 registered diisocyanates, which account for > 99.9 % of the registered tonnage and which are individually registered for at least 1 000 t/a (ECHA, 2019).

In addition to these 11 diisocyanates, it was discussed and agreed with the Steering Group that Polymeric MDI (pMDI, CAS#9016-87-9) and 4,4'-Diisocyanato-3,3'-dimethyl-1,1'-biphenyl (TODI, CAS#91-97-4, EC#202-112-7) were important substances that should also be included.

The study primarily investigates intentional use and where the release of diisocyanates during processes occurs.

1.3.3.3 Final selection

The 13 diisocyanates investigated in the study are listed in Table 1-2.

Table 1-2 Thirteen diisocyanates upon which the study focusses

Substance	Abbrev.	EC number	CAS number
Hexamethylene Diisocyanate	HDI	212-485-8	822-06-0
3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanat	IPDI	223-861-6	4098-71-9
4,4'-methylenediphenyl Diisocyanate	4,4'-MDI	202-966-0	101-68-8
o-(p-isocyanatobenzyl)phenyl isocyanate	2,4'-MDI	227-534-9	5873-54-1
2,2'-methylenediphenyl Diisocyanate	2,2'-MDI	219-799-4	2536-05-2
4,4'-methylenedicyclohexyl Diisocyanate	H12-MDI	225-863-2	5124-30-1
Polymeric MDI	pMDI	-	9016-87-9
1,3-bis(1-isocyanato-1-methylethyl)benzene	m-TMXDI	220-474-4	2778-42-9
1,3-bis(isocyanatomethyl)benzene	m-XDI	222-852-4	3634-83-1
1,5-naphthylene Diisocyanate	1,5-NDI	221-641-4	3173-72-6
m-tolylidene Diisocyanate	TDI	247-722-4	26471-62-5
4-methyl-m-phenylene Diisocyanate	2,4-TDI	209-544-5	584-84-9
4,4'-Diisocyanato-3,3'-dimethyl-1,1'-biphenyl	TODI	202-112-7	91-97-4

A summary of the REACH registration tonnages for the 13 diisocyanates focused upon within this study is provided in Table 1-3. The REACH registration tonnage range of the 13 diisocyanates is between 1.24 to 12.4 million tonnes per year and ECHA (ECHA, 2018b) estimate that a total tonnage of about 2.5 million tonnes per year are used throughout the EU.

Table 1-3 Summary of REACH registration tonnages for the 13 diisocyanates considered in this study

Substance	Tonnage per annum	Registration type	Status
Hexamethylene Diisocyanate	10 000 - 100 000	Full + Intermediate	Active
3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanat	10 000 - 100 000	Full	Active
4,4'-methylenediphenyl Diisocyanate	100 000 - 1 000 000	Full + Intermediate	Active
o-(p-isocyanatobenzyl)phenyl isocyanate	10 000 - 100 000	Full	Active
2,2'-methylenediphenyl Diisocyanate	1 000 - 10 000	Full + Intermediate	Active
4,4'-methylenedicyclohexyl Diisocyanate	10 000 - 100 000	Full	Active
Polymeric MDI	N/A	Polymer and not REACH registered	N/A
1,3-bis(1-isocyanato-1-methylethyl)benzene	1 000 - 10 000	Full	Active
1,3-bis(isocyanatomethyl)benzene	1 000 - 10 000	Full	Active
1,5-naphthylene Diisocyanate	1 000 - 10 000	Full	Active
m-tolylidene Diisocyanate	1 000 000 - 10 000 000	Full + Intermediate	Active
4-methyl-m-phenylene Diisocyanate	100 000 - 1 000 000	Full + Intermediate	Active
4,4’-Diisocyanato-3,3’-dimethyl-1,1’-biphenyl	100 - 1 000	Full	Active

A brief description of the primary uses of each diisocyanate is provided in Table 1-4.

Table 1-4 Brief description of the primary uses of the selected 13 diisocyanates

Diisocyanate	Description
Hexamethylene Diisocyanate (HDI)	Manufacture of the substance Formulation: Into mixture Industrial use: As a monomer/intermediate in a polymer matrix; Uses by professional workers: Scientific Research and Development
3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanat (IPDI)	Manufacture of the substance including filling / packing / transfer; Industrial use as laboratory agent during manufacturing/production, formulation process and use as intermediate (for internal use only) Formulation: Process (incl. re-packaging) and transfer from/to vessels or containers; Industrial use as laboratory agent during manufacturing/production, formulation process and use as intermediate (for internal use only) Industrial use: Use as intermediate; Industrial use as intermediate or monomer and transfer from/to vessels or containers; Use as intermediate or monomer at industrial sites Uses by professional workers: Mixing operations (open systems), indoor and outdoor use; Professional end use for coatings, hardeners, composites (outdoor); Professional use of sealants, indoor and outdoor use, near and far field
4,4'-methylenediphenyl Diisocyanate (4,4’-MDI)	Manufacture of substance Formulation: Resin / polyurethanes manufacturing, repackaging and distribution; adhesives and sealants; coatings; composite materials based on wood/man-made/mineral/natural fibres; Elastomers, TPU, Polyamide, Polyimide, Synthetic fibres and Manufacturing of other Polymers; flexible foam; Formulation (including Resin Manufacture), Packaging, Repackaging and Distribution; foundry applications; Manufacturing other composite materials; and rigid foam Industrial use: Adhesives & Sealants; Cleaning with Aprotic Polar Solvents; Cleaning with Non-Aprotic Polar Solvents; Coatings; composite materials based on wood/man-made/mineral/natural fibres; Elastomers, TPU, Polyamide, Polyimide, Synthetic fibres and Manufacturing of other Polymers; Flexible Foam; Formulation (including Resin Manufacture), Packaging, Repackaging and Distribution; Foundry; foundry applications; Manufacturing of other substances; Own Use / Polymerized monomer in polymer; Painting of automotives (Use of paints); Printing (use of ink); rigid foam; Use as polymer Uses by professional workers: Adhesives & Sealants; Application by professional workers; Cleaning with Non-Aprotic Polar Solvents; Coatings; Composite material based on wood/man-made/mineral/natural fibres; Coatings Professional Use; Other Composite Material; Painting of automotives (Use of paints); Printing (Use of ink); rigid foam Consumer uses: Adhesives & Sealants; Coatings; rigid foam
o-(p-isocyanatobenzyl) phenyl isocyanate (2,4’-MDI)	Manufacture of the substance Formulation: Resin manufacturing, repackaging and distribution; Uses at industrial sites for Adhesives & Sealants; Cleaning [no Aprotic Polar Solvents]; Cleaning with Aprotic Polar Solvents above 40°C; Cleaning with Aprotic Polar Solvents below 40°C; Coatings; Composite material based

Diisocyanate	Description
	on wood/man-made/mineral/natural fibres; Elastomers, TPU, Polyamide, Polyimide & Synthetic Fibres & Manufacturing of other polymers; Flexible Foam; Foundry; Manufacturing of other substances; Other Composite Material; Rigid Foam Uses by professional workers: Adhesives & Sealants; Cleaning [no Aprotic Polar Solvents]; Coatings; Composite material based on wood/man-made/mineral/natural fibres; Other Composite Material; Rigid Foam Consumer uses: Adhesives & Sealants; Coatings; Rigid Foam
2,2'-methylenediphenyl Diisocyanate (2,2'-MDI)	Manufacture of the substance Formulation: Resin manufacturing, repackaging and distribution Industrial use: Adhesives & Sealants Cleaning [no Aprotic Polar Solvents]; Cleaning with Aprotic Polar Solvents below 40°C; Coatings; Composite material based on wood/man-made/mineral/natural fibres; Elastomers, TPU, Polyamide, Polyimide & Synthetic Fibres; Manufacturing of other polymers; Flexible Foam; Foundry; Manufacturing of other substances Uses by professional workers: Adhesives & Sealants; Cleaning [no Aprotic Polar Solvents]; Coatings; Composite material based on wood/man-made/mineral/natural fibres; Other Composite Material; Rigid Foam Consumer uses: Adhesives & Sealants; Coatings; Rigid Foam
4,4'-methylenedicyclohexyl Diisocyanate (H12-MDI)	Manufacture of the substance Formulation: Industrial and professional use for formulation of preparations; Formulation, Transfer and Packing Industrial use: Adhesives/Sealants, Elastomers, TPU, Polyamide, Polyimide & Synthetic Fibres & Manufacturing of other polymers; Industrial use as an intermediate / monomer; Use as monomer; Use as polymer
Polymeric MDI (pMDI)	Manufacture of the substance Formulation: Elastomers and TPUs; Oil Additives; Elastomers and TPUs Industrial use: Rigid foam in several insulation applications Uses by professional workers: Rigid foam in several insulation applications
1,3-bis (1-isocyanato-1-methylethyl) benzene (m-TMXDI)	Manufacture of the substance Industrial use: Production of polyurethane polymers and polymeric resins
1,3-bis(isocyanatomethyl) benzene (m-XDI)	Manufacture of the substance Formulation: Preparations
1,5-naphthylene Diisocyanate (1,5-NDI)	Manufacture of the substance Formulation: Elastomers and TPUs; Oil Additives; Elastomers and TPUs
m-tolylidene Diisocyanate (TDI)	Manufacture of the substance Formulation: Adhesives and Sealants; Coatings; Elastomers, TPU, Polyamide, Polyimide and Synthetic Fibres Industrial Use; Flexible Foam; Formulating, Repackaging and Distribution; Manufacture of paints

Diisocyanate	Description
	(formulation); Manufacturing of other substances; mixing and blending; Other composite materials Uses at industrial sites: Adhesives and Sealants; Coating Industrial use: Developing & Printing process; Elastomers, TPU, Polyamide, Polyimide and Synthetic Fibres; Flexible Foam; Formulation and Repackaging and Distribution; Intermediate; Manufacturing of other substances; Other composite materials; Painting of automotives (Use of paints); Processing solvent; Sizing of carbon fiber (Use of sizing agent); use in industrial sites Uses by professional workers: Adhesives and Sealants; Coatings; Other composite materials; Painting of automotives (Use of paints)
4-methyl-m-phenylene Diisocyanate (2,4-TDI)	Formulation: Adhesives and Sealants; Coating; Elastomers, TPU, Polyamide, Polyimide and Synthetic Fibres; Flexible Foam; Formulating, Repackaging and Distribution; Import as polymer; Manufacturing of other substances; Manufacturing of TDI; Other Composite Material Industrial use: Adhesives and Sealants; Coating; Elastomers, TPU, Polyamide, Polyimide and Synthetic Fibres; Flexible Foam; Formulating, Repackaging and Distribution; Manufacturing of other substances; Manufacturing of TDI Uses by professional workers: Adhesives and Sealants; Coating; Other Composite Material
4,4’-Diisocyanato-3,3’-dimethyl-1,1’-biphenyl (TODI)	Industrial use: Industrial use of intermediates; industrial use of monomer in polymerization processes; use at industrial site leading to inclusion into/onto article

Source: ECHA Registration Dossiers (2020)

The physicochemical properties of 13 diisocyanates are described in Table 1-5.

Table 1-5 Identity and physicochemical properties of the selected 13 diisocyanates

Substance	Alternative names	EC number	CAS number	Chemical Formula	Appearance at 20 °C	Water Solubility	Molecular Weight g/mol
Hexamethylene diisocyanate	1,6-Hexamethylene diisocyanate 1,6-Hexanediol diisocyanate 1,6-Hexylene diisocyanate HDI	212-485-8	822-06-0	C8H12N2O2	Liquid	No data available	168.196
3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanat	1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane Isophorone diisocyanate Cyclohexane, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethyl- IPDI	223-861-6	4098-71-9	C12H18N2O2	Liquid	15 mg/L @ 23 °C	222.288
4,4'-methylenediphenyl diisocyanate	4,4'-Diphenylmethane diisocyanate 4,4’-MDI	202-966-0	101-68-8	C15H10N2O2	Solid	6.8 mg/L @ 25 °C	250.257
o-(p-isocyanatobenzyl) phenyl isocyanate	2,4'-Diisocyanatodiphenylmethane 2,4'-Diphenylmethane diisocyanate 2,4’-Methylenediphenyl diisocyanate Diphenylmethane-2,4'-diisocyanate Benzene, 1-isocyanato-2-((4-isocyanatophenyl)methyl)- 2,4'-MDI	227-534-9	5873-54-1	C15H10N2O2	Solid	7.5 mg/L @ 25 °C	250.257

Substance	Alternative names	EC number	CAS number	Chemical Formula	Appearance at 20 °C	Water Solubility	Molecular Weight g/mol
2,2'-methylenediphenyl diisocyanate	1,1'-Methylenebis(2-isocyanatobenzene) Diphenylmethane-2,2'-diisocyanate 2,2’-MDI	219-799-4	2536-05-2	C15H10N2O2	Solid	No data available	250.257
4,4'-methylenedicyclohexyl diisocyanate	4,4'-Diisocyanatodicyclohexylmethane 4,4'-methylenedi(cyclohexyl isocyanate) 1,1-Methylene bis(4-isocyanatocyclohexane) Dicyclohexylmethane-4,4'-diisocyanate H12-MDI	225-863-2	5124-30-1	C15H22N2O2	Liquid	No data available	262.353
Polymeric MDI	pMDI	-	9016-87-9				
1,3-bis(1-isocyanato-1-methylethyl) benzene	m-Tetramethylxyloldiisocyanate m-TMXDI	220-474-4	2778-42-9	C14H16N2O2	Liquid	No data available	244.294
1,3-bis(isocyanatomethyl) benzene	Isocyanic acid, m-phenylenedimethylene ester m-XDI	222-852-4	3634-83-1	C10H8N2O2	Liquid	No data available	188.186
1,5-naphthylene diisocyanate	1,5-Naphthyl diisocyanate Isocyanic acid, 1,5-naphthylene ester Naphthalene, 1,5-diisocyanato-	221-641-4	3173-72-6	C12H6N2O2	Solid	No data available	210.192

Substance	Alternative names	EC number	CAS number	Chemical Formula	Appearance at 20 °C	Water Solubility	Molecular Weight g/mol
	1,5-NDI						
m-tolylidene diisocyanate	1,3-diisocyanatomethylbenzene Toluene-diisocyanate TDI	247-722-4	26471-62-5	C9H6N2O2	Liquid	124 mg/L @ 25 °C	174.159
4-methyl-m-phenylene diisocyanate	2,4-toluene diisocyanate Toluene-2,6-diisocyanate Toluene 2,4-diisocyanate 2,4-TDI	209-544-5	584-84-9	C9H6N2O2	Solid	124 mg/L @ 25 °C	174.159
4,4’-Diisocyanato-3,3’-dimethyl-1,1’-biphenyl	1,1'-Biphenyl, 4,4'-diisocyanato-3,3'-dimethyl- 3,3'-Bitolylene-4,4'-diisocyanate 3,3'-Dimethyl-4,4'-biphenylene diisocyanate 4,4'-Diisocyanato-3,3'-bitolyl Bitolylene diisocyanate Isocyanic acid, 3,3'-dimethyl-4,4'-biphenylene ester TODI	202-112-7	91-97-4	C16H12N2O2	Solid	594.08 µg/L @ 25 °C	264.284

Source: ECHA REACH Registration dossiers, last checked 24.08.2021

1.4 Structure of the report

The report is organised as follows:

- Chapter 1 is the introduction;
- Chapter 2 sets out the problems and objectives;
- Chapter 3 sets out the options;
- Chapter 4 sets out the baseline analysis;
- Chapter 5 sets out the benefits of the relevant measures;
- Chapter 6 sets out the costs of the relevant measures;
- Chapter 7 summarises the market effects;
- Chapter 8 describes the distributional impacts;
- Chapter 9 describes the environmental impacts;
- Chapter 10 provides an overview of the limitations and the sensitivity analysis; and
- Chapter 11 compares the options.

This report is supplemented by five annexes:

- Annex 1: Summary of the consultation
- Annex 2: Diisocyanate questionnaire
- Annex 3: Exposure data summary from 2000
- Annex 4: Existing national limits
- Annex 5: Detailed percentages of enterprises and workers using di-isocyanates

2. Problems, objectives and options

This section comprises the following subsections:

- Section 2.1: Need for action as assessed by RAC
- Section 2.2: Summary of epidemiological and experimental data
- Section 2.3: Dose Response Relationship (non-carcinogenic effects)
- Section 2.4: Objectives

2.1 Need for action

2.1.1 The RAC opinion

On the 11th June 2020, the Committee for Risk Assessment (RAC) published its opinion on the scientific evaluation of OELs and STELs for diisocyanates, which is summarised in Table 2-1.

Table 2-1 RAC opinion on the scientific evaluation of occupational exposure limits (OELs and STELs) for diisocyanates

<table>
<tr><th>Derived limit value</th><th>Concentration</th></tr>
<tr><td>OEL as 8-hour TWA</td><td>For the ‘NCO group’* excess risk relationships for hyperresponsiveness or diisocyanate asthma as derived below.
<table>
<tr><td>Excess risk over a working life period</td><td>Exposure – response relations derived from Pronk et al., (2009), and Collins et al., (2018), in µg/m³ NCO in air</td></tr>
<tr><td>0.1%</td><td><0.025</td></tr>
<tr><td>0.5%</td><td>0.027-0.040</td></tr>
<tr><td>1%</td><td>0.055-0.070</td></tr>
<tr><td>2%</td><td>0.12-0.19</td></tr>
<tr><td>3%</td><td>0.22-0.33</td></tr>
<tr><td>4%</td><td>0.40-0.48</td></tr>
<tr><td>5%</td><td>>0.67</td></tr>
</table></td></tr>
<tr><td>STEL</td><td>A 15-minutes Short Term Exposure Limit (STEL) value which is maximally a factor 2 higher than a derived OEL based on the exposure - excess risk relation. This STEL value should not exceed 6 µg/m³ NCO.</td></tr>
<tr><td>BLV</td><td>No BLV proposed</td></tr>
<tr><td>BGV</td><td>Set at the limits of quantification (LOQs) for relevant diisocyanate metabolites (diamines) in urine</td></tr>
</table>

Source: (ECHA, 2020c)

*Note: *NCO Group - Isocyanates are organic compounds that contain one or more functional groups with the molecular formula -N=C=O. Diisocyanates are the most common group of isocyanates used at the workplace* (ECHA, 2018c)*. They are highly reactive compounds and undergo rapid exothermic reactions with all kinds of nucleophiles. In the reactive group (R-N=C=O) R can be aliphatic, cycloaliphatic or an aromatic group.*

2.1.2 Sensitisation

The RAC opinion (*ECHA, 2020b*) gives the following details about the sensitisation:

"Since all diisocyanates considered in this evaluation have a harmonised classification under CLP, either as skin sensitisers, respiratory sensitisers or both, "skin sensitisation" and "respiratory sensitisation" notations are warranted.

A 'skin' notation is proposed in order to ensure prevention of systemic immunological effects (i.e. respiratory sensitisation) from dermal contact with diisocyanates".

During the analysis, the study team assumes that if a company complies with the given OEL and STEL, it will comply with the requirements for the respiratory element of the sensitisation notation.

2.1.3 REACH Restriction

The REACH Restriction Regulation (EU) 2020/1149 (EUROPEAN PARLIAMENT, 2020) was introduced on 3 August 2020 and the primary effect was to introduce mandatory training in the use of diisocyanates for workers handling them. The training must be in place by 24 August 2023. The Restriction applies to diisocyanates, O = C=N- R-N = C=O, with R an aliphatic or aromatic hydrocarbon unit of unspecified length. In Annex XVII to Regulation (EC) No 1907/2006, the following entry is added:

1. Shall not be used as substances on their own, as a constituent in other substances or in mixtures for industrial and professional use(s) after 24 August 2023, unless:

(a) the concentration of diisocyanates individually and in combination is less than 0,1 % by weight, or

(b) the employer or self-employed ensures that industrial or professional user(s) have successfully completed training on the safe use of diisocyanates prior to the use of the substance(s) or mixture(s).

2. Shall not be placed on the market as substances on their own, as a constituent in other substances or in mixtures for industrial and professional use(s) after 24 February 2022, unless:

(a) the concentration of diisocyanates individually and in combination is less than 0,1 % by weight, or

(b) the supplier ensures that the recipient of the substance(s) or mixture(s) is provided with information on the requirements referred to in point (b) of paragraph 1 and the following statement is placed on the packaging, in a manner that is visibly distinct from the rest of the label information: "As from 24 August 2023 adequate training is required before industrial or professional use".

3. For the purpose of this entry "industrial and professional user(s)" means any worker or self-employed worker handling diisocyanates on their own, as a constituent in other substances or in mixtures for industrial and professional use(s) or supervising these tasks.

4. The training referred to in point (b) of paragraph 1 shall include the instructions for the control of dermal and inhalation exposure to diisocyanates at the workplace without prejudice to any national occupational exposure limit value or other appropriate risk management

measures at national level. Such training shall be conducted by an expert on occupational safety and health with competence acquired by relevant vocational training. That training shall cover as a minimum:

(a) the training elements in point (a) of paragraph 5 for all industrial and professional use(s).

(b) the training elements in points (a) and (b) of paragraph 5 for the following uses:

- handling open mixtures at ambient temperature (including foam tunnels);
- spraying in a ventilated booth;
- application by roller;
- application by brush;
- application by dipping and pouring;
- mechanical post treatment (e.g. cutting) of not fully cured articles which are not warm anymore;
- cleaning and waste;
- any other uses with similar exposure through the dermal and/or inhalation route.

(c) the training elements in points (a), (b) and (c) of paragraph 5 for the following uses:

- handling incompletely cured articles (e.g. freshly cured, still warm);
- foundry applications;
- maintenance and repair that needs access to equipment;
- open handling of warm or hot formulations (> 45 °C);
- spraying in open air, with limited or only natural ventilation (includes large industry working halls) and spraying with high energy (e.g. foams, elastomers);
- and any other uses with similar exposure through the dermal and/or inhalation route.

5. Training elements: (a) general training, including on-line training, on:

- chemistry of diisocyanates;
- toxicity hazards (including acute toxicity);
- exposure to diisocyanates;
- occupational exposure limit values;
- how sensitisation can develop;
- odour as indication of hazard;
- importance of volatility for risk;
- viscosity, temperature, and molecular weight of diisocyanates;
- personal hygiene;
- personal protective equipment needed, including practical instructions for its correct use and its limitations;
- risk of dermal contact and inhalation exposure;

- risk in relation to application process used;
- skin and inhalation protection scheme;
- ventilation;
- cleaning, leakages, maintenance;
- discarding empty packaging;
- protection of bystanders;
- identification of critical handling stages;
- specific national code systems (if applicable);
- behaviour-based safety;
- certification or documented proof that training has been successfully completed (b) intermediate level training, including on-line training, on:
- additional behaviour-based aspects;
- maintenance;
- management of change;
- evaluation of existing safety instructions;
- risk in relation to application process used;
- certification or documented proof that training has been successfully completed (c) advanced training, including on-line training, on:
- any additional certification needed for the specific uses covered;
- spraying outside a spraying booth;
- open handling of hot or warm formulations (> 45 °C);
- certification or documented proof that training has been successfully completed.

The Restriction is expected to have the effect of significantly reducing the exposure concentrations experienced by workers over the five years following the requirement for training. Cases are predicted to reduce by between 50% and 70%.

The impact of these reductions is covered in sections 4.17.1 and 4.17.3.

The OEL and STEL notations that would be introduced for diisocyanates under the CAD will be complementary to the REACH restriction. At present, not all EU Member States have an OEL or STEL for diisocyanates, see Table 4-1 and Table 4-2, an OEL and STEL for diisocyanates would provide the level playing field for businesses within the EU.

According to several stakeholders, industry had expected medical surveillance for workers to be introduced as part of the REACH Restriction, but it was not included.

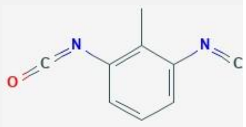
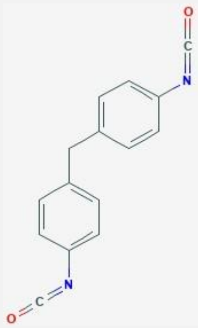
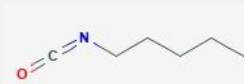
2.2 Summary of epidemiological and experimental data

2.2.1 Identity and classification

The report covers all diisocyanates with the structure O=C=N-R-N=C=O, where R is an aliphatic, cycloaliphatic or aromatic hydrocarbon unit of all lengths. This definition is identical to the definition specified in the RAC opinion on scientific evaluation of occupational exposure limits for diisocyanates (ECHA, 2020c) and the Restriction by the EU (Regulation (EU) 2020/1149), whereas the Restriction does not explicitly state the inclusion of cycloaliphatic diisocyanates.

The diisocyanates with the highest REACH registration tonnage in the EU are TDI, MDI and HDI and relevant studies for establishing an OEL have been performed nearly exclusively on these three diisocyanates. PMDI is the substance with the highest use, but polymeric substances are not REACH registered. The chemical identity of the isomer or of these four substances is presented in Table 2-2. A harmonized classification exists for TDI, MDI and HDI, these are given in Table 2-3. As explained below, data on individual substances can be extrapolated to generic diisocyanates sufficiently well for the relevant endpoints.

Table 2-2 Diisocyanates - identity

Substance	Polymeric MDI	m-tolylidene diisocyanate	4,4'-methylenediphenyl diisocyanate	Hexamethylene diisocyanate
Abbreviation	pMDI	TDI	MDI	HDI
Other names	-	1,3-diisocyanato methyl-benzene; m-toluene diisocyanate	1-isocyanato-4-[(4-isocyanatophenyl)methyl] benzene; 1,1-methylene bis(phenyl)diisocyanate	1,6-diisocyanatohexane; 1,6-hexane diisocyanate
CAS-Number	9016-87-9	26471-62-5	101-68-8	822-06-0
EC-Number	-	247-722-4	202-966-0	212-485-8
Sum Formula	-	C9H6N2O2	C15H10N2O2	C8H12N2O2
Chemical Structure	-			

Sub-stance	Polymeric MDI	m-tolylidene diisocyanate	4,4'-methylenedi-phenyl diisocya-nate	Hexamethylene diisocyanate
Molecular weight	149.15 g/mol	174.16 g/mol	250.26 g/mol	168.20 g/mol
Unit Transfor-mation	1 ppb pMDI = 6.07 µg TDI/m³ 1 µg pMDI/m³ = 0.56 µg NCO/m³	1 ppb TDI = 7.12 µg TDI/m³ 1 µg TDI/m³ = 0.48 µg NCO/m³	1 ppb MDI = 10.23 µg MDI/m³ 1 µg MDI/m³ = 0.36 µg NCO/m³	1 ppb HDI = 6.88 µg HDI/m³ 1 µg HDI/m³ = 0.50 µg NCO/m³

Sources ECHA (2020c) and (PubChem, no date)

Table 2-3 Diisocyanates – classification and labelling

Substance	Classification
TDI	Harmonized Classification: H315: Skin Irrit. 2 H319: Eye Irrit. 2 H317: Skin Sens. 1 H330: Acute Tox. 2 * H335: STOT SE 3 H334: Resp. Sens. 1 (C ≥ 0.1 %) H351: Carc. 2 H412: Aquatic Chronic 3
MDI	Harmonized Classification: H315: Skin Irrit. 2 (C ≥ 5 %) H319: Eye Irrit. 2 (C ≥ 5 %) H317: Skin Sens. 1 H332: Acute Tox. 4 * H335: STOT SE 3 (C ≥ 5 %) H334: Resp. Sens. 1 (C ≥ 0.1 %) H351: Carc. 2 H373: STOT RE 2 *
HDI	Harmonized Classification: H315: Skin Irrit. 2 H319: Eye Irrit. 2 H317: Skin Sens. 1 (C ≥ 0.5 %) H331: Acute Tox. 3 * H335: STOT SE 3 H334: Resp. Sens. 1 (C ≥ 0.5 %)

Sources: ECHA C&L Inventory (ECHA, 2020e)

The use of diisocyanates (as defined above) in the European Union is restricted. The use and placing on the market of diisocyanates or diisocyanate-containing mixtures above a 0.1% concentration limit is allowed only if workers with exposure are trained and appropriate protective measures are in place (Regulation (EU) 2020/1149). The German Technische Regeln für Gefahrstoffe (TRGS) 430[2] is an example for a regulation containing safety measures for the handling and production of diisocyanates as well as necessary contents of the educational training workers need to receive.

2.2.2 General toxicity profile, critical endpoints and mode of action

2.2.2.1 Toxicokinetics

Absorption

After inhalation, absorption of TDI in humans is evident by detection of amine metabolites (TDA, conjugated) in plasma and urine. Between 8% and 25% of inhaled TDI was found in the form of (conjugated) TDA in urine. (ECHA, 2020b). More quantitative data is available from studies in laboratory animals. In rats, the absorption of TDI has been reported to be 61-90 % (Timchalk et al., 1994). For MDI at a lower exposure concentration, Gledhill et al. (2005) determined an absorption of 32 %.

Dermal exposure is important to consider, as it is suspected that systemic sensitisation may be induced after dermal uptake, which enables respiratory allergy and asthma after subsequent inhalation exposure (Bello *et al.*, 2007). However, the role of dermal exposure for the elicitation of allergic asthma is less clear and not established.

Dermal uptake appears to be low, as studies determined uptake rates of lower than 1% for diisocyanates in humans and laboratory animals (Hamada et al. 2018, Hoffmann et al. 2010). In contrast, Vock and Lutz (1997) found a much higher absorption in rats (about 30% recovery in the faeces) but in this study oral uptake of the dermally applied substance cannot be excluded. As an explanation for the low dermal uptake in rats, a reaction of the diisocyanates with nucleophilic structures in the upper layers of the skin is discussed (ECHA, 2020b).

Distribution

Upon uptake, diisocyanates are systemically distributed via the plasma. Because of their high reactivity, they bind early after uptake to structures in the tissue of entry. In analyses on human blood, MDI and TDI have been observed to bind primarily to plasma albumin, but also to haemoglobin and other macromolecules present in the blood (HCN, 2018).

Metabolism

In the lung, diisocyanates are expected to undergo conjugation with glutathione. The conjugation products may be taken up and subsequently bind to macromolecules in the blood. In acidic environments, diisocyanates readily hydrolyze to amines, which may undergo acetylation (ECHA, 2020c). However, amines and acetylation products are present in much lower quantities than macromolecule conjugates. According to Timchalk et al (1994), after inhalation of TDI in rats about 90% of TDI in the blood was detected as conjugates, the remaining 10% as acetylated TDI and no free amines were found. Similarly, after inhalation of MDI no (free) amines were found besides some acetylation products (Gledhill et al. 2005).

[2] https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/TRGS-430.html, only available in German.

This study further identified polyurea derivatives formed by spontaneous reactions as the major form of excreted MDI in the faeces.

Elimination

Diisocyanate elimination occurs primarily via the faeces, with smaller amounts via urine. Nevertheless, the amine metabolites (after acidic hydrolyzation) are used for biomonitoring of diisocyanate exposure (Scholten *et al.*, 2020). In a study in rats using inhalation exposure of MDI, 48 hours after the exposure 12% of applied MDI was recovered as metabolites in bile, 14% in urine and 34% in faeces. After seven days, most of the MDI originally taken up was excreted, of which 5% was eliminated via the urine and 79% via the faeces (Gledhill et al. 2005). In this study, immediately after the end of (inhalation) exposure 30% of MDI was found in the gastrointestinal tract, therefore it is likely that a high fraction of MDI was taken up orally, not via inhalation. A similar picture was observed for TDI, where after inhalation exposure of the radiolabelled substance, 47% of the radioactivity was recovered from the faeces and 15% from urine (Timchalk et al, 1994). Timchalk et al (1994) also investigated excretion after oral uptake and, in comparison to inhalation, observed a higher fraction in faeces and a lower fraction in urine.

2.2.2.2 Target organs

Recent occupational risk assessments predominantly see respiratory sensitisation (with respiratory allergy and asthma as major manifestations) as the critical adverse health effects of diisocyanate exposure (ECHA, 2020b, HCN, 2018, ATSDR, 2018, Hartwig & MAK Commission, 2000). As is the case with skin sensitisation, respiratory sensitisation occurs in two steps. First, the initial induction of sensitisation which primes the immune system against the sensitizer, followed by the elicitation of the allergic reaction upon subsequent contact. It is relevant to the occupational risk assessment of diisocyanates that the two phases are considered to be triggered by both inhalation and dermal exposure (see section 2.2.2.3).

Further, at higher exposure concentrations, irritation effects of diisocyanates were observed: irritation of the skin, mucous membranes, eyes, and the respiratory tract may occur after brief exposure durations (ECHA, 2020b).

There are case reports of neurotoxicity from diisocyanate-exposed workers. However, due to limitations in the quality of these reports, no signs of neurotoxicity in animal studies and no mechanistic explanation, RAC concludes that there is no adequate evidence for a causal relationship (ECHA, 2020b).

2.2.2.3 Mode of action of respiratory sensitisation

Occupational asthma due to diisocyanate exposure occurs via different mechanisms. Immunoglobulin E (IgE)-mediated, allergic asthma is a known mechanism and a positive test for diisocyanate specific IgE is a good predictor for a case of occupational asthma. Lack of specific IgE, however, is a poor indication of the absence of occupational asthma, as only a small fraction of diisocyanate exposed workers diagnosed with asthma show specific IgE ATSDR (2018), ECHA (2020c). As an alternative mechanism explaining allergic asthma in IgE negative individuals, Type IV hypersensitivity is discussed due to the delay in the observed immunoresponse (ATSDR, 2018). A further mechanism through which diisocyanates may induce asthma is via irritation, which might be triggered after short, high exposures without a latency period HCN (2018), ECHA (2020c). Because of these different types of asthma, RAC stresses the use of endpoints which are suitable to measure occupational asthma induced by diisocyanates regardless of the type of mechanism. Therefore, endpoints like asthma itself or generally accepted proxies for asthma, such as bronchial hyperresponsiveness need to be used to derive dose response relationships.

Theoretical considerations suggest the existence of a threshold concentration for induction of respiratory sensitisation. However, ECHA (2020a) concludes that due to different aetiologies of occupational asthma in animals and lack of human data, identification of a dose or concentration without effects is currently not possible. Furthermore, it is possible that dermal exposure may lead to systemic sensitisation against diisocyanates. This mechanism could be responsible for sensitisation at air concentrations below a suspected threshold (Tsui *et al.*, 2020). The epidemiological key studies do not explicitly consider the contribution of dermal exposure. Yet, due to the longitudinal study design, possible sensitisations, which occurred after dermal exposure, cannot be distinguished from sensitisation via the inhalation route. This means that the epidemiological studies do not underestimate cases if dermal exposure to diisocyanates is indeed a relevant factor for occupational asthma in humans. On the other hand, if this hypothesized mechanism holds true and protective measures against dermal exposure had increased since the exposure of the evaluated cohorts, an overestimation of cases may occur.

2.2.3 Cancer – toxicological and epidemiological key studies (existing assessments)

Epidemiological data on diisocyanate carcinogenicity is available from three large cohorts of TDI exposed workers. Among these cohorts, incidences or mortality rates for various types of cancers (rectal, pancreatic or lung cancer, non-Hodgkin's lymphoma) are slightly increased but without statistical significance and with basically no congruence between the cohorts (Hagmar et al., 1993, Sorahan & Pope, 1993, Schnorr et al., 1996). Based on these analyses, IARC concludes in its assessment from 1999, (IARC, 1999a) that there is inadequate evidence for human carcinogenicity of TDI (Group2B, possibly carcinogenic to humans). Since the IARC assessment (IARC, 1999b), updated analyses of the same cohorts have been published, and revealed statistically significant increases in mortality of several types of cancers in the US cohort (Pinkerton et al., 2017). However, in a reviewing assessment integrating human, animal and mechanistic data, it was concluded that observed correlations between diisocyanate exposure and carcinogenicity are not in a causal relationship and more likely to be related to unadjusted confounders like smoking (Prueitt et al., 2013, Prueitt et al., 2017). In addition to TDI, IARC also assessed the data on MDI and determined MDI to be not classifiable regarding carcinogenicity to humans (Group 3). No relevant new data after the IARC assessment has been identified.

RAC agrees with the position that the data for MDI and the updated cohort analyses for TDI provide no reason to deviate from the existing IARC assessments and does not consider carcinogenicity to be relevant for the OEL of diisocyanates ECHA (2020a). In line with this opinion, this report does not provide exposure-response relationship based on carcinogenic effects.

It should be noted that based on experiments in rats on TDI, the compiled evidence is sufficient for IARC to classify TDI as carcinogenic in experimental animals (IARC, 1999c). This assessment is largely based on a gavage study, which led to an increased incidence of different types of tumours in several tissues. After inhalation exposure, no tumour formation related to treatment was observed (IARC, 1999c). RAC notes that the mechanism for tumour formation after oral exposure is likely to be dependent on the acidic environment in the stomach which leads to formation of amines as the acting carcinogens. Consequently, the carcinogenicity observed in oral experiments in rats is not considered to be relevant for workers (ECHA, 2020b) and no excess risk relationship is presented in this report.

2.2.4 Genotoxicity

A small number of studies indicated genotoxicity after diisocyanate exposure in both humans and laboratory animals. The positive results are however contradicted by a larger number of studies with negative outcome and the quality of the human data is limited. RAC considers the results as equivocal and inconclusive (ECHA, 2020b).

2.2.5 Non-cancer endpoints (respiratory sensitisation and irritation) – toxicological and epidemiological key studies (existing assessments)

2.2.5.1 Respiratory sensitisation

Numerous studies providing dose-response data are available, but few meet the requirements to allow derivation of a dose-response relationship suitable for evaluating an OEL. The two key studies identified by RAC and the most important studies in other assessments are presented in more detail in this section.

The quantitative risk assessment by RAC is based on the studies by Pronk et al. (2009) and Collins et al. (2017). These are also the critical studies for the Dutch assessment (HCN, 2018). In fact, RAC re-uses the assessment from (HCN, 2018).

The Pronk et al. (2009) study describes a sub cohort of 229 workers out of 581 workers in the Netherlands with occupational diisocyanate exposure, which was followed in an earlier study by the same group of researchers Pronk et al. (2009). Exposure was primarily against HDI. The 229 workers underwent a more detailed medical analysis including diagnosis of BHR20 (bronchial hyperresponsiveness with a decline of 20% in forced expiratory volume in one second (FEV1)) and asthma (defined in the study as BHR20 in combination with wheezing). Exposure was assessed as monthly exposures of individual workers by integrating measured exposure concentration for specific tasks with activity patterns for particular workers. The mean exposure was determined to be 4530 µg NCO/m³ per monthly working hour. The study found a positive correlation between exposure and the endpoints BHR20 and asthma. In addition, workers who tested positive for diisocyanate specific IgG had a higher prevalence for BHR20. The prevalence data for BHR20 and asthma is used in HCN (2018) and ECHA (2020a) to derive a dose-response relationship for diisocyanates (for details see section 2.3).

In the study reported by Collins et al. (2017), 197 workers from three US plants producing TDI were monitored over five years. For the exposure assessment, full-shift personal samples were collected for individual workers belonging to each of the identified job descriptions in the plants. Groups of similar exposure ("SuperSEGs") were formed across the different plants by categorizing each job description according to their 8h TWA exposure. Same job descriptions between different plants were often not comparable in exposure and in this case ended up in different SuperSEGs. Cumulative exposures were calculated for individual workers by multiplying the geometric mean of the 8h TWA of the respective SuperSEG with the length of exposure of that worker. Participants of the study were also asked whether they noticed an odour of TDI. 15.9% of monitored workers had been employed for less than a year. On average, the cohort in this study was exposed for 3.9 years. The monitored health endpoints were, among others, respiratory symptoms consistent with diisocyanate induced asthma and a decline in FEV1 of at least 350 mL or 10% over any 12-month period. The study found a positive correlation between asthma cases and cumulative exposure as well as a weak association of FEV1 decline with exposure. Moreover, this study used the 95th percentiles of the 8h TWA exposures as a proxy for peak exposures and found a correlation of the forementioned endpoints also with this exposure measure. Importantly, workers who reported an odour of TDI were also significantly more likely to have symptoms of asthma. Overall, about two thirds of study participants reported noticing the odour of TDI during the study period. The odour threshold of TDI is reported to be in the range of 580 µg NCO/m³ to 10 mg NCO/m³ (Middendorf *et al.*, 2017), a concentration which clearly exceeds established or proposed short-term limits. This suggests high peak exposures which might have led to irritative symptoms (not investigated by Collins et al., but see section 2.2.5.2 for irritative effects by diisocyanate exposure. The study provides predicted asthma prevalence for selected exposure-years (i.e. the product of exposure concentration and time), which are used by HCN (2018) and ECHA (2020a) to derive a dose-response relationship for asthma induced by diisocyanates (for details see section 2.3).

The conclusions of Collins et al. (2017), based upon exposure calculations by Middendorf *et al.* (2017), are contested by a recent re-evaluation of the same cohort data (Plehiers et al., 2020a, Plehiers et al., 2020b). This study was published after the RAC assessment; however, the findings were communicated to ECHA during the consultation phase and have been considered by RAC. Briefly, differences in the re-analysis by Plehiers et al. (2020a) include a different methodology for determining the average exposure burden of each group of similar exposure (Middendorf *et al.*, 2017) used geometric means of reported TWA values to calculate cumulative exposures; in contrast, Plehiers et al. (2020a) concluded that arithmetic means would better represent values below the limit of quantification and for the assessment of employment duration of individual workers (employment time before study initiation is generally not counted towards cumulative exposure). Using the re-calculated cumulative exposure data, Plehiers et al. (2020a) found a weak, albeit not statistically significant correlation using a linear or logarithmic logistic regression. They concluded that cumulative exposure should not be used as metric for asthma induced by TDI. Instead they proposed using surrogates for peak exposure, which is described in Plehiers et al. (2020b). In this publication, counts of 8h TWA exposure measurements over 10 µg NCO/m³ (3 ppb) (only samples for which no respiratory protection was used) are used as a proxy for high peak exposures. With this metric, they find a statistically significant correlation with asthma incidence. A discussion on the impact of these findings is included in the discussions on the derived DRRs.

A recent meta-regression study by Daniels (2018) used data from seven epidemiological studies (three cross-sectional and four longitudinal) on TDI to perform dose response modelling. The study selection in this meta-analysis was geared towards the goal of deriving a dose-response relationship. The meta-analysis aimed to include all studies on TDI which provided incidences for occupational asthma, an average exposure level and the number of person-years (sum of the individual years under exposure of study participants) covered by the study. Eight studies were identified that meet the criteria, of which one was disregarded due to exceptionably high incidence rates. A quadratic curve provided the best fit to the data and served to determine the dose corresponding to a working life (45 y) excess risk of 0.1% (0.3 ppb, corresponding to 1.0 µg NCO/m³).

This meta-analysis is criticized due to the quality of the underlying data: the studies used different criteria for diagnosis of a case of occupational asthma and the studies are fairly old with questionable exposure measurements (ECHA, 2020b). RAC states that differences between studies in average exposure as well as the disease rate range up to about a factor of 2, which could easily be due to these differences in the original studies. In addition, the authors used cross-sectional studies to extrapolate to the working life risk, which does potentially give false estimations of the exposure risk relationship as old or morbid workers may have dropped out of the cohort shortly before taking the cross-sectional sample. In conclusion, RAC considers the meta-regression analysis by Daniels (2018) unsuitable for deriving a dose-response relationship. Neither is any of the individual studies used by Daniels et al. considered suitable for this task (ECHA, 2020b).

Two studies included in the regression of the Daniels et al. analysis warrant discussion in more detail, because both were deemed suitable as point of departure (POD) in the assessment by ATSDR 2018. In the Diem et al. (1982) study, 277 workers in a US plant were followed for five years. Over 100 of study participants were introduced to the study during the five years and had little diisocyanate exposure before inclusion in the study. A median 8h TWA exposure was calculated from approximately 2,000 personal samplings and was 2 ppb (25th and 75th percentile: 1.1 ppb and 3.6 ppb). At the end of the study period, 12 cases of occupational asthma had been diagnosed among a total of 1200 exposure years. A dose response relationship was not derived in this study (Diem et al., 1982).

The second study by Clark et al. (1998) reports a study cohort of workers from twelve plants in the UK. A significant annual decline in FEV and forced vital capacity (FVC)was observed in the sub-cohort without earlier exposure, but no significant changes could be observed in the whole cohort. Asthma was not addressed specifically as an endpoint. The average 8h TWA exposure was 1.2 ppb. A dose response relationship was not derived in this study. ATSDR considered the 8h TWA concentrations from both studies suitable as a POD for their limit value derivation and decided to use the lower of the two as POD (ATSDR, 2018). In line with the RAC opinion, these studies are also not considered further in the present study, as they would provide only an unreliable basis for the dose response relationship and better alternatives are available.

A longitudinal study investigating 49 workers exposed to TDI analysed isocyanate related health effects by means of FEV1, specific IgG and questionnaires (Gui *et al.*, 2014). The cohort was followed from pre-employment up to one year of employment. Exposure monitoring was performed continuously during the study year at fixed points supported by a small number of personal samples. Exposure was usually below the limit of detection (0.3 µg NCO/m³) and the maximum concentration during the study duration was 34 µg NCO/m³. The 8h TWA never exceeded the 17 µg NCO/m³ (corresponding to the ACGIH limit value) and on average was significantly below that threshold. Under these conditions, seven workers developed either asthma symptoms, specific IgG, airflow obstruction or a decline in FEV1. This study cannot be used for a quantitative risk assessment (primarily because there is no exposure data for individuals or sub-cohorts, and also because of the small size of the cohort and the short time period). However, the results provide evidence that occupational asthma symptoms occur also at low diisocyanate concentrations (near 0.3 µg NCO/m³), supporting the opinion of RAC that the threshold concentration for humans probably lies at concentrations below (most) exposures in epidemiological studies. The studies by Cassidy et al. (2010) and Hathaway et al. (2014) investigated cohorts with similarly low exposures but found no increase in symptoms. Limitations of these studies (small cohort and/or no control group) also prevent the derivation of a limit value.

Several more epidemiological studies are presented in the annex to the RAC opinion (ECHA 2020a) but are all considered to be unsuitable for a quantitative risk assessment by RAC.

2.2.5.2 Irritation

Animal studies suggest that irritation and sensitisation occur with a threshold at similar concentrations (Pauluhn, 2014, Schupp and Collins, 2012). ANSES (2019) based its OEL on the threshold for irritative effects in rats. However, RAC states that “Diisocyanate-induced sensory irritation of the upper respiratory tract in animal models (i.e. rodents), quantified as a reflex reduction in the respiratory rate, is not considered relevant for irritation threshold derivation in humans”. With regard to other irritation effects in animal models, RAC concluded that results are difficult to transfer to humans due to “differences in toxicokinetics…, different exposure patterns and limitation in experimental methodology or reporting” (ECHA 2020b).

Human data investigating irritative responses is scarce, but WHO (1987) compiled results from old volunteer studies according to which irritation of the eye and nose occurs after short-term exposure above a threshold of 0.17-0.44 mg NCO/m³ (conversion according to RAC). This concentration greatly exceeds limit values which correspond to a reasonable risk for occupational asthma for long-term exposure. One of the studies considered by WHO (1987) is used in this report to derive a DRR for irritation. Henschler et al. (1962) performed 30-minute exposures of various concentrations of TDI isomers on up to six volunteers. Tested concentrations ranged from 35 µg NCO/m³ to 1.7 mg NCO/m³. At the latter concentration symptoms were severe, with every volunteer experiencing lacrimation and a burning throat. The concentration of 256 µg NCO/m³ was the lowest concentration where all volunteers experienced first symptoms of irritation (tingling or stinging sensation in the nose). A difference in the irritative potency was observed in this study: 2,6-TDI was more potent than 2,4-TDI. WHO (1987) noted that this study reports lower effect levels than other contemporary studies, which may be explained by more accurate analytical methods.

An important study, not covered by WHO (1987) is the volunteer study by Vandenplas 1999. 17 volunteers (without previous exposure or asthma symptoms) were exposed to five ppm TDI (17 µg NCO/m³) for six hours, followed by 20 ppm TDI (70 µg NCO/m³) for 20 minutes. The two exposures were at least four weeks apart, which makes additive effects (regarding irritation) unlikely. Under these conditions, effects indicative for irritation were observed (protein leakage into the lining fluid, maximal expiratory flow). The French assessment uses this study as POD (lowest adverse effects concentration (LOAEC) 70 µg NCO/m³) for the STEL derivation. Using an assessment factor of 15 (three to extrapolate to a no effect concentration and five for intraspecies variability) a 15 min STEL corresponding to 4.6 µg NCO/m³ is derived (ANSES, 2019).

In the study by Lee and Phoon (1992), 26 TDI exposed workers from polyurethane foam factories were matched (regarding age, race, smoking status) to 26 unexposed controls. Exposure assessment was performed by means of personal sampling in the breathing zone with sampling times between 30 and 92 minutes. At an average exposure of 546 µg NCO/m³ (personal sampling, representative for an 8h TWA), 54% of workers experienced coughing and 50% experienced eye irritation.

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

Some Member States have implemented biological limit values (BLV). These are Germany (for MDI and HDI), Slovenia (HDI) and Hungary (MDI). Additionally, the UK has implemented a BLV for HDI, MDI, TDI, IPDI. Some more details on available BLVs can be found in section 4.2.4.

RAC does not propose a BLV, as it is difficult to find a correlation between air concentrations of the sum of NCO groups and biomarkers. Published studies on correlations between exposure to diisocyanates and biomarker levels usually investigate correlations of specific diisocyanates. Even for specific diisocyanates, the data are fairly limited. An additional argument against a BLV for (unspecific) diisocyanates is that the excretion kinetics vary between the different substances (ECHA, 2020b).

2.2.7 Group approach for all diisocyanates (NCO group)

The mechanistic link between the NCO Groups in diisocyanates and their toxicology is well established. The reaction of the NCO group with nucleophilic substructures like hydroxyl or amino groups in proteins leads to many adverse processes in biological systems, e.g. sensitisation or irritation (ECHA, 2020b). Several expert committees concluded that a joint assessment for all diisocyanates based on NCO concentration is adequate. For example, in the Netherlands and the UK the national limits are established based on the metric µg NCO/m³ (HCN, 2018). RAC proposes this approach as well, but also states that there is not enough data to assess potency differences for individual diisocyanates. It should be noted that other panels derived limit values for individual diisocyanates based on substance specific data, for example, the German MAK commission.

The following conversions apply:

- µg isocyanate/m³ = ppb (v/v) x total molecular weight/24.45[3]
- µg NCO/m³ = µg isocyanate/m³ x 84.03[4]/total molecular weight

Conversion factors for the most important diisocyanates are included in Table 2-4.

Table 2-4 Conversion table for NCO diisocyanate OELs and STELs

Substance	**Ms [g/mo]**	**Exposure unit**	**OEL and STEL options and their conversions**							
NCO	**42.0168**	**µg NCO / m³**	**0.025**	**0.05**	**1**	**2**	**3**	**6**	**12**	**17.5**
Diisocyanate		**ppb Diiso**	**0.007**	**0.015**	**0.3**	**0.58**	**0.87**	**1.75**	**3.5**	**5.1**
HDI	168.2	µg Diiso / m³	0.1	0.1	2.0	4.0	6.0	12.0	24.0	35.0
TDI / 2,4-TDI	174.16	µg Diiso / m³	0.1	0.1	2.1	4.1	6.2	12.4	24.9	36.3
mXDI	188.18	µg Diiso / m³	0.1	0.1	2.2	4.5	6.7	13.4	26.9	39.2
NDI	210.19	µg Diiso / m³	0.1	0.1	2.5	5.0	7.5	15.0	30.0	43.8
IPDI	222.29	µg Diiso / m³	0.1	0.1	2.6	5.3	7.9	15.9	31.7	46.3
TMXDI	244.29	µg Diiso / m³	0.1	0.1	2.9	5.8	8.7	17.4	34.9	50.9
4,4'-MDI / 2,4'-MDI / 2,2'-MDI	250.25	µg Diiso / m³	0.1	0.1	3.0	6.0	8.9	17.9	35.7	52.1
H-MDI	262.35	µg Diiso / m³	0.1	0.2	3.1	6.2	9.4	18.7	37.5	54.6
TODI	264.28	µg Diiso / m³	0.1	0.2	3.1	6.3	9.4	18.9	37.7	55.0
pMDI	149.15	µg Diiso / m³	0.1	0.2	3.5	7.1	10.6	21.3	42.6	31.1

2.3 Dose Response Relationship (non-carcinogenic effects)

2.3.1 Starting point

As explained in more detail in section 2.2.5.1 respiratory sensitisation, manifested in the form of occupational asthma, is the key toxicological endpoint for occupational exposure to diisocyanates. At occupational exposure levels which offer reasonable protection for

[3] Volume [L] of one mole of gaseous diisocyanate, assuming 25°C and 1013.25 hPa (1 atm).

[4] Molecular weight [g/mol] of both isocyanate groups

respiratory sensitisation, the risk of developing other adverse effects (particularly irritation) is negligible. Therefore, a DRR for respiratory sensitisation is presented in this report and is likely to be the primary driver of the impact assessment. However, at the levels of current Member State OELs, irritation cannot be excluded. As the baseline scenario for the impact assessment corresponds to an exposure at the median of Member State OELs, a DRR for irritation is needed as well and is derived below.

The starting point for the DRR for occupational asthma is the assessment by ECHA (2020c), which is based on the studies by Pronk et al. (2009) and Collins et al. (2017). As recognised by ECHA (2020c), these studies represent the most appropriate investigations of the relationship between exacerbation of symptoms for occupational asthma and occupational exposure to diisocyanates. No relevant studies have been published since the assessment by RAC.

The DRR derived by Pronk et al. (2009) uses individual worker exposure data, which are correlated with the prevalence for BHR20 (bronchial hyperresponsiveness with a decline of 20% in FEV1). The individual data are not given in Pronk et al. (2009) but were available to the authors of the HCN (2018) report, who performed a logistic regression. RAC apparently[5] took the logistic regression from HCN (2018) and derived the concentrations corresponding to a series of discrete excess risks (risk above background risk) for BHR20 as shown in Table 2-5.

Table 2-5 Excess risk of BHR20

Excess risk [%]	Estimated exposure µg NCO/m³
0.1	0.05
0.5	0.08
1.0	0.11
2.0	0.23
3.0	0.44
4.0	0.79
5.0	1.33

Source: Pronk et al. (2009) as given in the RAC opinion (ECHA, 2020b)

The second DRR, from Collins et al. (2017), is based on the risk estimates derived from a logistic regression given by the authors of the original study. The exposure data in Collins et al. (2017) is given as exposure-years, which is transformed by RAC to 8h TWA concentrations by dividing by the average duration of employment (11.8 years). The resulting excess risk is shown in Table 2-6.

[5] From the RAC Opinion and the Annex to the RAC opinion, it is not clear how the excess risks presented by RAC were derived. Although RAC states "Pronk et al., performed a logistic regression analysis […] RAC used this regression coefficient to estimate the risk […]", it appears more likely that the estimates from the HCN report were used, as Pronk et al. (2009) did not use a logistic regression. The level of details on the risk calculation given in the RAC opinion precludes a full comprehension of what was done.

Table 2-6 Excess risk of occupational asthma

Excess risk [%]	Estimated exposure µg NCO/m³
0.1	0.006
0.5	0.054
1.0	0.14
2.0	0.38
3.0	0.65
4.0	0.96
5.0	1.34

Source: Collins et al. (2017) as given in the RAC opinion (ECHA, 2020b)

For irritation, no study providing a dose response relationship that could be used in the impact assessment could be identified. The study team propose a pragmatic approach for estimating irritation effects at higher exposure concentrations, which uses the no observed adverse effect concentration (NOAEC) derived from the Vandenplas et al. (1999) study as the starting point.

2.3.2 DRR for respiratory sensitisation

RAC presented the expected excess risks only in tabular form with predefined excess risks and the corresponding exposure concentrations as given in Table 2-5 and Table 2-6. To derive DRRs for the full exposure range relevant for this impact assessment, these two relationships are first described as parametrized logistic regression models.

For the Collins et al. data, this is relatively easily achieved as RAC uses the same relationship as HCN (2018). The annex of HCN (2018) study concisely describes how a parametrized regression model was derived. The original study by Collins et al. (2017) does not provide the original data or parameters of the logistic regression model. However, due to the linear relationship between the log of the exposure and the log of the odds, sufficiently accurate parameters of a logistic model can be calculated (Equation 1, red line in Figure 2-1). For the model presented below, the same calculation was used as that as described in HCN (2018), except that the exposure data was already transformed to 8h TWA values. This was done to harmonize the exposure measure between the two models and makes no difference in the resulting excess risks.

For the Pronk et al. data, no clear description was available explaining how RAC derived the tabularized excess risks. The following procedure derives a model equation which reproduces the risks presented by RAC. The baseline risk (risk of unexposed workers developing the symptoms) of 6.25% is added to the excess risks in Table 2-5 to give the total risk. From the total risk, the odds were calculated (odds = p/(1-p)). Correlation of the log odds with the log exposure resulted in a linear relationship which reproduces the risk calculation by RAC for all concentrations which are predicted to have an excess risk above 0 (all concentrations at or above 0.0487 µg NCO/m³). For all exposure concentrations below this point the excess risk is artificially set to zero to avoid negative excess risks and to stay consistent with the RAC assessment (Equation 2, blue line in Figure 2-1).

The resulting model for the Collins et al. (2017) data:

Equation 1
$$\mathrm{ER(conc)} = \frac{1}{1+\mathrm{e}^{-(-3.1550+0.7328*\ln(\mathrm{conc}))}}$$ where *conc* refers to the exposure as µg NCO/m³ on the normal scale and the resulting ER is in fractions of 1.

The resulting model for the Pronk et al. (2009) data:

Equation 2
$$\mathrm{ER(conc)} = \begin{cases} \frac{1}{1+\mathrm{e}^{-(-2.1238+0.1933*\ln(\mathrm{conc}))}} - 0.0625, & conc \geq 0.0487 \\ 0, & conc < 0.0487 \end{cases}$$ where *conc* refers to the exposure as µg NCO/m³ on the normal scale and the resulting ER is in fractions of 1.

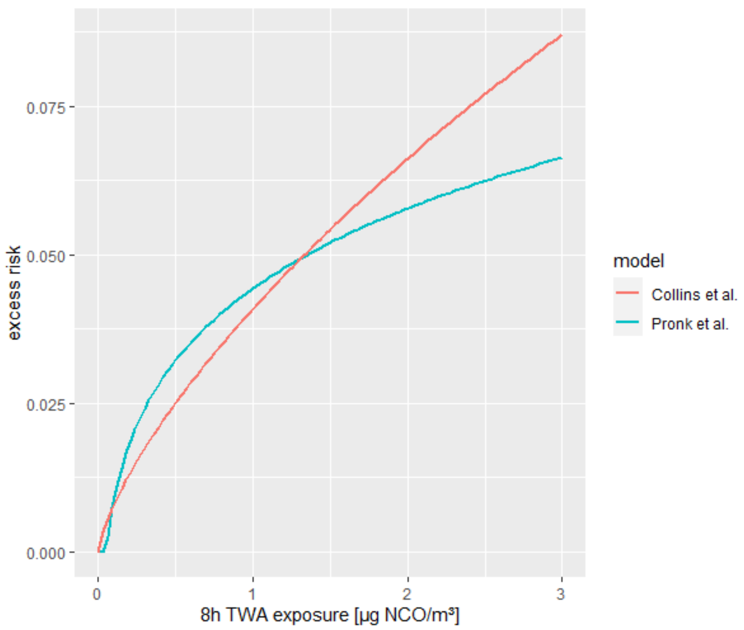


Figure 2-1 Excess risk according to the relationships

Source: Pronk et al. (2009) and Collins et al. (2017)

As can be seen in Figure 2-1, the two DRRs intersect at two locations, meaning which one of the two models predicts the higher excess risk depends on the exposure concentration. For the benefit analysis the two DRRs are merged into one in a way that the more conservative one is always chosen (i.e. the one corresponding to higher benefits).

The risk calculated by the two studies (Table 2-5 and Table 2-6) does not correspond to the cumulative risk over a full working life. For the Collins et al. study, the excess risk corresponds to the average employment duration of 11.8 years and the worker cohort was on average 40 years old. For the Pronk. et al. study, the median age of the cohort was 42 years. To adjust the calculated excess risk to be applicable for a full working life, the exposure needed to obtain the risk as determined by Pronk et al. (2009) and Collins et al. (2017)

was reduced by RAC by a factor of two. This procedure is conservative but justified (see discussion). The two relationships, including this correction for cumulative exposure over the full working life, are shown in Figure 2-2.

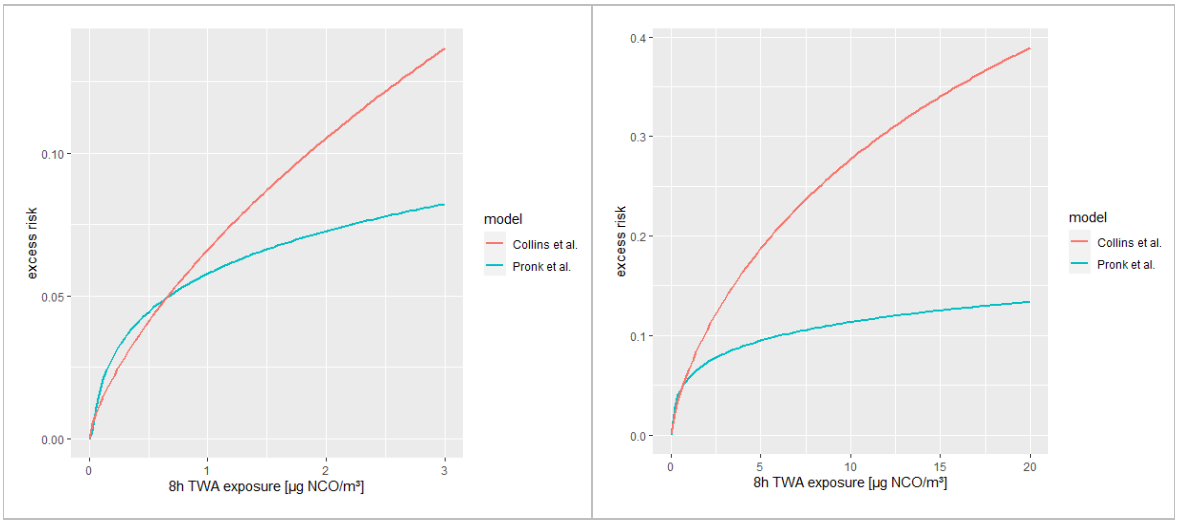


Figure 2-2 Excess risk for a working lifetime exposure. On the left is the concentration range 0 to 3 µg NCO/m³ and on the right the full range of exposures covered by the scenarios in the impact assessment.

Source: Pronk et al. (2009) and Collins et al. (2017)

The two relationships derived by RAC were not intended to be used for concentrations as high as the baseline scenario in this study (17.5 µg NCO/m³). At this concentration, the two relationships deviate quite strongly from another. The data from which the Collins et al. model was derived does not extend beyond exposures of approximately 6 µg NCO/m³. The concentration range covered by the data used in the Pronk model is not clear, but Figure 1 in the original publication (Pronk et al. (2009) suggests that the exposure range covers the full range of concentrations relevant to this report. However, this should not be used as a reason to choose the Pronk over the Collins model for the high concentration range because at the concentration where there is still exposure data in Collins et al., the excess risk predicted by the Collins et al. model (about 20%) clearly exceeds the risk according to the Pronk model, even at the highest concentrations relevant to this report (about 13% at 17.5 µg NCO/m³). In addition, two studies contained in the meta-regression analysis by Daniels (2018) provide risk estimates at concentrations close to the 17.5 µg NCO/m³. According to these studies, the excess risk at these concentrations is around 25%, which is about in the middle of the Collins et al. and Pronk et al. predictions. (RAC advises against using the meta-regression by Daniels (2018) for various reasons, however this does not affect the suitability of these studies to assess the plausibility of the models in question). These two studies also indicate that the Pronk et al. data might represent an underestimation of the risk at high concentrations. Taken together, the Collins et al. model seems to be the best alternative and should be used also for these high exposure concentrations. Doing so likely yields conservative risk estimations. The resulting final DRR is shown in Equation 3.

Equation 3
$\mathrm{ER(conc)} = \begin{cases} \dfrac{1}{1+\mathrm{e}^{-(-2.1238+0.1933*\ln(2*\mathrm{conc}))}} - 0.0625, & 0.0445 < conc < 0.654 \\ \dfrac{1}{1+\mathrm{e}^{-(-3.1550+0.7328*\ln(2*\mathrm{conc}))}}, & else \end{cases}$

where *conc* refers to the exposure as µg NCO/m³ on the normal scale and the resulting ER is in fractions of one (for example, an ER of 0.1 means 10% of exposed workers develop symptoms which would not occur without the occupational exposure).

The benefit analysis also takes into consideration MinEx (minimum time workers need to be exposed to get diseased) and MaxEx (employment time after which additional exposure does not further increase the risk).

Regarding MinEx, the study by Meredith et al. (2000) provides relevant data. In this study, workers with occupational asthma were compared with healthy workers which were matched to the asthma cases according to sex, type of work, age and duration of employment. For each case of asthma, one or preferably two matched reference workers without asthma were included in the study, totalling to 34 cases of asthma and 63 references across two sites. There was a high number of cases with low employment durations (nine within three months and additional three within one year, at both sites combined). The Collins et al. (2017) study, described in more detail above, adds evidence that a low value for MinEx is warranted, as four of the seven asthma cases occurred after less than one year of employment. These data indicate that occupational asthma already occurs after employment durations well below one year and MinEx should be set to zero.

Regarding MaxEx, RAC acknowledges that there are studies which indicate that the additional risk due to prolonged exposure is levelling off. However, at the same time there are studies which conclude on a relatively constant increase of risk with increasing time, which was considered by RAC by using an additional factor of two. Therefore, as RAC's ERR refers to a full working life of 40 years, MaxEx is set to the maximum value of 40 years (increasing risk over the full working life).

2.3.3 DRR for irritation

No suitable DRR for irritation is available from published research. A pragmatic DRR is derived based on the STEL proposed by RAC and the study by Henschler et al. (1962) which provides a second point to linearly extrapolate to.

2.3.3.1 Irritation DRR for 8h TWA exposure estimates

The discussion of a suitable STEL by RAC is based on the study by Vandenplas et al. (1999). After 20 minutes of exposure to 68 µg/m³, volunteers experienced symptoms of respiratory irritation (LOAEC). The application of a factor of three converts the LOAEC to a NOAEC, together with a factor of five for intraspecies variability not covered by the few study volunteers, giving the concentration of 4.58 µg/m³ calculated by RAC. This value is derived from a 20-minute exposure and RAC adjusted this concentration to a 15 min exposure period, resulting in a concentration of 6 µg/m³. RAC considered this database weak and proposed to set a STEL at a maximum of two times the OEL, with an upper limit of the STEL at 6 µg/m³ (15 min).

To derive a concentration without irritating effects based on 8h TWA exposure averages, the exposure duration needs further consideration. The Vandenplas et al. (1999) data indicates that the exposure duration has an impact on the concentration needed to provoke symptoms of irritation, as a shorter exposure at same concentrations did not cause the symptoms. But irritation as an endpoint does also not warrant the strict application of Haber's rule (concentration x exposure duration = constant risk). A factor of two is considered to cover the increase in risk of developing symptoms of irritation with exposure durations longer than 20 minutes. The high uncertainty associated with this factor is acknowledged. While the Vandenplas et al. (1999) study provides a strong argument that a correction needs to be performed when extrapolating from such short exposure times to risks associated with longer exposure times, the choice of the factor (two) remains to a large extent arbitrary as no data could be identified which may lead to a better-informed choice. Consequently, the threshold concentration expected to lead to zero excess risk is set to 2.25 µg NCO/m³ (8h TWA). This value is compatible with the maximum STEL value of 6 µg NCO/m³ (15 min) as proposed by RAC.

Two studies provide possible points towards which the extrapolation could be made. In the study by Lee and Phoon (1992), 26 TDI exposed workers were matched to 26 unexposed controls. At an average exposure of 546 µg NCO/m³ (personal sampling, representative for an 8h TWA), 54% of workers experienced coughing and 50% experienced eye irritation.

The study by Henschler et al. (1962) was performed with volunteers who reported irritative symptoms after being exposed to various concentrations of TDI. Beginning at a concentration of 256 µg NCO/m³, all volunteers reported irritation symptoms. Exposure lasted for 30 minutes and with the same reasoning and uncertainties as above for the 20-minute exposure in the Vandenplas et al. (1999) study, a factor of two is applied in order to be comparable to a 8h TWA. The Henschler et al. (1962) study clearly corresponds to a higher excess risk for irritation (100% at 128 µg NCO/m³) than the Lee and Phoon (1992) study (54% at 546 µg NCO/m³). Although both studies have their weaknesses, there are no apparent reasons why the data from Lee and Phoon (1992) should be preferred over the Henschler et al. (1962) study. Therefore the conservative study result is used and the DRR is derived based on the data from Henschler et al. (1962). The excess risk according to this DRR is zero until the threshold concentration (2.3 µg/m³) and then increases linearly to 128 µg/m³ where the excess risk is assumed to be 100%. The DRR is shown in Equation 4 and visualized in Figure 2-3.

Equation 4

$$\mathrm{ER}(\mathrm{conc}) = \begin{cases} 0.00795 * \mathrm{conc} - 0.0179, & conc > 2.3 \\ 0 & else \end{cases}$$

where *conc* refers to the exposure as µg NCO/m³ (8h TWA) on the normal scale and the resulting ER is in fractions of one (for example, an ER of 0.1 means 10% of exposed workers develop symptoms which would not occur without the occupational exposure).

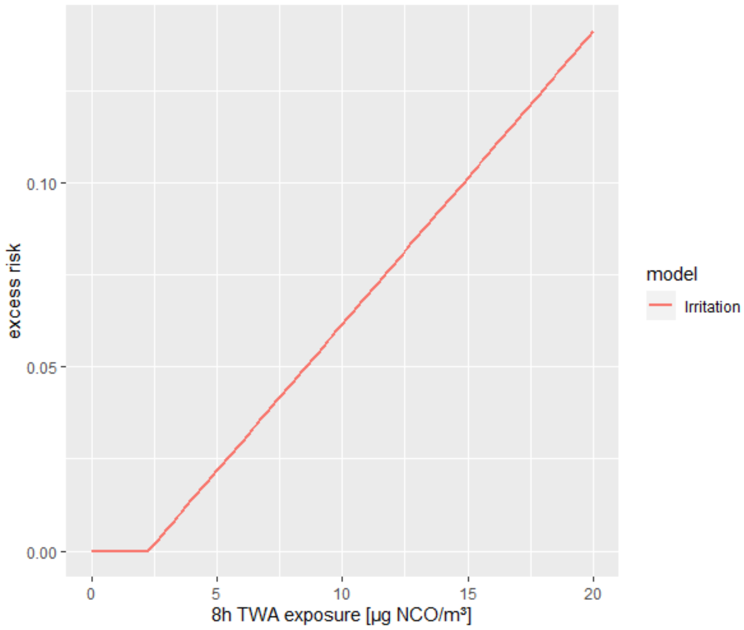


Figure 2-3 Excess risk for irritation (8h TWA exposure)

As irritation may occur within minutes after exposure Henschler et al. (1962), MinEx should be set to the minimum value. MaxEx is difficult to determine. It should be set to a value which is compatible with the notion that the risk does not further increase after a relatively short amount of time. This time needs to be longer than the exposure duration of the Vandenplas et al. (1999) study (20 minutes). A MaxEx value of one day seems large enough and is recommended.

2.3.3.2 Irritation DRR for peak exposure estimates

Because the development of an irritant effect takes place in relatively short period of time, short peak exposures likely have a strong impact on the incidence of irritation. A DRR based on short term exposure measurements may be a viable alternative to the DRR based on 8h TWA concentration, if peak exposure data is available. To derive this DRR, the same data as for the TWA DRR is used. As this data is from studies using short exposure durations (20 and 30 minutes), the uncertainty caused by extrapolation to longer exposure times has little impact here. The data is however adjusted to correspond to 15 minutes exposure concentrations by assuming that Haber's rule applies within these short time regimes. This is in line with the derivation of the upper limit of a possible STEL by RAC (6 µg NCO/m³) and supported by the additional 5-minute experiments reported by Vandenplas et al. (1999) which showed no effects at similar concentrations than the 20 minute experiments. Accordingly, the highest concentration representing no excess risk is 6 µg NCO/m³ (20 min/15min x 4.5 µg NCO/m³). From there the risk increases linearly to the 100% risk determined by Henschler et al. (1962) at 256 µg NCO/m³ (30 min/15min x 128 µg NCO/m³). The DRR is shown in Equation 5 and visualized in Figure 2-4.

Equation 5
$$\mathrm{ER(conc)} = \begin{cases} 0.004 * \mathrm{conc} - 0.024, & conc > 6 \\ 0 & else \end{cases}$$ where *conc* refers to peak exposure concentrations (15 minutes) and the resulting ER is in fractions of one (e.g., an ER of 0.1 means 10% of exposed workers develop symptoms which would not occur without the peak exposure).

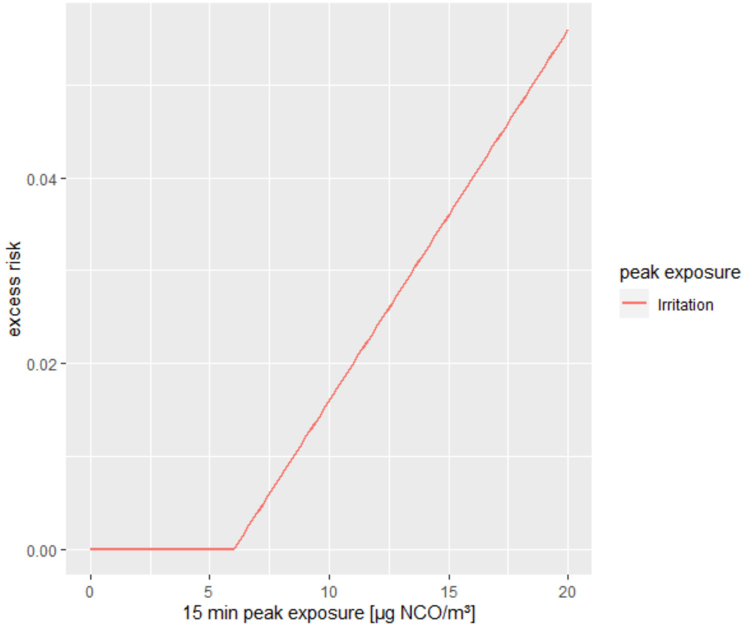


Figure 2-4 Excess risk for irritation (15 min peak exposures)

The high uncertainty of the DRR at higher exposure concentrations is acknowledged.

As only short-term exposures are considered here (15 min exposure periods), no MaxEx is set.

2.3.4 Discussion

The DRR for respiratory sensitisation is developed by closely following the RAC argument (ECHA, 2020c). It is based on the two models derived from the Collins et al. and Pronk et al. data. While the Collins model from ECHA (2020c) could be exactly reproduced, the Pronk et al. model which RAC originally used could not. The Pronk et al. model was instead reconstructed from the excess risks given in the RAC opinion. This procedure reproduces the risks calculated by RAC with high accuracy and the error introduced by this approximation is negligible compared to other uncertainties associated with the DRR.

For the Pronk et al. model, RAC used the baseline prevalence of BHR20 and asthma (BHR20 and wheeze) from Pronk et al. (2009), which is 6.25%. These figures are derived from a relatively small cohort (three workers with BHR20 among 48 control workers) but have quite a significant impact on the DRR. A single diagnosed case of BHR20 more (or less) among the control workers would result in approximately 2% higher (or lower) baseline risk and consequently would have an impact on the calculated excess risks, especially at low concentrations. The impact of this uncertainty on the final DRR is however low, because the study team's approach for the whole concentration range is to take the more conservative model (which at the low concentrations is the one based on the Collins. et al. data).

The data from the cohort used by Collins et al. (2017) was re-evaluated by Plehiers et al. (2020a) using a modified methodology. Among other differences, the authors used arithmetic instead of geometric means to calculate cumulative exposure for groups of exposed workers (details in section 2.2.5.1). Based on their regression analysis, Plehiers et al. argue against using cumulative exposure as a predictor for occupational asthma, as they didn't find a statistically significant relationship with asthma incidence. The regression coefficients are not given in the publication. To approximately compare the risks obtained using this re-evaluation with the proposed DRR, the median cumulative exposure was estimated for the exposure groups given in Table 2 of Plehiers et al. (2020a) using the histogram in Figure 1 and a logistic regression was performed with the incidences in Table 2. The resulting risks are roughly up to a factor of two lower than the risks calculated by Collins et al. (2017) according to Equation 1. The re-analysis by Plehiers et al. (2020a) illustrates the uncertainties introduced by methodological choices and indicates that Collins et al. (2017) is likely to be on the conservative side. RAC was aware of the results of Plehiers et al. (2020a) and did not identify an impact on their procedure to derive excess risks for diisocyanate exposure.

In contrast to cumulative exposure, the same authors found a correlation between occupational asthma (given as the incidence per hundred person-years) and a proxy metric for short term exposure (i.e., frequency of 8h TWA values above approximately 10 µg NCO/m³) determined for four different exposure groups (support, maintenance, field operators, loaders) (Plehiers et al., 2020b). The number of cases was 3, 1, and 3 for maintenance, field operators and loaders, respectively, whereas no case was reported for support workers, serving as control group. However, it is not clear whether the frequency of high TWA concentrations is indicative of peak exposures, as it might reflect general differences in exposures in these groups: from the data presented it is clear that average exposures were distinctly higher for loaders and field operators compared to the others. When establishing DRRs for sensitisation, it is not feasible to derive a DRR for peak exposures based on this proxy metric. The same holds true for the 95th percentile of 8h TWA values, which Collins et al. (2017) used as a proxy for peak exposure measurements. Also, deriving meaningful figures for the frequency with which certain TWA exposure levels were exceeded from the data reported by companies, would be a challenge. Plehiers et al. (2020b) as well as Collins et al. (2017) agree that there is a correlation between short-term and average exposure. RAC (2020b) concluded that exposure peaks might be important for sensitisation, but that measuring peak exposure is practically not possible. In conclusion, there is no new data available which would allow to better reflect the quantitative role of peak exposures for respiratory sensitisation and which would justify deviating from the DRR as proposed by RAC.

The two models which serve as basis for the DRR developed by RAC are not measuring the exact same endpoint. The endpoint for the Pronk et al. model is BHR20 (not considering wheezing in the diagnosis), while the Collins et al. data is for asthma (i.e., including wheezing in the diagnosis). The two endpoints are closely related but it appears plausible that BHR20 has a higher prevalence than asthma. In fact, this is supported by the data in the original Pronk et al. (2009) study itself, which includes also BHR20 in combination with wheezing as a measured endpoint – with a lower excess risk. The reason why BHR20 was chosen is that the data had a better fit to the statistical model. It is possible that using the prevalence data for BHR20 in combination with wheezing would result in a DRR with a lower predicted excess risk in the concentration range from about 0.045 µg NCO/m³ to 0.65 µg NCO/m³ but the study team decided not to deviate from the RAC opinion and refrained from attempting to fit a model based on the BHR20 and wheezing data.

During discussions it was argued that the correlations of Pronk and Collins and, consequently, the derived DRR are not validated for exposure levels below the current (which are often above 10 µg NCO/m³). However, TDI TWA exposures from TDI production included in the analysis by Middendorf et al. (2017) ranged from 0.072 to 655 µg/m³ and the cumulative TWA exposures used in the Collins et al. study ranged from 0.04 to 21.6 ppb-years, which is equivalent to approx. 0.01 to 6 µg NCO/m³. In the study by Pronk et al. exposure levels during spray painting in various industries covered a large range from >LOQ to 2643 µg NCO/m³ (task-related measurements; respective TWA values would amount to approx. 50% of these values). Actually, the DRR carries the highest uncertainty in the high concentration range (around 17.5 µg NCO/m³ which is used for the baseline scenario). No DRR was proposed for this region by RAC (as RAC did not envisage an OEL setting in this concentration range). The predicted excess risk by the two models deviates quite significantly with the Collins et al. model predicting a nearly 3-fold higher risk than the Pronk et al. model.

As already explained above, the risk according to the Collins data appears high, while at the same time there are plausible arguments that the Pronk et al model may underestimate the risk at these concentration levels. Other data of lower quality suggests a risk in between the two models. Taken together, choosing the Collins et al. model for the high concentration seems to be the more appropriate choice, but it is likely to be a conservative one.

Respiratory sensitisation is clearly the most important toxicological endpoint for diisocyanates. However, for the impact assessment it is necessary to consider all health endpoints which may lead to adverse effects at the exposure concentrations associated with the various scenarios investigated. RAC, when developing opinions for OEL setting, as a matter of principle proposes health based OELs for effects associated with thresholds but derives DRRs for effects for which no thresholds could be identified. The latter is the case for respiratory sensitisation caused by exposure to DIC and therefore RAC derived a DRR. Irritating effects were only considered by RAC regarding their relevance for concluding on a STEL. In contrast, for the impact assessment a quantitative assessment of irritating effects occurring at higher exposure concentrations was required and, in consequence, a DRR for these effects starting at the maximum STEL as given by RAC was established.

Due to the limited availability of data which may be used for a quantitative risk estimation, the DRR for irritation carries a great deal of uncertainty. The DRR is approximated by a linear relationship established from two observation points from human studies. The concentration associated with zero risk is based on an evaluation by an expert committee ANSES (2019) and supported by RAC. The DRR is further based on the steeper, more conservative slope out of two possible options, both of which are not of the best quality and with no clear reason to prefer one over the other. Considering the available options, deriving the DRR using the more conservative slope seems the most adequate choice. Further, the study team used a factor of two to correct the concentration for the fact that the corresponding prevalence were determined after short exposures. This reflects the notion, supported by limited data in Vandenplas et al. (1999), that the risk for irritation increases with continued exposure, but that this increase is not particularly strong for long exposure periods. As already pointed out, the necessity for such a factor seems clear, but the magnitude of the factor remains somewhat arbitrary given the absence of study data to determine a more appropriate factor. As such, this correction factor carries considerable uncertainty as well. A higher correction factor could be applied to ensure the conservativeness of the DRR. However, in comparison with the DRR for respiratory sensitisation, the DRR for irritation produces rather low predicted prevalence in workers. Because of the high NOAEC, irritation is only projected to contribute to the scenarios with high exposure. Consequently, although the uncertainty associated with the DRR for irritation is rather high, it probably plays a minor role in the impact assessment.

2.3.5 DRRs used in the model

Ideally, there would be separate cost benefit analyses (CBA) for both the 8hr TWA and short term peak exposure scenarios, to assess each the OEL and STEL independently. However, there is only a DRR for 8hr TWA for asthma because there is no data available to derive a peak exposure DRR.

Two DRRs are available for irritation (8 hour TWA and peak exposure), however, it is only available for C20 Chemicals and the C22 sectors, with minimal data for other sectors. In addition, this data is poor quality, with exposure concentrations that are lower for 15-minute short term exposures than for 8hr TWA.

The only cost benefit analysis possible is that based upon the 8hr TWA, providing the information upon which to assess OEL. It is therefore assumed that the STEL is set at twice the OEL. Therefore, throughout the main analysis sections of this study, the analysis is of the OEL options.

This is a major source of uncertainty as one area of considerable unanimity between stakeholders consulted was that peak exposures (measured as short term 15 minute exposure) are the primary cause of asthma caused by diisocyanates and not long-term low-level exposure (measured as 8hr TWA exposure).

2.4 Objectives

One of the key aims of the study is to provide the Commission with the most recent, updated and robust information on diisocyanates to support the European Commission in preparing an Impact Assessment report to accompany a potential proposal to amend Directive 98/24/EC.

The general objectives with regard to these chemical agents include a detailed assessment of the baseline scenario (past, current, and future), as well as the assessment of the impacts of introducing a new OELs, new Short-Term Exposure Limits STELs, respiratory sensitisation and skin sensitisation.

3. Options

3.1 Option values for the assessment (OELs and STELs)

The study compares the costs and benefits of a range of OEL and STEL options (as opposed to one or several specific OELs and STELs).

However, specific values are established for the consultation exercise to provide option points to respondents who would have found it difficult to provide data on the all the possible scenarios considered.

Throughout the analysis of benefits and costs, eight option are considered for OELs and eight for STELs, these are shown in Table 3-1 and Table 3-2.

As there is no current OEL for diisocyanates, the baseline is taken to be the median level of the national OELs for diisocyanates or 17.5 NCO µg/m^3.

Table 3-1 NCO diisocyanate OEL options

Level	Reason for inclusion
17.5 µg/m^3	The median level for a national OEL
10 µg/m^3	Intermediate level
6 µg/m^3	Intermediate level that some companies are achieving
3 µg/m^3	This is half of the maximum STEL recommended by RAC and RAC also recommend that the STEL is at most two times the OEL
1 µg/m^3	This is the lowest OEL in a Member State
0.5 µg/m^3	Intermediate level
0.1 µg/m^3	Intermediate level
0.025 µg/m^3	This value represents the lowest excess risk given by RAC (0.1%)

Table 3-2 NCO diisocyanate STEL options

Level	Reason for inclusion
35 µg/m^3	The median level for a national STEL
20 µg/m^3	Intermediate level
12 µg/m^3	Two times intermediate level
6 µg/m^3	The maximum STEL recommended by RAC
2 µg/m^3	Two times the lowest OEL in a Member State

Level	Reason for inclusion
1 µg/m³	Intermediate level
0.2 µg/m³	Intermediate level
0.05 µg/m³	Two times the lowest excess risk given by RAC (0.1%)

As indicated by ECHA in the restriction dossier, chemical reactivity of different substances should be compared on a molar and not mass basis, relevant dose metrics were therefore converted to the concentration of NCO groups to compensate for differences in molecular weight. The same conversion factors were used in this study. As part of the consultation exercise a conversion table was included to assist responding companies

Table 3-3 Conversion table of OEL and STEL options from ppb to µg NCO/m³

Substance	Ms [g/mo]	Exposure unit	OEL and STEL options and their conversions						
NCO	42.0168	µg NCO / m³	0.025	0.05	1	2	3	6	12
Diisocyanate		ppb NCO Diiso	0.007	0.015	0.3	0.58	0.87	1.75	3.5
HDI	168.2	µg HDI / m³	0.1	0.1	2.0	4.0	6.0	12.0	24.0
TDI / 2,4-TDI	174.16	µg TDI / m³	0.1	0.1	2.1	4.1	6.2	12.4	24.9
mXDI	188.18	µg mXDI / m³	0.1	0.1	2.2	4.5	6.7	13.4	26.9
NDI	210.19	µg NDI / m³	0.1	0.1	2.5	5.0	7.5	15.0	30.0
IPDI	222.29	µg IPDI / m³	0.1	0.1	2.6	5.3	7.9	15.9	31.7
TMXDI	244.29	µg TMXDI / m³	0.1	0.1	2.9	5.8	8.7	17.4	34.9
4,4'-MDI / 2,4'-MDI / 2,2'-MDI	250.25	µg MDI / m³	0.1	0.1	3.0	6.0	8.9	17.9	35.7
H-MDI	262.35	µg H-MDI / m³	0.1	0.2	3.1	6.2	9.4	18.7	37.5
TODI	264.28	µg TODI / m³	0.1	0.2	3.1	6.3	9.4	18.9	37.7
pMDI	149.15	µg pMDI / m³	0.0	0.1	1.8	3.5	5.3	10.6	21.3

4. The Baseline Analysis

4.1 Introduction

This chapter comprises the following sections:

- Section 4.2: Existing national limits
- Section 4.3: Impact of OELs for other substances
- Section 4.4: Relevant sectors, uses, and operations
- Section 4.5: Exposure concentrations
- Section 4.6: Exposed workforce
- Section 4.7: Current risk management measures
- Section 4.8: Market analysis
- Section 4.9: Alternatives
- Section 4.10: Voluntary industry initiatives
- Section 4.11: Best practice
- Section 4.12: Standard monitoring methods/tools
- Section 4.13: Relevance of REACH restrictions and authorisations
- Section 4.14: Intermediate uses not covered by certain REACH procedures
- Section 4.15: Impact of Covid-19
- Section 4.16: Current disease burden (CDB)
- Section 4.17: Future disease burden (FDB)
- Section 4.18: Summary of the baseline scenario

4.2 Existing national limits

4.2.1 OELs in Member States

The OELs for diisocyanate compounds under consideration in EU Member States and selected non-EU countries are shown in Table 4-1 (8-h TWA for diisocyanates converted to NCO, unconverted values appear in Annex 4). OELs and STELs for diisocyanate compounds were identified in Member State legislation. Some Member State Authorities provided more up to date information in the consultation questionnaire.

Table 4-1 Adjusted NCO OELs (µg/m³, 8-h TWA) in EU Member States and selected non-EU countries for diisocyanates (status: 18.08.2021)

EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4'-MDI	2,4'-MDI	2,2'-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³
Austria[1,2]	17	34	17			17				36		17			
Belgium[1,2]	17	17 (1)	17			17					17	17			
Bulgaria[1,3]	50														
Croatia[1,4]															10
Cyprus[1]															
Czech Republic[1]															
Denmark[1,2,5]	17	17	17			17				17		17			
Estonia[1,]	17	17	17							17		17			
Finland[1,2,6]															
France[1,2,7]	37	34	34							38		39			
Germany[1,2,8]	17 (1)	17 (1)	17 (1)(2)	17	17 (1)		28 (1)(2)			20		17 (1)			
Greece[1]															

EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4'-MDI	2,4'-MDI	2,2'-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³
Hungary[1,2,9]	17		17							36		3			
Ireland[1,2,10]	17 (1)	17 (1)	17 (1)								3 (1)	3 (1)			20 (1)
Italy[1,2]	500														
Latvia[1,2,11]	25											24			
Lithuania[1,12]	15	19	17							16		19			17 (1)
Luxembourg[1,13]															
Malta[1]															
Netherlands[1,14]															
Poland[1,2,15]	20	15	10	10	10						3	3			
Portugal[1]															
Romania[1,2,16]	25											34 (1)			
Slovakia[1,17]															
Slovenia[1,18]	17	17	17	17	17		28			20	17	17			

EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4’-MDI	2,4'-MDI	2,2’-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³
Spain[1,2,19]	17	17	17			18				17		17		0.002	
Sweden[1,2,20]	10	7	10							7	7	7			
Non-EU countries															
Australia[1,21]															20
Canada, Ontario[1,22]	17	17	17		17							17			
Canada, Québec[1,23]	17	17	17		17						17				
China[1,24]	15	19	17									48			
Israel[1]	17	17	17									17			
Japan - JSOH[1,25]	17		17								17 68 (1)				
Norway[1,2, 26]	17	17	17		16					16		17		0.005	
Russia[27]	25		168									24			

EU Member State / Country	**Specific diisocyanates**													**Diisocyanates**	
	HDI	**IPDI**	**4,4’-MDI**	**2,4'-MDI**	**2,2’-MDI**	**H12-MDI**	**pMDI**	**m-TMXDI**	**m-XDI**	**1,5-NDI**	**TDI**	**2,4-TDI**	**TODI**	**ppm**	**µg/m³**
South Korea[1]	17	17	18									19			
Switzerland[1,2,28]															20
Turkey[29]															
United Kingdom[1,2,30]															20
USA, NIOSH[1,2,31]	17	17	17							16					
USA, OSHA[1,2,32]		198,469	67									68			

Notes:
Belgium (1) Additional indication "D" means that the absorption of the agent through the skin, mucous membranes or eyes is an important part of the total exposure. It can be the result of both direct contact and its presence in the air.
Germany (1) Inhalable fraction (2) Skin
Ireland (1) as NCO
Lithuania (1) OEL also applies to isocyanates in the form of dusts or droplets (aerosols), including prepolymerised isocyanates (adducts).
Romania (1) Only valid for 2,4-TDI
Japan (1) Occupational exposure limit ceiling: Reference value to the maximal exposure concentration of the substance during a working day
Sources:
1: Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) GESTIS– International Limit Values. Available at: http://limitvalue.ifa.dguv.de/ accessed on 17.10.2018
2: RAC, Committee for Risk Assessment (2020) ANNEX 1 in support of the Committee for Risk Assessment (RAC) for evaluation of limit values for diisocyanates at the workplace. Available at: https://echa.europa.eu/documents/10162/b74681f6-b553-56de-68bb-7b329cb03b2b, accessed on 04.01.2021
3: Bulgaria, (2018) List of limit values. Available at: https://www.lex.bg/laws/ldoc/2135477597, accessed on 04.01.2021

EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4'-MDI	2,4'-MDI	2,2'-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³

4: Croatia, (2018) List of limit values. Available at: https://narodne-novine.nn.hr/clanci/sluzbeni/2018_10_91_1774.html, accessed on 04.01.2021
5: Denmark, (2018) List of limit values (HTP). Available at: https://at.dk/regler/bekendtgoerelser/graensevaerdier-stoffer-materialer-698/bilag-2/, accessed on 04.01.2021
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12: Lithuania, (2018) List of limit values. Available at: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.405920/qmafVPRFbo?positionInSearchResults=0&searchModelUUID=ae46f2fa-df10-44ca-a17c-8e225bec6956, accessed on 04.01.2021
13: Luxembourg, (2018) List of limit values. Available at: http://legilux.public.lu/, accessed on 04.01.2021
14: Netherlands, (2018): List of limit values. Available at: https://wetten.overheid.nl/BWBR0008587/2018-10-01, accessed on 04.01.2021
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EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4'-MDI	2,4'-MDI	2,2'-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³

23: Canada, Québec, (2018) Regulation respecting occupational health and safety, chapter S-2.1, r. 13. Available at: http://legisquebec.gouv.qc.ca/en/pdf/cr/S-2.1,%20R.%2013.pdf, accessed on 04.01.2021
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32: USA, OSHA (2018) Permissible Exposure Limits / OSHA Annotated Table Z-1. Available at: https://www.osha.gov/dsg/annotated-pels/tablez-1.html, accessed on 04.01.2021

4.2.2 STELs in Member States

The STELs for diisocyanate compounds under consideration in EU Member States and selected non-EU countries are shown in Table 4-2 (15-minute STEL for diisocyanates converted to NCO, unconverted values appear in Annex 4). OELs and STELs for diisocyanate compounds were identified in Member State legislation. Some Member State Authorities provided more up to date information in the consultation questionnaire.

Table 4-2 Adjusted NCO STELs (µg/m³, 15-min STEL) in EU Member States and selected non-EU countries for diisocyanates (status: 18.08.2021)

EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4'-MDI	2,4'-MDI	2,2'-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³
Austria[1,2]	17	68	34			17				72		82			
Belgium[1,2]											68 (1)	68 (1)			
Bulgaria[1,3]															
Croatia[1,4]															34
Cyprus[1]															
Czech Republic[1]															
Denmark[1,2,5]	35	34	34			35				32		34			
Estonia[1,]	34	34	34							34		34			
Finland[1,2,6]															35
France[1,2,7]	75	68	67							76		77			
Germany[1,2,8]	17 (1)(2)	17 (1)(2)	17 (4)(5)	17 (1)	17 (1)(2)		28 (4)(5) (2)			20 (1)		17 (1)(2)			

EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4'-MDI	2,4'-MDI	2,2'-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³
Germany ceiling limit[1,2,8]	35 (1)(3)	35 (1)(3)	34 (3)(4)(5)	34 (2)	34 (1)(3)		56 (3)(4)(5)			40 (2)		68 (1)(3)			
Greece[1]															
Hungary[1,2,9]	17		17							36		17			
Ireland[1,2,10]												3 (1)(2)			70 (1)(2)
Italy[1,2]															
Latvia[1,2,11]															
Lithuania[1,12]	35	34	34							36		34		0.01	
Luxembourg[1,13]															
Malta[1]															
Netherlands[1,14]															
Poland[1,2,15]	40		30 (1)		30						10	10			
Portugal[1]															

EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4’-MDI	2,4'-MDI	2,2’-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³
Romania[1,2,16]			50 (1)									72 (1)(2)			
Slovakia[1,17]															
Slovenia[1,18]	17 (1)	17 (1)	17 (1)	17 (1)	17 (1)		28 (1)			20 (1)	17 (1)	17 (1)			
Spain[1,2,19]												68			
Sweden[1,2,20]	15 (1)	17 (1)	17 (1)							18 (1)	19 (1)	19 (1)		0.005 (1)	
Non-EU countries															
Australia[1,21]															70
Canada, Ontario[1,22]	69	69	84		69							69			
Canada, Québec[1,23]											68 (1)				
China[1,24]		38 (1)	34 (1)									97 (1)			
Israel[1]		68 (1)	71 (1)									68 (1)			
Norway[1,2,25]															10

EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4’-MDI	2,4'-MDI	2,2’-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³
Russia[26]															
South Korea[1]												72			
Switzerland[1,2,27]															20 (1)
Turkey[28]															
United Kingdom[1,2,29]															70
USA, NIOSH[1,2,30]	70 (1)	68 (1)	67 (1)		35 (1)					68 (1)					
USA, OSHA[1,2,31]			67									68			

Notes:
Austria (1) Ceiling limit value
Belgium (1) 15 minutes average value
Germany (1) Inhalable aerosol and vapour (2) 15 minutes reference period (3) Ceiling limit value (4) Inhalable fraction and vapour (5) Skin
Ireland (1) as NCO (2) 15 minutes reference period
Poland (1) Celling limit value
Romania (1) Only valid for 2,4-TDI (2) 15 minutes average value
Slovenia (1) The EU Member State Authority indicated the OEL and STEL values are the same
Sweden (1) Short-term limit value, 5 minutes average value
Canada – Québec (1) 15 minutes average value
China (1) 15 minutes average value
Israel (1) 15 minutes average value

EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4'-MDI	2,4'-MDI	2,2'-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³

Switzerland (1) as NCO
USA – NIOSH (1) Ceiling limit value (10 min)
Sources:
1: Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) GESTIS– International Limit Values. Available at: http://limitvalue.ifa.dguv.de/ accessed on 17.10.2018
2: RAC, Committee for Risk Assessment (2020) ANNEX 1 in support of the Committee for Risk Assessment (RAC) for evaluation of limit values for diisocyanates at the workplace. Available at: https://echa.europa.eu/documents/10162/b74681f6-b553-56de-68bb-7b329cb03b2b, accessed on 04.01.2021
3: Bulgaria, (2018) List of limit values. Available at: https://www.lex.bg/laws/ldoc/2135477597, accessed on 04.01.2021
4: Croatia, (2018) List of limit values. Available at: https://narodne-novine.nn.hr/clanci/sluzbeni/2018_10_91_1774.html, accessed on 04.01.2021
5: Denmark, (2018) List of limit values (HTP). Available at: https://at.dk/regler/bekendtgoerelser/graensevaerdier-stoffer-materialer-698/bilag-2/, accessed on 04.01.2021
6: Finland, (2018) List of limit values (HTP). Available at: http://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/160967/STM_09_2018_HTParvot_2018_web.pdf?sequence=1&isAllowed=y, accessed on 04.01.2021
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10: Ireland, Health and Safety Authority (2021) Code of Practice. Available at: https://www.hsa.ie/eng/publications_and_forms/publications/chemical_and_hazardous_substances/2021-code-of-practice-for-the-chemical-agents-and-carcinogens-regulations.pdf, accessed on 02.06.2021
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13: Luxembourg, (2018) List of limit values. Available at: http://legilux.public.lu/, accessed on 04.01.2021
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15: Poland, (2018) List of limit values. Available at: http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU20180001286/O/D20181286.pdf, accessed on 04.01.2021
16: Romania, (2018) List of limit values. Available at: http://www.mmuncii.ro/j33/images/Documente/Legislatie/HG584-2018.pdf, accessed 04.01.2021
17: Slovakia (2018) List of limit values. Available at: http://www.epi.sk/, accessed on 04.01.2021
18: Slovenia (2018) List of limit values. Available at: http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV4030, accessed on 04.01.2021
19: Spain, (2018) List of limit values (VLA). Available at: https://www.insst.es/documents/94886/188493/L%C3%ADmites+de+exposici%C3%B3n+profesional+para+agentes+qu%C3%ADmicos+2018/623ca35b-6212-419f-9213-20eeadbe2b5b, accessed on 04.01.2021
20: Sweden, Arbetsmiljöverket (2018) Hygieniska gränsvärden (AFS 2018:1). Available at: https://www.av.se/arbetsmiljoarbete-och-inspektioner/publikationer/foreskrifter/hygieniska-gransvarden-afs-20181-foreskrifter/, accessed on 04.01.2021

EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4'-MDI	2,4'-MDI	2,2'-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³

21: Australia, Safe Work Australia (2018) Workplace exposure standards for airborne contaminants. Available at: https://www.safeworkaustralia.gov.au/system/files/documents/1804/workplace-exposure-standards-airborne-contaminants-2018_0.pdf, accessed on 04.01.2021
22: Canada, Ontario, (2018) Current Occupational Exposure Limits for Ontario Workplaces Required under Regulation 833. Available at: https://www.labour.gov.on.ca/english/hs/pubs/oel_table.php, accessed on 04.01.2021
23: Canada, Québec, (2018) Regulation respecting occupational health and safety, chapter S-2.1, r. 13. Available at: http://legisquebec.gouv.qc.ca/en/pdf/cr/S-2.1,%20R.%2013.pdf, accessed on 04.01.2021
24: China (2007), List of limit values. Available at: http://jk.sipcdc.com/ZYWS/Detail/1207, accessed on 04.01.2021
25: Norway (2021) List of limit values. Available at: https://www.arbeidstilsynet.no/globalassets/regelverkspdfer/forskrift-om-tiltaks--og-grenseverdier, accessed on 28.06.2021
26: Russia (2021) List of limit values. Available at: http://publication.pravo.gov.ru/Document/View/0001202102030022?index=21&rangeSize=1, accessed on 28.06.2021
27: Switzerland, Suva (2018) Aktuelle MAK- und BAT-Werte. Available at: https://www.suva.ch/de-CH/material/Richtlinien-Gesetzestexte/grenzwerte-am-arbeitsplatz-aktuelle-werte/#59317A47178F431595269A7BB5018B2A=%3Flang%3Dde-CH, accessed on 04.01.2021
28: Turkey (2013) List of limit values. Available at: https://www.resmigazete.gov.tr/eskiler/2013/08/20130812-1.htm, accessed on 28.06.2021
29: United Kingdom, Health and Safety Executive, EH40/2005 Workplace exposure limits, Available at: http://www.hse.gov.uk/pubns/priced/eh40.pdf, accessed on 04.01.2021
30: USA, NIOSH (2018) Pocket Guide to Chemical Hazards. Available at: https://www.cdc.gov/niosh/index.htm, accessed on 04.01.2021
31: USA, OSHA (2018) Permissible Exposure Limits / OSHA Annotated Table Z-1. Available at: https://www.osha.gov/dsg/annotated-pels/tablez-1.html, accessed on 04.01.2021

4.2.3 Minimum, maximum and average national OELs

The minimum, maximum and average NCO OELs for the diisocyanates for Member States are given in Table 4-3.

Three Member States already have lower diisocyanate NCO OELs than other EU Member States, these are Ireland, Poland and Sweden. Both Ireland and Poland have a lower µg/m^3 NCO level for TDI where both levels are less than 10 µg/m^3 NCO. In Ireland, the 2,4-TDI STEL level is 3 µg/m^3 NCO, this is the only STEL level that is below the RAC opinion of 6 µg/m^3 NCO. Poland also has some of the lowest 8-h TWA and STEL levels set for diisocyanates.

Table 4-3 Maximum, minimum and average of NCO OELs (µg/m³, 8-h TWA) in EU Member States for diisocyanates

Maximum, minimum and averages	All compounds
Maximum	500
Minimum	3
Median	17.4
Mode	16.8
Mean	26.7

Source: Study team (calculated January 2021)

4.2.4 National biological limit values (BLVs)

A few countries also published biological limit values (BLV) for diisocyanate compounds. For HDI, a BLV of 15 µg/g creatinine in urine was established by Germany (BAuA, 2015) and Slovenia (Official Gazette of the Republic of Slovenia, 2018). For MDI, Hungary derived a BLV of 0.01 mg/l or 0.05 µmol/l in urine (Hungarian Minister of Human Resources, 2020). In the USA, ACGIH derived a value of 5 µg/g creatinine in urine for 2,4- and 2,6-TDI (ACGIH, 2021). The United Kingdom published a value of 1 µmol isocyanate-derived diamine/mol creatinine in urine for isocyanates (applies to HDI, isophorone diisocyanate (IPDI), TDI, and MDI) (Health and Safety Executive, 2020).

4.2.5 Groups at extra risk

In section 2.2 about epidemiological and experimental data, there is no evidence of specific health effects for women compared with men. Therefore, no assessment of the impacts disaggregated by gender is made.

4.2.6 Member States with existing OELs and STELs

If a Member State has implemented an OEL, in theory, all companies in this Member State could be assumed to be complying with the OEL. This means that companies and workers in this Member State should be excluded from the analysis of the cost of risk management measures to comply and benefits where the OEL option being modelled is above the Member State's OEL. It also means that the companies in Member States with an OEL are already monitoring, or doing what is necessary for the enforcement authorities, to prove compliance.

However, for diisocyanates there are some issues that make this challenging. Some Member States have several different OELs and STELs for different diisocyanates, see Table 4-1 and Table 4-2. For example, Austria has similar NCO OEL levels for TDI, HDI and MDI whereas Sweden has a lower NCO OEL for TDI than it does for HDI and MDI. Many Member States only have an OEL for some diisocyanates. Therefore, a decision would be required about the appropriate OEL to be taken for the Member State. Broadly speaking, if a Member State has an OEL for a given diisocyanate, it also has a STEL.

Furthermore, many of the existing OELs in Member States are at or above the baseline of 17.5 NCO µg/m^3, which means that they do not have any impact upon the analysis of the cost of risk management measures to comply in section 6 and benefits analysis in section 5. Several member States have OELs of 17 NCO µg/m^3 and STELs of 34 NCO µg/m^3, as these are so close to the baseline values of 17.5 NCO µg/m^3 and 35 NCO µg/m^3, they are assumed to be the same.

In Table 4-4, the information in Table 4-1 and Table 4-2 has been analysed to indicate the Member States that have an OEL and/or STEL for one or more MDI and TDI diisocyanates, showing if this is at or above the baseline of 17.5 NCO µg/m^3 or lower than the baseline. It also shows the population of the Member States. Croatia, Ireland, Poland and Sweden have TDI OELs less than 15 µg/m^3 (7.2 NCO µg/m^3) and they represent approximately 10% of the population of the EU, and thus it can be assumed 10% of the companies are in Member States that have an OEL below the baseline.

Similarly, only six EU Member States (Germany, Hungry, Ireland, Poland, Slovenia and Sweden) currently have an MDI or TDI STEL that is lower than the baseline of 35 NCO µg/m^3, however, the German STELs has two levels, the higher tolerated level, which is the same as the baseline and the lower accepted level, which is the same as the OEL (baseline).

A further complication is that for several sectors, the number of companies, and their split into small, medium and large, are based upon information from industry about the companies specifically using diisocyanates. The only source of data to subdivide the companies by Member State is Eurostat, but this would be inaccurate as it applies to much larger groups of companies.

For these reasons, the companies in Member States that have implemented OELs/STELs are not removed from the analysis. This means that both the costs and benefits will be overestimated by approximately 10% because it is the OELs that are modelled throughout the analysis. However, they should both be overestimated to the same extent, so the cost benefit ratios are expected to be broadly correct.

Similar calculations based upon Table 4-4, show that approximately 65% of companies are in Member States with OELs and will already be monitoring, or doing what is necessary for the enforcement authorities, to prove compliance. Therefore, some adjustment is made in the analysis of monitoring costs in section 6.4.3.

Table 4-4 Member States with OEL/STELs for MDI and TDI and their population

Member State	OEL		STEL		Population Millions
	MDI	TDI	MDI	TDI	
Austria	Baseline	Baseline	Baseline	Baseline	9
Belgium	Baseline	Baseline	None	Baseline	11
Bulgaria	None	None	None	None	7
Croatia	None	None	None	None	4
Cyprus	None	None	None	None	0.9
Czech Republic	None	None	None	None	11
Denmark	Baseline	Baseline	Baseline	Baseline	6
Estonia	Baseline	Baseline	Baseline	Baseline	1
Finland	None	None	Baseline	Baseline	6
France	Baseline	Baseline	Baseline	Baseline	67
Germany	Baseline	Baseline	LOW	LOW	83
Greece	None	None	None	None	11
Hungary	Baseline	LOW	LOW	LOW	10
Ireland	Baseline	LOW	None	LOW	5
Italy	None	None	None	None	61
Latvia	None	Baseline	None	None	2
Lithuania	Baseline	Baseline	Baseline	Baseline	3
Luxembourg	None	None	None	None	0.6
Malta	None	None	None	None	0.5
Netherlands	None	None	None	None	17
Poland	LOW	LOW	Baseline	LOW	38
Portugal	None	None	None	None	10
Romania	None	Baseline	Baseline	Baseline	20
Slovakia	None	None	None	None	5
Slovenia	Baseline	Baseline	LOW	LOW	2
Spain	Baseline	Baseline	None	Baseline	47
Sweden	LOW	LOW	LOW	LOW	10
Total					**446**

Source: Study team
Notes: Baseline means an OEL/STEL around or above the baseline of 17.5/35 NCO µg/m³
Low means an OEL/STEL below the baseline

4.3 Impact of OELs for other substances

The study team is not aware of any impact upon the exposure levels or numbers of exposed workers relating to diisocyanates from recently implemented OELs for other substances or OELs in the process of being introduced for other substances.

Regarding the other substances in this study, asbestos and lead and its compounds are also used in the construction sector, but in completely different processes to those using diisocyanates. Therefore, no impact from OELs or other limit values for asbestos and lead and its compounds is expected upon the exposure levels or numbers of exposed workers relating to diisocyanates.

4.4 Relevant sectors, uses, and operations

4.4.1 Overview of uses

Diisocyanates are important industrial chemicals that have several applications; these can primarily be categorised as:

- Polyurethane;
- CASE:
  - **C**oatings (surface treatment like paints and lacquers);
  - **A**dhesives;
  - **S**ealants (e.g. fillers/joint fillers), and
  - **E**lastomers (e.g. rubber and thermoplastic elastomers).

The use of diisocyanates consists of manufacturing and professional uses.

Diisocyanates are used as a raw material in the production of all polyurethane products. Polyurethane foams (flexible and rigid) are strong, durable, resistant to abrasion, resistant to corrosion, have low thermal conductivity, and easily fill voids and can be shaped. Combined, these properties make polyurethane foams ideal for use in insulated building panels, mattresses, upholstered furniture, car seats, domestic refrigerators, freezers, composite wood panels, truck bodies and footwear.

Diisocyanates may be present at concentrations of between 0-50% in coatings/paint products and 0.01-90% in adhesive and sealant products (Danish Environmental Protection Agency, 2014). CASE products are widely used and occupational exposure may occur during both the manufacturing of the relevant products as well as professional use. This includes settings such as construction, manufacturing of electrical and related equipment, manufacturing of shoes and textiles, manufacturing of wood, transport and machinery manufacturing, and the repair of transport and machinery.

PMDI is used to produce both flexible and rigid foams, typically rigid foam is used in metal insulation, insulation boards and cool chain applications (fixed and mobile refrigeration and freezers). Flexible foam manufacturing is the largest consumer of TDI by volume and second largest consumer of MDI. The largest consumer of MDI is the rigid foam sector (in the form of pMDI) and the elastomer sector. CASE products typically contain MDI, HDI or TDI. Table 4-5 subdivides the 2011 MDI and TDI consumption data for volumes on the EU market (EU27+Norway) into the main application categories.

Insulating products manufactured with diisocyanates contribute highly to the EU's food and medicine quality, and also significantly contribute to business and residential energy savings. CASE products are currently widely used, and the product properties contribute significantly to the sectors they are used in.

Table 4-5 Yearly MDI and TDI consumption data for EU (plus Norway) subdivided into main application areas.

EU27+Norway (2011)	Polymeric MDI (pMDI) (t/year)	Monomeric MDI (t/year)	TDI (t/year)	Total MDI and TDI (t/year)	Speciality Diiso cyanates (t/year)
Adhesives	17,900	28,500	18,300	64,700 (4%)	11,600
Coatings	35,500	10,900	30,100	76,500 (5%)	66,800
Elastomers	0	101,500	2,500	104,000 (7%)	5,300
Sealants	5,300	6,700	4,400	16,400 (1%)	600
Binders	145,900	0	500	146,400 (10%)	0
Flexible Foam	83,400	32,700	305,200	421,300 (27%)	0
Rigid Foam	708,000	0	0	708,000 (46%)	0
Total	996,000	180,300	361,000	1,537,300	84,300

Source: IAL Consultants (2013) as reported by the Danish Environmental Protection Agency (2014).
Notes: IAL Consultants roughly estimates that the uncertainty on these figures is about 5% (+/-)

4.4.2 Manufacturing processes (PROCs) in REACH registration dossiers

The manufacturing processes (PROCs) in REACH registration dossiers relating to diisocyanates that are in scope (those indicated in Table 1-2) appear in Table 4-6. PMDI is the substance with the highest use, however, as it is not REACH registered and no information appears in Table 4-6 for pMDI.

Table 4-6 Diisocyanates and their PROCs according to REACH Registration Dossiers (2020)

Process	HDI	IPDI	4,4'-MDI	2,4'-MDI	2,2'-MDI	H12-MDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI
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 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		✓	✓	✓	✓	✓				✓	✓	

Process	HDI	IPDI	4,4’-MDI	2,4'-MDI	2,2’-MDI	H12-MDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI
PROC 11: Non-industrial spraying					✓							
PROC 13: Treatment of articles by dipping and pouring		✓	✓	✓	✓	✓		✓		✓	✓	
PROC 14: Tabletting, compression, extrusion, pelletisation, granulation		✓	✓	✓	✓	✓		✓		✓	✓	✓
PROC 15: Use as laboratory reagent	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
PROC 21: Low energy manipulation of substances bound in materials and/or articles		✓	✓	✓	✓	✓			✓	✓	✓	✓
PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles			✓	✓	✓							
PROC 28: Manual maintenance (cleaning and repair) of machinery										✓		✓
PROC 0: Other: PROC0a: Removal of solidified material from containers/vessels/blenders			✓		✓							

Source: ECHA Registration Dossiers (ECHA, 2021b)
Note: PMDI is the substance with the highest use, however, it is not REACH registered and does not appear in the table

4.4.3 Overview of sectors

4.4.3.1 Sources of information about sectors using diisocyanates

The study team identified a total of 42 industrial sectors based on NACE codes, see Table 4-8, where diisocyanates are claimed to be used and where there is a potential for occupational exposure. Upon review, 24 sectors were excluded leaving 18 sectors, and some sectors were sub divided to make a total of 21 sectors,

Several sources were reviewed, some sources contained data on the number of exposed workers or companies with exposed workers by sector, others covered exposure levels by sector, whilst some sources simply described the sectors of use.

- Study consultation 2021, which holds information about the exposure levels and numbers of exposed workers for specific processes at specific sites (confidential).
- Chemical safety reports (CSRs) (2020) from the REACH registration process for the use of the specific diisocyanates (MDI, NDI and TDI) (confidential).
- The European Diisocyanate & Polyol Producers Association (ISOPA) provided the study team with a description of the sectors within the supply chain and the processes within them. Additional discussion about the use of diisocyanates within sectors were held with CEPE, Euro-Moulders, EUROPUR, FEICA, PU Europe, Flexible Packaging Europe and Europanels.
- REACH registration dossiers describe the sectors of use for the 13 diisocyanates selected, see Table 4-7.
- RAC background (ECHA, 2020f) to the RAC opinion (ECHA, 2020g) describes the sectors using diisocyanates and includes references to several studies studying occupational exposure of diisocyanates.
- The International Agency for Research on Cancer (IARC, 1987, 1999c, 1999a) in some cases mentions the uses of MDI and TDI but not NDI.
- The EU Risk Assessment Report (Commission, 2002) for MDI (4,4’-MDI, 2,4'-MDI, 2,2’-MDI) describes sectors using MDI and occupational exposure within these sectors.
- The French National Research and Safety Institute for the Prevention of Occupational Accidents and Diseases (INRS, 2020) provides exposure levels experienced by employees exposed to diisocyanates by sector for the EU.
- The Medical Monitoring Survey of Professional Risks (SUMER, 2020) provides estimates of employees exposed to diisocyanates by sector for France.
- Data as reported in the German MEGA database from 2000 to 2011 for HDI, MDI and TDI (IFA, 2009, 2011, 2013). The study steering group were also able to provide the study team with German MEGA database from 2000 to 2019 for HDI, IPDI, MDI and TDI.
- CAREX Canada (CAREX, no date) provides an overview of the main uses and an estimate of employees exposed to TDI in Canada and in the five largest sectors in Canada.
- The UK HSE Report (2005) provides information on the use and occupational exposure of diisocyanates in several sectors, number of workers exposed in sectors, the use of RPE and ventilation by task.

- The Register of Occupational Hygienic Measurements, Finnish Institute of Occupational Health (Finnish National Institute of Occupational Health, no date) includes diisocyanate concentrations of TDI, MDI and HDI in working air in different industries in the years 2008-2016.
- The Danish Ministry of the Environment (2014) provides information on the use and occupational exposure of diisocyanates in several sectors.
- The study by Pronk *et al.* (2009) investigates exposure to spray painters and is used by RAC to estimate 8-hour time weighted average exposure, based on exposure response relations.
- The study by Collins *et al.* (2017) investigates exposure to TDI during its production and is used by RAC to estimate 8-hour time weighted average exposure, based on exposure response relations.
- The study by Brzeźnicki and Bonczarowska (2015) investigates occupational exposure to HDI, MDI and TDI in several different industrial sectors in Poland.
- The study by Henriks-Eckerman *et al.* (2015) describes occupational exposure to MDI in the boat building sector.
- The US NTP (2014) describes uses and sectors where TDI is used.

4.4.3.2 Sectors of use (SU) in REACH registration dossiers

The sectors of use (SU) in REACH registration dossiers relating to diisocyanates is shown in Table 4-7. PMDI is the substance with the highest use, however, as it is not REACH registered no information appears in Table 4-7 for pMDI. Important sectors of use for pMDI include SU 12: Manufacture of plastics products, including compounding and conversion (C22), SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment (C28, C29, C30) SU 19: Building and construction work (F41, F42 and F43).

Table 4-7 Diisocyanates and their sectors of use according to REACH dossiers

Sector of Use (NACE code)	HDI	IPDI	4,4’ -MDI	2,4’-MDI	2,2’ -MDI	H12-MDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI
SU 2a: Mining (without offshore industries) (B)										✓		
SU 2b: Offshore industries (B)										✓		
SU 3: Industrial uses: Uses of substances as such or in preparations at Industrial Sites (C)		✓	✓									
SU 5: Manufacture of textiles, leather, fur (C13)										✓		
SU 7: Printing and reproduction of recorded media (C18)			✓							✓		
SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) (C19)		✓	✓						✓	✓	✓	
SU 9: Manufacture of fine chemicals (C20)	✓		✓						✓	✓	✓	
SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) (C20)		✓	✓			✓		✓		✓	✓	
SU 11: Manufacture of rubber products (C22)			✓			✓						
SU 12: Manufacture of plastics products, including compounding and conversion (C22)	✓	✓	✓			✓		✓		✓		✓
SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment (C28, C29, C30)			✓							✓		
SU 19: Building and construction work (F41, F42 and F43)		✓	✓									
SU 20: Health services (Q86)	✓		✓									
SU 21: Professional uses (M74)			✓									
SU 22: Consumer uses			✓									
SU 24: Scientific research and development (M72)	✓		✓		✓						✓	
SU 0: Other:		✓	✓			✓				✓		

Source: ECHA Registration Dossiers (ECHA, 2021b)

In Table 4-7, under “SU 0: Other” the following text appeared in the relevant REACH registration dossiers:

- IPDI:
    - SU3: Industrial uses: Uses of substances as such or in preparations at industrial sites
    - SU10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)
- 4,4'-methylenediphenyl diisocyanate (4,4'-MDI):
    - Use for adhesives, lubrication, soldering, moulding or processing aids in various industry sectors (No SU provided)
    - SU10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)
- H12-MDI:
    - Not indicated, however, likely related to industrial end use as intermediate / monomer
- TDI:
    - SU3: Industrial uses: Uses of substances as such or in preparations at industrial sites

4.4.3.3 Summary of sector data

An overview of the types of data from these sources is shown in Table 4-8. This information is further analysed in Section 4.4.5 to select coherent sectors that serve as the basis for the analysis in this study. A comprehensive list of all potentially relevant sectors identified from the sources reviewed in this study, together with their associated NACE codes, is shown in Table 4-8.

Table 4-8 Summary of sectors using diisocyanates according to data sources

NACE	Name	Consultation (1)	CSRs	REACH SU	RAC (2)	IARC	EU RAR	CAREX Canada	INRS	SUMER	Danish Ministry of the Environment	FIOH	US NTP	Brzeźnicki and Bonczarowska	German MEGA	UK HSE	Henriks-Eckerman
Type of data (3)		E, M, W	E	M	E, M	W	E, M	W	E, M	W	E, M	E, M	M	E	E	E, M	E, M
Year		2021		2020	2020	1987 - 1999	2005	2021	1987 - 2018	2010	2014	2008 - 2016	2014	2015	2000 - 2011	2005	2015
C13	Manufacture of textiles	Y		Y	Y	Y	Y	Y	Y	Y			Y		Y		
C14	Manufacture of wearing apparel				Y				Y	Y	Y						
C15	Manufacture of leather and related products	Y		Y	Y		Y		Y	Y	Y	Y	Y	Y	Y		
C16	Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials				Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	
C17	Manufacture of corrugated paper and paperboard and of containers of paper and paperboard	Y							Y	Y							
C18	Printing and reproduction of recorded media			Y			Y		Y	Y					Y	Y	
C19	Manufacture of coke and refined petroleum products			Y													
C20	Manufacture of chemicals and chemical products		Y	Y	Y	Y	Y		Y	Y	Y	Y	Y		Y	Y	
C22	Manufacture of rubber and plastic products	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	

NACE	Name	Consultation (1)	CSRs	REACH SU	RAC (2)	IARC	EU RAR	CAREX Canada	INRS	SUMER	Danish Ministry of the Environment	FIOH	US NTP	Brzeźnicki and Bonczarowska	German MEGA	UK HSE	Henriks-Eckerman
C23	Manufacture of other non-metallic mineral products								Y	Y		Y			Y		
C24	Manufacture of basic metals	Y			?		Y		Y	?		Y			Y	Y	
C25	Manufacture of fabricated metal products, except machinery and equipment				Y		Y		Y	?				Y	Y		
C26	Manufacture of computer, electronic and optical products								Y	Y		Y		Y	Y		
C27	Manufacture of electrical equipment						Y	Y	Y	Y		Y	Y	Y	Y	Y	
C28	Manufacture of machinery and equipment n.e.c.			Y	Y		Y		Y	Y		Y		Y	Y		
C29	Manufacture of motor vehicles, trailers and semi-trailers	Y		Y	Y	Y		Y	Y	Y			Y	Y	Y	Y	
C30	Manufacture of other transport equipment	Y		Y		Y		Y	Y	Y		Y	Y			Y	Y
C31	Manufacture of furniture	Y			Y				Y			Y	Y		Y		
C32	Other manufacturing								Y			Y					
C33	Repair and installation of machinery and equipment				Y		Y			Y		Y				Y	
F41	Construction of buildings			Y						Y					Y		
F42	Civil engineering			Y	Y		Y			Y					Y		

NACE	Name	Consultation (1)	CSRs	REACH SU	RAC (2)	IARC	EU RAR	CAREX Canada	INRS	SUMER	Danish Ministry of the Environment	FIOH	US NTP	Brzeźnicki and Bonczarowska	German MEGA	UK HSE	Henriks-Eckerman
F43	Specialised construction activities			Y	?		Y		Y	Y		Y			Y	Y	
G45	Wholesale and retail trade and repair of motor vehicles and motorcycles				Y		Y		Y	Y		Y			Y		
G47	Retail trade, except of motor vehicles and motorcycles																
H49	Land transport and transport via pipelines														?		
H50	Water transport														?		
H51	Air transport								Y						?		
J59	Motion picture, video and television programme production, sound recording and music publishing activities																
K64	Financial service activities, except insurance and pension funding								Y								
K66	Activities auxiliary to financial services and insurance activities																
L68	Real estate activities								Y								
M70	Activities of head offices; management consultancy activities								Y								
M71	Architectural and engineering activities; technical testing and analysis						Y							Y	Y		

NACE	Name	Consultation (1)	CSRs	REACH SU	RAC (2)	IARC	EU RAR	CAREX Canada	INRS	SUMER	Danish Ministry of the Environment	FIOH	US NTP	Brzeźnicki and Bonczarowska	German MEGA	UK HSE	Henriks-Eckerman
M72	Scientific research and development			Y	Y		Y										
N82	Office administrative, office support and other business support activities																
O84	Public administration and defence; compulsory social security																
P85	Education								Y								
Q86	Human health activities			Y											Y		
Q87	Residential care activities																
S94	Activities of membership organisations								Y								
S95	Repair of computers and personal and household goods																

Sources: CSRs (confidential), ECHA (2020e), ECHA Registration Dossiers (ECHA, 2021b), Commission (2002), IARC (1987, 1999c, 1999a), CAREX (no date), INRS (2020), SUMER (2020), Danish Ministry of the Environment (2014), Finnish National Institute of Occupational Health (no date) US NTP (2014), Brzeźnicki and Bonczarowska (2015), IFA (2009, 2011, 2013), UK HSE (2005) and Henriks-Eckerman et al. (2015)

1 Consultation responses include response received to data in the questionnaire and meetings with industry associations

2 ECHA RAC Annex contained several occupational exposure studies from several different sectors

3 W = workers, E = exposure, M = mention

4.4.4 Criteria for selection of sectors for further analysis

The summary of sectors in Table 4-8, which are the NACE divisions rather than the NACE classes, shows that defining the sectors using diisocyanates is complex. Two main factors were considered in selecting sectors for analysis:

- Are there mentions or sources of data for this sector from multiple sources?
- Is there any indication that occupational exposure is likely to be significant?

This leads to the key sectors, which are described in the following section. The study team believes that a specific difficulty arises around the wide use of diisocyanates in many sectors including their consumer-like uses, for example as sealants. Some sources also indicate occupational uses in some unexpected sectors. Several sectors appearing in many sources of data initially puzzled the study team and the industry associations as no activity using diisocyanates is known in these sectors. Examples of these sectors are:

- Manufacture of coke and refined petroleum products
- Retail trade, except of motor vehicles and motorcycles
- Land transport and transport via pipelines
- Water transport
- Air transport
- Motion picture, video and television programme production, sound recording and music publishing activities
- Financial service activities, except insurance and pension funding
- Activities auxiliary to financial services and insurance activities
- Real estate activities
- Activities of head offices; management consultancy activities
- Office administrative, office support and other business support activities
- Public administration and defence; compulsory social security
- Education
- Residential care activities
- Activities of membership organisations
- Repair of computers and personal and household goods

However, after much discussion, the study team believes that the activities causing the presence of diisocyanates exposure data are likely to be:

- Companies providing services relating to the C20 Manufacture of chemicals and chemical products (in particular C20.14 Manufacture of other organic basic chemicals, C20.16 Manufacture of plastics in primary forms, C20.17 Manufacture of synthetic rubber in primary forms, C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics, C20.52 Manufacture of glues and C20.60 Manufacture of man-made fibres).

- Companies providing services relating to the C22 Manufacture of rubber and plastic products (in particular C22.21 Manufacture of plastic plates, sheets, tubes and profiles and C22.29 Manufacture of other plastic products).
- Companies involved in the manufacture of products, including C13 Manufacture of textiles, C14 Manufacture of wearing apparel, C15 Manufacture of leather and related products, C16 Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials, C26 Manufacture of computer, electronic and optical products, C27 Manufacture of electrical equipment, C28 Manufacture of machinery and equipment n.e.c. and C31 Manufacture of furniture.
- Companies involved in the manufacture and repair of transportation, including C29 Manufacture of motor vehicles, trailers and semi-trailers, C30 Manufacture of other transport equipment, C33 Repair and installation of machinery and equipment and G45 Wholesale and retail trade and repair of motor vehicles and motorcycles.
- Companies involved in the construction industry, including F41 Construction of buildings, F42 Civil engineering and F43 Specialised construction activities.
- Companies involved in the repair of good, S95 Repair of computers and personal and household goods.

These activities and the relevant sectors are discussed further below.

4.4.5 Description of key sectors

This section describes the sectors selected for a detailed analysis. in the study and provides a first indication of the significance of occupational exposure to diisocyanates – more detailed information on the occupational exposure is provided in Sections 4.5. and 4.6.

4.4.5.1 C13 Manufacture of textiles

Companies under NACE code C13 Manufacture of textiles appear to use diisocyanates in the manufacturing of textiles. For example, polyurethanes are used for coating textiles and producing elastomeric fibres (e.g. Spandex and Lycra), where the production of these might be covered by C22.22. However, not all uses within the sector are clear and there might be some use throughout the whole sector, including:

- C13.10 Preparation and spinning of textile fibres
- C13.30 Finishing of textiles
- C13.91 Manufacture of knitted and crocheted fabrics
- C13.92 Manufacture of made-up textile articles, except apparel
- C13.93 Manufacture of carpets and rugs
- C13.94 Manufacture of cordage, rope, twine and netting
- C13.95 Manufacture of non-wovens and articles made from non-wovens, except apparel
- C13.96 Manufacture of other technical and industrial textiles
- C13.99 Manufacture of other textiles n.e.c.

4.4.5.2 C14 Manufacture of wearing apparel

Companies under NACE code C14 Manufacture of wearing apparel appear to use diisocyanates in apparel, for example, the manufacturing of gloves and protective cloths for workplace protection. The use of diisocyanates in CASE products means there might be some uses across the whole sector:

- C14.11 Manufacture of leather clothes
- C14.12 Manufacture of workwear
- C14.13 Manufacture of other outerwear
- C14.14 Manufacture of underwear
- C14.19 Manufacture of other wearing apparel and accessories
- C14.20 Manufacture of articles of fur
- C14.31 Manufacture of knitted and crocheted hosiery
- C14.39 Manufacture of other knitted and crocheted apparel

4.4.5.3 C15 Manufacture of leather and related products

Companies under NACE code C15 Manufacture of leather and related products appear to use diisocyanates in some situations, for example, it is clear that the manufacture of footwear will often involve the use of an adhesive to bind the shoe together (C15.20 Manufacture of footwear). The manufacture of rubber boots, shoe heels, soles, other rubber and plastic footwear parts falls under C22. The use of CASE also means there might be some uses across the whole sector:

- C15.11 Tanning and dressing of leather; dressing and dyeing of fur
- C15.12 Manufacture of luggage, handbags and the like, saddlery and harness
- C15.20 Manufacture of footwear

4.4.5.4 C16 Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials

Companies under NACE code C16 Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials appear to use diisocyanates in some situations, for example, the use of adhesives in the production of particle boards. The use of CASE also means there might be some uses across most of the sector:

- C16.21 Manufacture of veneer sheets and wood-based panels
- C16.22 Manufacture of assembled parquet floors
- C16.29 Manufacture of other products of wood; manufacture of articles of cork, straw and plaiting materials

4.4.5.5 C20 Manufacture of chemicals and chemical products

Companies under NACE code C20 Manufacture of chemicals and chemical products routinely use diisocyanates in the manufacturing of several types of chemicals and chemical products. The subsectors that are likely to use diisocyanates are:

- C20.14 Manufacture of other organic basic chemicals;

- C20.16 Manufacture of plastics in primary forms;
- C20.17 Manufacture of synthetic rubber in primary forms;
- C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics;
- C20.52 Manufacture of glues; and
- C20.60 Manufacture of man-made fibres

4.4.5.6 C22 Manufacture of rubber and plastic products

Companies under NACE code C22 Manufacture of rubber and plastic products routinely use diisocyanates in the manufacturing of several different types of rubber and plastic products. The subsectors that are likely to use diisocyanates are:

- C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres;
- C22.19 Manufacture of other rubber products;
- C22.21 Manufacture of plastic plates, sheets, tubes and profiles; and
- C22.22 Manufacture of plastic packing goods
- C22.29 Manufacture of other plastic products

However, C22 also includes C22.23 Manufacture of builders' ware of plastic and C22.29 Manufacture of other plastic products, therefore, the whole sector is considered to be relevant.

The manufacturing of foams uses a significant volume of all pMDI, TDI and MDI within EU Member States. The two most important uses of foam are in the manufacturing of rigid foams in sandwich insultation panels (C22.21 Manufacture of plastic plates, sheets, tubes and profiles) and the manufacturing of flexible foams (C22.29 Manufacture of other plastic products). Due to the importance of these two uses, the study team decided to spilt C22 to treat these uses separately whilst considering all of the other uses together.

4.4.5.7 C26 Manufacture of computer, electronic and optical products

Companies under NACE code C26 Manufacture of computer, electronic and optical products are likely to use diisocyanates as part of CASE use in:

- C26.11 Manufacture of electronic components
- C26.12 Manufacture of loaded electronic boards
- C26.20 Manufacture of computers and peripheral equipment
- C26.30 Manufacture of communication equipment
- C26.40 Manufacture of consumer electronics
- C26.51 Manufacture of instruments and appliances for measuring, testing and navigation
- C26.52 Manufacture of watches and clocks
- C26.60 Manufacture of irradiation, electromedical and electrotherapeutic equipment
- C26.70 Manufacture of optical instruments and photographic equipment

- C26.80 Manufacture of magnetic and optical media

4.4.5.8 C27 Manufacture of electrical equipment

Companies under NACE code C27 Manufacture of electrical equipment may use diisocyanates as part of CASE use in:

- C27.11 Manufacture of electric motors, generators and transformers
- C27.12 Manufacture of electricity distribution and control apparatus
- C27.20 Manufacture of batteries and accumulators
- C27.31 Manufacture of fibre optic cables
- C27.32 Manufacture of other electronic and electric wires and cables
- C27.33 Manufacture of wiring devices
- C27.40 Manufacture of electric lighting equipment
- C27.51 Manufacture of electric domestic appliances
- C27.52 Manufacture of non-electric domestic appliances
- C27.90 Manufacture of other electrical equipment

4.4.5.9 C28 Manufacture of machinery and equipment n.e.c.

Companies under NACE code C28 Manufacture of machinery and equipment n.e.c. may use diisocyanates as part of CASE use in:

- C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines
- C28.12 Manufacture of fluid power equipment
- C28.13 Manufacture of other pumps and compressors
- C28.21 Manufacture of ovens, furnaces and furnace burners
- C28.22 Manufacture of lifting and handling equipment
- C28.23 Manufacture of office machinery and equipment (except computers and peripheral equipment)
- C28.24 Manufacture of power-driven hand tools
- C28.25 Manufacture of non-domestic cooling and ventilation equipment
- C28.29 Manufacture of other general-purpose machinery n.e.c.
- C28.30 Manufacture of agricultural and forestry machinery
- C28.41 Manufacture of metal forming machinery
- C28.49 Manufacture of other machine tools
- C28.91 Manufacture of machinery for metallurgy
- C28.92 Manufacture of machinery for mining, quarrying and construction
- C28.93 Manufacture of machinery for food, beverage and tobacco processing

- C28.94 Manufacture of machinery for textile, apparel and leather production
- C28.95 Manufacture of machinery for paper and paperboard production
- C28.96 Manufacture of plastic and rubber machinery
- C28.99 Manufacture of other special-purpose machinery n.e.c.

4.4.5.10 C31 Manufacture of furniture

Companies under NACE code C31 Manufacture of furniture are likely to use diisocyanates across the whole sector:

- C31.01 Manufacture of office and shop furniture
- C31.02 Manufacture of kitchen furniture
- C31.03 Manufacture of mattresses
- C31.09 Manufacture of other furniture

The uses will consist of CASE as part of the manufacturing processes. Although foam is used in the manufacturing of furniture, the foam will likely be manufactured offsite by a foam manufacturer covered by C22.29.

4.4.5.11 C29 Manufacture of motor vehicles, trailers and semi-trailers

Companies under NACE code C29 Manufacture of motor vehicles, trailers and semi-trailers use diisocyanates in a number of situations. Adhesives and sealants are used to bind and seal components together, and protective paints and coatings are applied to the vehicle body. Polyurethane foams and used in car seats (covered by C22.29), however, in most cases these are not produced onsite and only the finished product is installed in the car on a production line. Rigid polyurethane foam is used to insulate refrigerated vehicles and trailers.

The use of CASE means that diisocyanates are likely to be use across the subsectors:

- C29.10 Manufacture of motor vehicles
- C29.20 Manufacture of bodies (coachwork) for motor vehicles; manufacture of trailers and semi-trailers
- C29.31 Manufacture of electrical and electronic equipment for motor vehicles
- C29.32 Manufacture of other parts and accessories for motor vehicles

4.4.5.12 C30 Manufacture of other transport equipment

Companies under NACE code C30 Manufacture of other transport equipment use diisocyanates in a number of situations similar to those in C29. Adhesives and sealants are used to bind and seal components together, paints and coatings are applied to the body. Polyurethane foams and used in seating (C22.29), however, these are not produced onsite and only the finished product is installed.

The use of CASE means that diisocyanates are likely to be use across the subsectors:

- C30.11 Building of ships and floating structures
- C30.12 Building of pleasure and sporting boats
- C30.20 Manufacture of railway locomotives and rolling stock

- C30.30 Manufacture of air and spacecraft and related machinery
- C30.40 Manufacture of military fighting vehicles
- C30.91 Manufacture of motorcycles
- C30.92 Manufacture of bicycles and invalid carriages
- C30.99 Manufacture of other transport equipment n.e.c.

4.4.5.13 C33 Repair and installation of machinery and equipment

Companies under NACE code C33 Repair and installation of machinery and equipment are likely to use diisocyanates primarily for:

- C33.15 Repair and maintenance of ships and boats
- C33.16 Repair and maintenance of aircraft and spacecraft
- C33.17 Repair and maintenance of other transport equipment

The use will likely consist of CASE as part of repair and maintenance. There may be some other CASE related uses across the sector, but these are likely to be the most significant uses.

4.4.5.14 G45 Wholesale and retail trade and repair of motor vehicles and motor-cycles

Companies under NACE code G45 Wholesale and retail trade and repair of motor vehicles and motor-cycles are likely to use diisocyanates only for:

- G45.20 Maintenance and repair of motor vehicles
- G45.40 Sale, maintenance and repair of motorcycles and related parts and accessories

The uses consist of CASE as part of repair and maintenance.

4.4.5.15 F41.20 Construction of residential and non-residential buildings

Companies under NACE code F41.20 Construction of residential and non-residential buildings will use diisocyanates containing products as part of the construction of a building. For example, in some painting/coating products inside and outside of buildings, the use of adhesives/sealants in joinery applications as well as floor and wall coverings. Construction activities will also involve installing articles that contain diisocyanates.

Use of RPE and PPE in the sector is widespread and training, as required by the REACH restriction, should see its use improve.

4.4.5.16 F42 Civil engineering

Companies under NACE code F42 Civil engineering will use diisocyanates in some situations. for example, painting/coating of civil engineering projects and the use of sealants or elastomers in joinery applications. The use of CASE means that diisocyanates are likely to be use across the subsectors:

- F42.11 Construction of roads and motorways
- F42.12 Construction of railways and underground railways
- F42.13 Construction of bridges and tunnels

- F42.21 Construction of utility projects for fluids
- F42.22 Construction of utility projects for electricity and telecommunications
- F42.91 Construction of water projects
- F42.99 Construction of other civil engineering projects n.e.c.

4.4.5.17 F43 Specialised construction activities

Companies under NACE code F43 Specialised construction activities will use diisocyanates in a number of situations, for example, paints as part of painting and glazing operations, adhesives and sealants as part of joinery installation and floor and wall covering. Although these are expected to be some of the most significant uses, the use of CASE means that diisocyanates are likely to be use across the subsectors:

- F43.21 Electrical installation
- F43.22 Plumbing, heat and air conditioning installation
- F43.29 Other construction installation
- F43.32 Joinery installation
- F43.33 Floor and wall covering
- F43.34 Painting and glazing
- F43.39 Other building completion and finishing
- F43.91 Roofing activities
- F43.99 Other specialised construction activities n.e.c.

Employees in the sector that do not use diisocyanates might also be exposed due to working in close proximity to applications of diisocyanates, for example, plasterers (F43.31 Plastering).

The use of diisocyanates in spray foams as part of F43.29 Other construction installation involves the use of significant volumes of diisocyanates and the exposure risk associated with spray foams is different to adhesives and sealants containing diisocyanates. Due to the difference in use and exposure risk, the study team decided to treat the use of spray foams separately from the rest of specialised construction.

4.4.5.18 S95 Repair of computers and personal and household goods

Companies under NACE code S95 Repair of computers and personal and household goods are likely to use diisocyanates mainly in:

- S95.23 Repair of footwear and leather goods
- S95.24 Repair of furniture and home furnishings

4.4.6 Excluded sectors

The following sectors appear in some sources, but are accounted for as follows:

- C17 Manufacture of corrugated paper and paperboard and of containers of paper and paperboard – only C17.29 Manufacture of other articles of paper and paperboard may involve the use of diisocyanates in some cases. Around 10% of companies may use adhesives/sealants containing diisocyanates to manufacture products. This is shown in the German MEGA database (IFA, 2021) where several related datapoints are below the LOD and the majority are below 6 µg/m^3 NCO, however, a P95 of 11.4 µg/m^3 total NCO was recorded in the sector.

- C18 Printing and reproduction of recorded media – the main use might be for C18.14 Binding and related services where adhesives containing diisocyanates might be used, however, the industrial processes are likely to reduce occupational exposure. In most occupational exposure studies, the levels were below the LOD. CEPE indicated that printing inks are unlikely to contain diisocyanates.
- C19 Manufacture of coke and refined petroleum products – if diisocyanates are used during these manufacturing processes, the occupational exposure levels are expected to be very low.
- C23 Manufacture of other non-metallic mineral products – although diisocyanates appear to be used during these manufacturing processes, the occupational exposure levels in most cases are expected to be very low. This is shown in the most recent German MEGA database (IFA, 2021) where all related datapoints are below the LOD. In previous versions of the German MEGA database (IFA, 2009, 2011, 2013) most related datapoints were also below the LOD.
- C24 Manufacture of basic metals – although diisocyanates appear to be used during these manufacturing processes, the occupational exposure levels in most cases are expected to be very low. This is shown in the most recent German MEGA database (IFA, 2021) where the majority of related datapoints are below the LOD and all datapoints are below 1.5 µg/m^3 NCO.
- C25 Manufacture of fabricated metal products, except machinery and equipment – although diisocyanates appear to be used during these manufacturing processes, the occupational exposure levels in most cases are expected to be very low.
- C32 Other manufacturing – although diisocyanates appear to be used during these manufacturing processes, for example medical and dental instruments and supplies, the occupational exposure levels in most cases are expected to be very low due to the controlled environments the products are manufactured in.
- G47 Retail trade, except of motor vehicles and motorcycles – the study team believes that occupational exposure in this sector will be very low.
- H49 Land transport and transport via pipelines – the study team believes that occupational exposure in this sector will be very low.
- H50 Water transport – the study team believes that occupational exposure in this sector will be very low.
- H51 Air transport – the study team believes that occupational exposure in this sector will be very low.
- J59 Motion picture, video and television programme production, sound recording and music publishing activities – the study team believes that occupational exposure in this sector will be very low.
- K64 Financial service activities, except insurance and pension funding – the study team believes that occupational exposure in this sector will be very low.
- K66 Activities auxiliary to financial services and insurance activities – the study team believes that occupational exposure in this sector will be very low.

- L68 Real estate activities – the study team believes that occupational exposure in this sector will be very low.
- M70 Activities of head offices; management consultancy activities – the study team believes that occupational exposure in this sector will be very low.
- M71 Architectural and engineering activities; technical testing and analysis – the study team believes that occupational exposure in this sector will be very low.
- M72 Scientific research and development – appears to be low quantities used in laboratories; any associated exposure levels are very low.
- N82 Office administrative, office support and other business support activities – the study team believes that occupational exposure in this sector will be very low.
- O84 Public administration and defence; compulsory social security – the study team believes that occupational exposure in this sector will be very low.
- P85 Education – the study team believes that occupational exposure in this sector will be very low.
- Q86 Human health activities – although there is likely to be some exposure to orthopaedic practitioners when applying casts, the occurrence, exposure duration and occupational diisocyanate concentrations are expected to be low. This is shown in the German MEGA database (IFA, 2009, 2011, 2013) where all inpatient measurements were below the LOD.
- Q87 Residential care activities – the study team believes that occupational exposure in this sector will be very low.
- S94 Activities of membership organisations – the study team believes that occupational exposure in this sector will be very low.

In the sectors above where the study team believes that occupational exposure will be very low, the diisocyanate use might be restricted to infrequent use of a sealant or adhesive.

4.4.7 Summary of sectors

The sectors taken forward for analysis are outlined in Table 4-9.

Table 4-9 Sectors using diisocyanates selected for analysis

NACE	Sector	Short name for sector
C13	Manufacture of textiles	C13 Textiles
C14	Manufacture of wearing apparel	C14 Apparel
C15	Manufacture of leather and related products	C15 Leather
C16	Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials	C16 Wood
C20	Manufacture of chemicals and chemical products	C20 Chemicals

NACE	Sector	Short name for sector
C22	Manufacture of rubber and plastic products	C22 Other
C22.21	Manufacture of plastic plates, sheets, tubes and profiles	C22.21 Rigid foam
C22.29	Manufacture of other plastic products	C22.29 Flexible foam
C26	Manufacture of computer, electronic and optical products	C26 Computers
C27	Manufacture of electrical equipment	C27 Electrical equipment
C28	Manufacture of machinery and equipment n.e.c.	C28 Machinery
C29	Manufacture of motor vehicles, trailers and semi-trailers	C29 Motor vehicles
C30	Manufacture of other transport equipment	C30 Transport
C31	Manufacture of furniture	C31 Furniture
C33	Repair and installation of machinery and equipment	C33 Machinery Repair
F41.20	Construction of residential and non-residential buildings	F41.20 Construction
F42	Civil engineering	F42 Civil engineering
F43	Specialised construction	F43 Specialised construction
F43.29	Other construction installation	F43.29 Other installation
G45	Wholesale and retail trade and repair of motor vehicles and motor-cycles	G45 Vehicle repair
S95	Repair of computers and personal and household goods	S95 Repairs

4.5 Exposure concentrations

4.5.1 Introduction

This section considers exposure data from many sources to arrive at the study team's estimates of exposure distributions for each of the key sectors. There are two main sources:

- Published sources
- Confidential sources – CSRs and consultation data (survey data, interviews and site visits)

4.5.2 Impact of other OELs

As discussed in section 4.3, no other OEL is thought to have any impact upon the exposure concentrations and number of exposed workers for diisocyanates.

4.5.3 Impact of REACH Restriction

4.5.3.1 Impact on the baseline

In August 2020, a new REACH Restriction was issued (EUROPEAN PARLIAMENT, 2020), which comes into effect in August 2023. The implications of the Restriction are explained in section 2.1.3.

The future burden of disease is usually estimated using the data in the preceding sections for exposed workers, see Table 4-29, and exposure levels, see Table 4-15, from 2000 to present day and predicts the number of cases over the next 40 years. The future burden of disease does not include cases that are the result of exposure in previous years. The FDB is the baseline against which reductions in cases due to reductions in exposure due to new OELs and STELs are measured.

However, the impact of the REACH Restriction is expected to be significant and therefore the baseline for this impact assessment needs to be adjusted.

The estimated reduction in the number of cases is between 50% and 70% after four years, or by 2027, see Figure 4-1. This is expected to occur due to reductions in both inhalation and dermal exposure. However, there is no clear data indicating the relative impacts of inhalation and dermal exposure, only that inhalation is essential and that dermal clearly plays a role in the process of inducing asthma, see section 2.2.2.1. Furthermore, there is no linear relationship between airborne concentrations and cases: even if all of the reduction of cases was due to a reduction in airborne concentrations, reducing the number of cases by 50% does not imply that airborne concentrations are all reduced by 50%. However, to run the cost model, the reduced exposure levels following the introduction of the Restriction are required. The steering group agreed that the study team should assume that the Restriction has the more conservative effect of reducing all airborne concentrations by 50%.

Any new OEL/STEL is likely to come into effect in approximately 2023 or 2024 and therefore there will be a couple of years during which the Restriction is still taking effect at the beginning of the 40-year period after the new OEL/STEL takes effect. The study team has calculated that this would lead to approximately a 2% underestimation of cases under the revised baseline. This is insignificant compared with the uncertainties due to the impact of the REACH Restriction and the effect of the limit of quantification, see section 4.5.5, the range in DRRs, see section 2.3.2, and the inability overall to model peak exposure, see sections 2.3.2, 2.3.4 and 2.3.5.

ECHA estimate that there are 1.44 million workers potentially at high risk in EU and that restriction is estimated as avoiding over 3,000 new occupational asthma cases per year in EU (ECHA, 2021a). ECHA estimate that the benefits per year are €369.4 million. The benefits of the risk reduction are estimated to outweigh the costs of the Restriction after 3 - 6 years.

In section 10.2.4, the sensitivity analysis compares the impacts of an even more conservative reduction in cases of 30% and the highest anticipated reduction in cases of 70%.

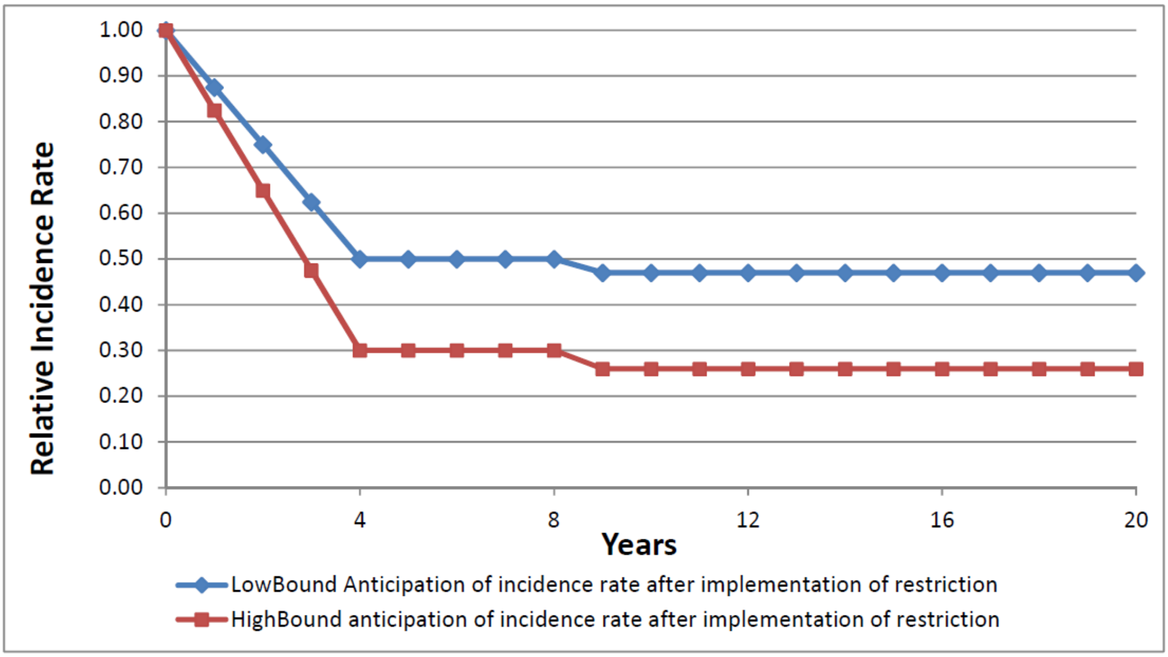


Figure 4-1 Forecast (low/high bound) for the relative development of the incidence rate after implementation of the proposed Restriction

Source: (ECHA, 2018d)

4.5.3.2 Industry view of the REACH Restriction's likely impact

In the consultation survey, industry representatives were about the impact that they expected the REACH Restriction training obligations to have on exposure concentrations. Table 4-10 outlines the results; there is variation of anticipated impact across sectors. Particularly C22 Plastics (polyurethane manufacturers) and C26 Computers anticipate an impact, whereas the other sectors responding do not. Generally, the sectors that are heavy users of diisocyanates believe it will have less impact, probably because they are already implementing training at the level of the REACH restriction. Responses by Member State, see Table 4-11, are consistently split regarding anticipated impacts of REACH Restrictions.

Respondents were asked to indicate which type of impact they anticipate will affect their organisation in the future. As shown in Table 4-12, nearly all responses citied an increase in worker training measures in accordance with REACH which will reduce worker exposure to diisocyanates.

In the consultation survey, trade unions were supportive of training, not just for diisocyanates but for all chemical related risks. One trade union also highlighted the risk of singling out one chemical over other chemicals and how this might cause confusion and may risk leaving other important chemicals in its shadow.

Table 4-10 Estimated impact of future REACH Restriction Training obligations on workplace exposure, by sector (n= 205)

Response	Yes	No
C16 Wood	0.0% (0)	100.0% (8)
C20 Chemicals (A)	5.9% (3)	94.1% (48)
C22.21 Rigid foams	20.0% (3)	80.0% (12)

Response	Yes	No
C22.29 Flexible foams (B)	13.5% (7)	86.5% (45)
C22 Other	94.0% (47)	6.0% (3)
C26 Computers	94.7% (18)	5.3% (1)
C29 Motor vehicles	0.0% (0)	100.0% (1)
F43 Specialise construction	0.0% (0)	100.0% (4)
Total	**39% (78)**	**61% (122)**

Source: Consultation survey

Notes: (A): Approximately half of the responses in C20 were provided by three companies; (B) All responses in C22.29 were provided by five companies

Table 4-11 Estimated impact of future REACH Restriction Training obligations on work-place exposure, by split by Member State (n= 190)

Member State	Yes	No
Austria	33.3% (1)	66.7% (2)
Belgium	25.0% (2)	75.0% (6)
Czechia	0.0% (0)	100.0% (5)
Denmark	50.0% (1)	50.0% (1)
Estonia	0.0% (0)	100.0% (1)
Finland	0.0% (0)	100.0% (2)
France	38.1% (8)	61.9% (13)
Germany	41.8% (28)	58.2% (39)
Hungary	16.7% (1)	83.3% (5)
Italy	56.0% (14)	44.0% (11)
Lithuania	0.0% (0)	100.0% (1)
Luxembourg	0.0% (0)	100.0% (1)
Netherlands	41.7% (5)	58.3% (7)
Poland	25.0% (1)	75.0% (3)
Portugal	83.3% (5)	16.7% (1)
Romania	0.0% (0)	100.0% (4)
Slovak republic	0.0% (0)	100.0% (1)
Slovenia	100.0% (1)	0.0% (0)
Spain	66.7% (12)	33.3% (6)
Sweden	0.0% (0)	100.0% (2)
Total	**42% (79)**	**58% (111)**

Source: Consultation survey
Note: Total number excludes non-Member State responses.

Table 4-12 Estimated impact of future REACH Restriction Training obligations on work-place exposure, type of impact (n= 85)

Response	Frequency
Increased training of workers	96% (69)
Mandatory medical surveillance	8% (6)
Increased monitoring	4% (3)
Other unclassified comments	10% (7)

Source: Consultation survey
Note: Total may not equal 100% due to rounding. Respondents were able to provide multiple responses to the questionnaire (i.e. one for each facility in their organisation). These percentages include responses from the same respondent.

4.5.4 Mix of diisocyanates

Data about workers exposed to diisocyanates and the associated exposure levels are usually available as individual diisocyanate substances, individual diisocyanate substances expressed as NCO or total NCO values.

The different physical properties of diisocyanates results in differences in their potential to be breathed in. HDI and TDI are more hazardous than other diisocyanates, the are the two diisocyanates with the lowest molecular weight and they are the most volatile diisocyanates meaning vapour is more likely to become airborne and therefore more likely to be breathed in. Although the molecular weight of pMDI is low compared with MDI, pre-polymers are less volatile.

As noted by Allport et al. (1998), the saturated vapour concentrations (SVC) of a chemical is the concentration in air of that chemical when in equilibrium with the liquid or solid phase of the chemical at a given temperature. The SVC is an important concept because of the relationship between SVC and real exposure, i.e. the potential that a worker will breathe in air saturated with the substance of interest. At lower temperatures, TDI and HDI are available at significantly higher concentrations than other diisocyanates, see Table 4-13.

Table 4-13 Saturated vapour concentration of most heavily used diisocyanates

Substance	Saturated vapour concentration
TDI	160,000 µg/m^3 (calculated at 25 °C)
HDI	99,544 µg/m^3 (calculated at 25 °C)
MDI	1,500 µg/m^3 (calculated at 45 °C)
pMDI	150 µg/m^3 (calculated at 25 °C)
IPDI	5,728 µg/m^3 (calculated at 20 °C)
HMDI	204 µg/m^3 (calculated at 25 °C)

Sources: TDI (ISOPA, 2013b), MDI and pMDI (ISOPA, 2013a), HDI, IPDI and HMDI (American Chemistry Council, 2016)

In section 4.2, in those EU member states with an OEL and STEL level, the levels are typically lower for TDI compared with the other diisocyanates.

The exposure risk from TDI is expected to be higher than that of the other diisocyanates. The study team identified a greater number of TDI occupational exposure studies >6 µg/m^3 than studies for other diisocyanates.

Some sectors involve exposure to more than one type of diisocyanate. Flexible foam manufacturing is the largest consumer of TDI by volume and second largest consumer of MDI. The largest consumer of pMDI/MDI is the rigid foam sector. CASE products typically contain MDI, HDI or TDI. HDI-based diisocyanates are primarily used as hardeners for motor vehicle and airplane polyurethane spray paints, including primers, sealers, and clear coats (Fent et al, 2008).

In the construction sector, products containing HDI, IPDI, MDI and TDI are used. The German Social Accident Insurance for Construction organisation, BG Bau, offers analytical services for compliance with OELs. BG Bau and FEICA performed occupational exposure testing of products typically used in the construction sector, this included floor coatings, adhesives, sealants and foam in-can products. The floor coating products tested mainly contained MDI, the MDI concentrations were higher than the TDI or HDI concentrations present in products. In floor coating tests, MDI exposure was the lowest and usually below detection limits. However, although TDI and HDI were present at lower concentrations in the products, these could sometimes be measured above the detection limits. Only TDI was occasionally detectable at levels above 1 NCO µg/m^3. The situation was similiar for parquet adhesives, most adhesives contained MDI but MDI levels were not detected. Some parquet adhesives contain TDI and in only two out of 43 cases was TDI measured at 1 – 5 NCO µg/m^3. A total of ten measurements were made from different one component foam in-can products, these typically contained 15% MDI; in all of the tests MDI was not detected. Joint sealants were tested in an unventilated room, this would typically be the worst case exposure application of sealants. The different joint sealants contained MDI, TDI and/or IPDI in concentrations between 0.01% and 0.6%: only TDI could be analytically detected at 0.8 NCO µg/m^3.

The type of diisocyanate use is also very important, for example, aerosolization from spraying operations is a potentially significant source of exposure. This includes HDI in vehicle spray painting and MDI as part of spray foam insulation.

The RAC opinion and the derivation of the DRRs for asthma are based upon one report is based entirely on TDI (Collins *et al.*, 2017) and one based entirely on spray painting HDI (Pronk *et al.*, 2009).

For these and other reasons, sensitising substances present specific challenges as it is hard to model how sensitisation and occupational asthma occurs. Further consideration of the best approach to use when analysing occupational asthmagens is required but is beyond the scope of this study.

4.5.5 Limit of quantification

Many data sources for exposure concentrations have records where the recorded value is below the limit of quantification (LOQ). The LOQ is assumed to be 1 µg/m^3 for the diisocyanate or 0.5 NCO µg/m^3. In these cases, the assumed exposure concentration when the level is record as less that LOQ is taken as half of the LOQ or 0.5 µg/m^3 for the diisocyanate or 0.25 NCO µg/m^3.

However, this means that the lowest data values of 0.25 NCO µg/m^3 are still ten times higher than the lowest scenario level of 0.025 NCO µg/m^3.

4.5.6 Confidential sources

4.5.6.1 Chemical Safety Reports (CSRs) – exposure with RPE

There is detailed information about exposure levels in the CSRs, which were available for HDI, MDI and TDI. All exposure levels were taken with RPE if it was used; therefore, they represent the exposure levels experienced by workers. These levels are used to calculate ill-health and thus the cost of ill-health and the benefits of lowering the OEL.

The CSR data have been analysed and included in the exposure estimations in Annex 3.

4.5.6.2 Chemical Safety Reports (CSRs) – exposure without RPE

This data is similar to that in section 4.5.6.1, except that these are the exposure levels when RPE has not been used. These levels are used to calculate ill-health and thus the cost of ill-health and the benefits of lowering the OEL.

The CSR data have been analysed and included in the exposure estimations in Annex 3.

4.5.6.3 Consultation (2021)

During the online survey, respondents were asked to provide five levels of exposure data for diisocyanates:

- Minimum
- Maximum
- Mean
- Median
- 95th percentile

Approximately 238 respondents responded to the survey, some enterprises provided additional response for their different sites. About 180 response included exposure data, some respondents supplied data about all requested levels (15-min and 8-hour TWA), whilst others provided data for only some of them (15-min or 8-hour TWA).

The data was cleaned. This included checking unusually high values (outliers) of which there were very few. In some cases, where the data could have been µg/m^3 or mg/m^3, there were clues in other parts of the response that allowed the study team to deduce the likely unit. The majority of data was presented as specific measurements of diisocyanate substances rather than an NCO but the relevant data was converted in µg/m^3 NCO values.

4.5.7 Discussion of sectors and sources of exposure data

In Annex 3, the information from the published and confidential sources is summarised by sector together with data from ECHA's (2020a) Annex to the opinion on diisocyanates and additional sources. Only information from studies conducted after 2000 has been included in Annex 3, although there are several studies published prior to 2000 (also prior to 1990, 1980 and 1970) that are available.

4.5.8 Summary of exposure data

Based upon the values in Annex 3, the study team arrived at a set of representative exposures (8 hr-TWA) for median, 75th, 90th, 95th percentiles and maximum for every relevant sector. These are shown in Table 4-14. These exposure levels are used to estimate the current burden of disease which is based upon the exposure over the last 40 years, see section 4.16.

A similar set of data based upon exposure levels since 2000 are shown in Table 4-11. These exposure levels are used to estimate the future burden of disease for the next 40 years, see section 4.17, and the baseline scenario in section 4.17.4.

There was less exposure data available for 15-minute short term exposure levels (STEL). Most STEL data was concentrated in two sectors. In some cases, STEL data was only available to calculate the current and not future burden of disease. The study team took the approach that the STEL data used in the model was taken as twice the 8 hr-TWA exposure data in Table 4-14 and Table 4-11.

In some occupational exposure studies, the use of RPE is clearly described, in the studies where the use of RPE is clearly described a conservative 50% reduction factor was applied to the exposure measurement. For some occupational exposure studies conducted since 2000, where it was not clear whether RPE was being used, but the use of RPE was common at similarly high levels in that sector, a 50% reduction factor was also applied. For those studies that took place prior to 2000, a 50% reduction was only applied where RPE was clearly described as being used.

The median, 75th, 90th, 95th percentiles are calculated based on the combined median values identified while the maximum value is calculated based on the combined average value.

In Table 4-14 and Source: *Study team*

Table 4-15, the maximum exposure levels in several sectors typically relate to TDI exposure, exceptions being MDI exposure in F43.29 Other installation, high levels of HDI, MDI and TDI in C29 Motor vehicles, C30 Transport and G45 Vehicle repair.

Table 4-14 Median, 75^{th}, 90^{th}, 95^{th} percentiles and maximum exposure levels (8 hr-TWA) to diisocyanates NCO µg/m^3 (all sources regardless of publication date)

Sector	Median	75th	90th	95th	Maximum
C13 Textiles	0.62	1.77	3.13	7.16	14.1
C14 Apparel	0.62	1.77	3.13	7.16	14.1
C15 Leather	0.25	0.25	0.25	0.25	0.82
C16 Wood	0.25	0.25	0.25	0.76	19.34
C20 Chemicals	0.25	0.25	0.60	1.68	32.80
C22.21 Rigid foam	0.25	0.25	0.28	1.13	12.76
C22.29 Flexible foam	0.30	0.34	0.95	2.20	14.47
C22 Other	0.25	0.25	0.34	1.00	13.47
C26 Computers	0.25	0.25	0.25	0.25	17.07
C27 Electrical equipment	0.25	0.25	0.25	0.97	12.83

Sector	Median	75th	90th	95th	Maxi-mum
C28 Machinery	0.25	0.25	0.25	0.31	36.33
C29 Motor vehicles	0.25	0.25	0.40	0.95	108.01
C30 Transport	0.25	0.25	0.54	1.36	20.90
C31 Furniture	0.25	0.25	0.25	0.48	171.51
C33 Machinery repair	0.25	0.25	2.00	3.36	53.66
F41.2 Construction	0.25	0.25	0.29	0.58	10.14
F42 Civil engineering	0.25	0.25	0.29	0.58	319.48
F43 Specialised construction	0.25	0.25	2.92	4.83	15.86
F43.29 Other installation	0.25	0.25	0.25	0.25	38.11
G45 Vehicle repair	0.25	0.25	0.72	2.48	25.13
S95 Repairs	0.25	0.25	0.25	0.25	0.82

Source: Study team

Table 4-15 Median, 75th, 90th, 95th percentiles and maximum exposure levels (8 hr-TWA) to diisocyanates NCO µg/m^3 (measurements taken or published since 2000)

Sector	Median	75th	90th	95th	Maxi-mum
C13 Textiles	0.62	1.77	3.13	6.87	51.50
C14 Apparel	0.62	1.77	3.13	6.87	51.50
C15 Leather	0.25	0.25	0.25	0.25	0.82
C16 Wood	0.25	0.25	0.25	0.76	3.39
C20 Chemicals	0.25	0.25	0.49	1.60	24.19
C22.21 Rigid foam	0.25	0.25	0.28	0.50	6.64
C22.29 Flexible foam	0.28	0.31	0.90	1.89	9.23
C22 Other	0.25	0.25	0.34	0.95	3.44
C26 Computers	0.25	0.25	0.25	0.25	17.07
C27 Electrical equipment	0.25	0.25	0.25	0.83	14.90

Sector	Median	75th	90th	95th	Maxi-mum
C28 Machinery	0.25	0.25	0.25	0.31	36.33
C29 Motor vehicles	0.25	0.25	0.40	0.93	28.57
C30 Transport	0.25	0.25	0.54	1.36	20.90
C31 Furniture	0.25	0.25	0.25	0.48	17.34
C33 Machinery repair	0.25	0.25	1.00	2.00	63.21
F41.2 Construction	0.25	0.25	0.29	0.58	10.14
F42 Civil engineering	0.25	0.25	0.25	0.88	33.55
F43 Specialised construction	0.25	0.25	0.25	0.60	6.95
F43.29 Other installation	0.25	0.25	0.25	0.25	38.11
G45 Vehicle repair	0.25	0.25	0.72	2.48	16.48
S95 Repairs	0.25	0.25	0.25	0.25	0.82

Source: Study team

4.5.9 Trends

Throughout interviews, stakeholders in industry indicated that they were continually working to reduce peaks. If the STEL was being modelled, this trend is likely to have an impact upon the future exposure levels. However, occasionally peak have less impact upon the 8-hour TWA, and the exposure concentrations used to model the OEL are assumed to be static.

4.5.10 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 Source: *Study team*

Table 4-15. The exposure level assumed to be experienced by this group is calculated as shown in Table 4-16.

Table 4-16 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%	Median or 50th percentile
51 - 75	25%	Arithmetic mean of 50th and 75th percentiles
76 - 90	15%	Arithmetic mean of 75th and 90th percentiles
91 - 95	5%	Arithmetic mean of 90th and 95th percentiles

Percentiles	Proportion of workers or enterprises	Calculation for exposure level assumed for modelling
96 - 100	5%	Geometric mean of 95th and 100th percentiles

4.6 Exposed workforce

4.6.1 Introduction

This section provides the published sources and other methods of evaluating the number of workers exposed to diisocyanates. These include:

- Published sources
  - CAREX Canada
  - SUMER (2010)
- Other methods
  - Extrapolating from Eurostat data about employees in sectors
  - Consultation responses
  - Data from EU trade associations

The estimates at the EU-27 level are split by sector, showing that the different sources provide a range of estimates.

4.6.2 Self-employed

Self-employed using diisocyanates in construction are expected to comply with OELs/STELs under the 92/57/EEC directive on temporary and mobile construction sites. Therefore, self-employed workers in the construction sectors are included in the numbers of exposed workers. For example, in the construction sector Eurostat (European Commission, 2021c) gives the number of self-employed workers (3,072,700) and Eurostat (European Commission, 2021b) the total number of persons employed (12,142,526) in the construction sector, which means that approximately 25% are self-employed in the construction sector in the EU27. This is in line with the findings of Irish Government (Government of Ireland, 2020) which suggest that 30% of people in the construction sector are self-employed in Ireland.

In many other sectors, there are also numerous self-employed workers, particularly craftworkers and repairers, who use diisocyanates. These are not legally obliged to comply with the CAD and are therefore not included in the scope of the study.

Eurostat contains data on the number of employees and enterprises for NACE code S95 Repair. However, in Eurostat, some classes within S95 Repair appear to have more enterprises than employees. For example, in 2018, S95.23 Repair of footwear and leather goods had 16,779 enterprises and 7,806 employees. This is probably due to the number of self-employed workers in S95 repair complicating the numbers.

4.6.3 Consumers

Any consumers with a craft hobby may regularly use adhesives, paints, coatings or sealants and may have a higher than anticipated exposure to diisocyanates. Some consumers may also use adhesives, paints, coatings, or sealants as part of decorating, home repairs and vehicle repairs, these uses might include short term exposure once or a couple of times a year. Consumers are not included under the scope of this study.

4.6.4 Adults with existing asthma condition

A proportion of the adult population of the EU already have asthma and therefore cannot be given it again. Therefore, adults with asthma need to be removed from the population of exposed workers. Some workers with asthma already could potentially have their asthma further aggravated by exposure but there is no way of distinguishing this from the data. In addition many enterprises remove any worker with any history or indications of breathing issues from a task that might involve exposure to diisocyanates, either before they take up the role through screening, see section 4.11.2, or as a result of medical surveillance, see section 4.11.3.

Approximately 10% of the adult population of the EU have asthma (ECHA, 2018d) and adults with asthma thus need to be removed from the population of exposed workers. Upon further investigation, the calculations carried out in the process of the DRR indicate that, based on academic papers, this should be 6.25% (see section 2.3.2, and the study team will use this in future calculations. The study team uses 6.25% to be consistent with the academic research in the RAC opinion and to ensure that the approach taken is consistent with the DRR presented in section 2.3.

4.6.4.1 Occupational asthma

Similar average annual costs per asthma patient in Europe have been estimated by several sources. In 2010 the cost was estimated to be €1,583 per patient (Accordini *et al.*, 2013), this cost consisted of direct medical expenditures (doctor visits (general practitioner and specialist), clinical and laboratory tests (spirometry, skin tests for allergy, blood tests for allergy, chest X-rays), pharmacological treatment, emergency department visits and nights spent in hospital) and indirect nonmedical costs (working days lost and days with limited, not work-related activities). Similar cost estimates of €1,467 (Accordini *et al.*, 2017) and €1,760 (ECHA, 2017) per patient were estimated for 2013.

The combined costs for occupation asthma across the EU (direct, indirect and intangible costs) were calculated at an average of €14,589 per person per year (ECHA, 2018d).

In France, it was identified that leading causes of occupational asthma in France were due to flour (20% of all cases) and ammonium compounds (15% of all cases) (European Lung Foundation, 2014). In France, between 2001-2009, the number of cases of occupational asthma from diisocyanates saw a significant decline whilst cases from quaternary ammonium compounds significantly increased (Paris *et al.*, 2012).

In the UK, it is recommended that compensation claims for occupational asthma can be between £4,390 and £56,100 depending on the severity of the disease (AWH Solicitors, 2021). The HSE (2006) suggest that the lifetime costs per worker of diisocyanate related occupational asthma are £128,000-£138,000 for men and £97,000-£107,000 for women (based on 2013 costs).

In Germany, instances of exposure to diisocyanates together with other substances in the construction industry were described, which may have contributed to the occupational asthma, such as epoxy resins, other plastic resins, acrylic lacquers, wood dust, solvents (Informationsverbund Dermatologischer Kliniken, 2016).

Information on the number of occupational asthma cases has previously been identified by ECHA (2017) for four EU Member States.

Table 4-17 Occupational asthma cases in four EU Member States

Country	Number of workers	Reporting period (number of years)	Total cases [n]	Respiratory disease cases [n]	Unspecified disease cases [n]	Estimated annual incidence rate in %
Belgium	13,600-17,600	2002-2014 (13)	59	-	51	0.02
Czech Republic	2,312	2000-2014 (15)	133	133	5	0.03
Austria	5,268	2000-2014 (15)	59	59	-	0.07-0.33
Finland	1,474	2000-2013 (14)	31	31	1	0.18

Source: ECHA (2017)

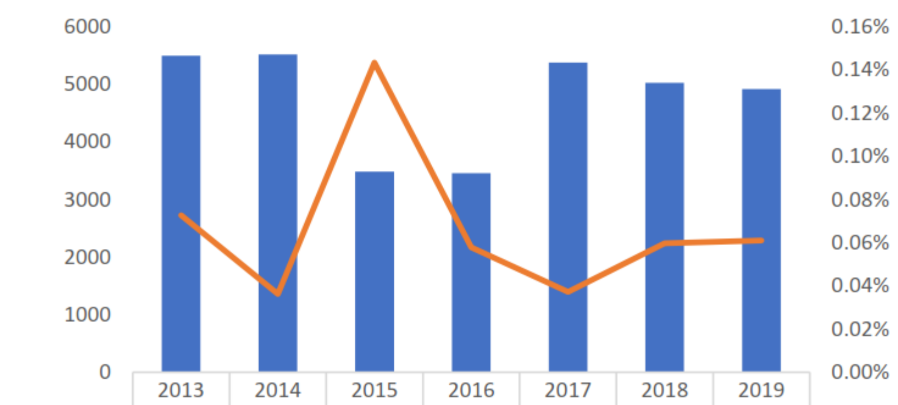
In addition to producing best practice guidance, EUROPUR and EURO-MOULDERS performed an occupational asthma survey in 2013 covering the years 2001-2012. In total, 68 foam production plants (slabstock and moulded polyurethane foam) representing over 12,500 employees answered the survey. Over the period 2001 to 2012, a total of 63 cases of occupational asthma were reported from 17 production plants. An overview of the cases if occupational asthma and the associated activity is shown in Table 4-18.

Table 4-18 Summary of occupational asthma cases from slabstock and moulded polyurethane foam production and the occupational activity

Activity	Number of cases
Unloading / truck handling	0
Weighing	1
Foam Production	29
Preparation work	0
Manual unmoulding	14
Maintenance	2
Post-treatment	1
Storage	1
Laboratory	6
Other	6
N/A	3
Total	**63**

Source: EUROPUR and EURO-MOULDERS (2021)

Since the initial survey took place, EUROPUR and EURO-MOULDERS have conducted annual occupational asthma surveys and have calculated an occupational asthma incidence rate, see Figure 4-2.



	2013	2014	2015	2016	2017	2018	2019
Reported number of workers under medical surveilance	5498	5519	3486	3460	5378	5028	4919
Incidence Rate	0.07%	0.04%	0.14%	0.06%	0.04%	0.06%	0.06%

Figure 4-2 Results of the Flexible PU Foam Industry - Occupational Asthma Survey
Source: EUROPUR and EURO-MOULDERS (2021)

4.6.5 Average exposed workers per company with exposed workers

The numbers of exposed workers is generally estimated from several sources:

- Eurostat data for the specific NACE code multiplied by the percentage of companies in the sector using diisocyanates and then multiplied by the percentage of workers in those companies that are exposed to diisocyanates. Trade associations provided both percentages and the consultation data can provide the percentage of workers in companies that are exposed to diisocyanates
- Trade associations' views on the total number of exposed workers in the entire sector

The consultation data for numbers of exposed workers at a facility as a percentage of all workers at that facility has been analysed. In most cases, the consultation data aligned with the estimates provided. In some sectors, only a few consultation responses were provided and a comparison could not be made.

The trade associations' estimates of the percentages of enterprises using diisocyanates and the percentage of exposed works are in Table 4-19. The study team have used the estimates when estimating the number of exposed workers in section 4.6.6; in several sectors different assumptions were made for different NACE classes within a sector. However, when sectors were reviewed different assumptions were used for different divisions within the same sector. These are described in more detail in section 4.6.6, some of these numbers will be different to those in Table 4-19.

Table 4-19 Percentage of companies in sectors using diisocyanates and percentage of workers in those companies that are exposed to diisocyanates

Sector	% of companies using diisocyanates	% of exposed workers in companies using diisocya-nates
C13 Textiles	10	30
C14 Apparel	10	30
C15 Leather	95	50
C16 Wood	50	20
C20 Chemicals	20	10
C22.21 Rigid foam	7.5	20
C22.29 Flexible foam	7.5	5
C22 Other	20	10
C26 Computers	25	10
C27 Electrical equipment	20	5
C28 Machinery	20	10
C29 Motor vehicles	90	10
C30 Transport	90	10
C31 Furniture	30	10
C33 Machinery repair	30	20
F41.2 Construction	90	50
F42 Civil engineering	90	20
F43 Specialised construction	80	50
F43.29 Other installation (foam)	95	50
G45 Vehicle repair	95	50
S95 Repairs	95	95

Source: Study team

4.6.6 Study team analysis of Eurostat, survey and industry data

For key sectors, the number of exposed workers is investigated more thoroughly, as is the number of enterprises with exposed workers in section 4.8. Each sector is considered in turn following discussions with industry associations and companies in the sector to develop either an estimate based upon one of the following methods:

- Defining the actual companies operating in the sector (where the number is small), adding together the number of workers employed and either using their data on the number of exposed workers or applying a percentage derived from the companies where data is available to calculate the number of exposed workers. As values for small, medium and large companies are also required, the calculations may need to be adjusted because in some sectors there are no large enterprises, for example in the repair sector.
- Defining a NACE code into which the sector falls and estimating the percentage of companies within that sector that will use diisocyanates, which when multiplied by the number of companies in that NACE code which has exposed workers. This number is then multiplied by the percentage of exposed operators to workers in the company: this is taken from Table 4-19. The numbers of exposed workers is generally estimated from several sources:
- Eurostat data for the specific NACE code multiplied by the percentage of companies in the sector using diisocyanates and then multiplied by the percentage of workers in those companies that are exposed to diisocyanates. Trade associations can provide both percentages and the consultation data can provide the percentage of workers in companies that are exposed to diisocyanates.
- Trade associations' views on the total number of exposed workers in the entire sector or parts of the sector
- Responses to the consultation questionnaire from companies. For several sectors, companies provided information about their total workforce and the number of workers exposed to diisocyanates. Care was taken with those sectors where only one consultation response was provided as this may under- or over-estimate the total workforce.

Generally, if no other data is available, the study team has made an assumption on the number of workers in an enterprise using diisocyanates that will be exposed to them. Where an assumption has been made, the reasoning behind the assumption is briefly explained.

4.6.6.1 C13 Textiles

According to Eurostat, in 2018, there are 58,878 enterprises in sector C13 Textiles and these enterprises had 520,054 employees. However, the use of diisocyanates in the textiles industry is expected to be limited to specific parts of the sector. The manufacture of textiles using diisocyanates is covered by another NACE code (C20) as would the manufacturing of foam carpet underlay (C22).

In the consultation survey, there were no responses from the textile industry. The industry association FIECA indicated that diisocyanates are used in C13.95. FEICA indicated that around 10% of enterprises are expected to use diisocyanates and around 30% of employees are likely to be exposed. In Eurostat, the most recent year enterprise information is available for C13.95 is for 2016, in 2016 there were 770 enterprises in C13.95. In 2018, there were 26,947 employees in C13.95. The exposure estimate by FEICA would equate to around 758 employees exposed (once 6.25% of no occupational asthma cases are excluded).

As a precaution, to include the possible use of diisocyanates in other parts of the textile industry, it has been assumed that 5% of all other enterprises in C13 Textiles may use diisocyanates and that 15% of employees at these enterprises may be exposed.

In total the study team estimates that 2,982 enterprises use diisocyanates (77 enterprise in C13.95) and 4,225 employees who might be occupationally exposed to diisocyanates (once 6.25% of no occupational asthma cases are excluded).

The study teams assumptions on the total number of enterprises with exposure to diisocyanates across the whole of the sector might overestimate the number of enterprises with exposure. This estimate results in around 1.42 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. When only C13.95 is considered, there are around 3.3 workers exposed per enterprise.

4.6.6.2 C14 Apparel

In Eurostat, in 2018, there are 125,000 enterprises in sector C14 Apparel and these enterprises had 797,031 employees. However, much like C13 Textiles, the use of the use of diisocyanates in the apparel industry is expected to be limited to specific parts of the sector. Due to a lack of available exposure data, the exposure data for C13 Textiles is used for C14 Apparel.

In the consultation survey, there were no responses from apparel manufactures. Most industry associations questioned were not aware of any use of diisocyanates being use in the sector. However, CEPE indicated that they were aware of a leather tanner that place PU prints on leather. The Danish Environmental Protection Agency (2014) suggest that uses of diisocyanates include use within swimwear and mittens/gloves, therefore use might primarily relate to C14.19 Manufacture of other wearing apparel and accessories. Any foams (articles) used in the manufacture of other apparel might be produced by a foam manufacture rather than on site. The study team took a similar approach for C14 Apparel as they did for C13 Textiles. For C14.11 Manufacture of leather clothes and C14.19 Manufacture of other wearing apparel it was assumed that 10% of enterprises may use diisocyanates and around 30% of employees may be exposed. As a precaution, to include the possible use of diisocyanates in other parts of the apparel industry, it has been assumed that 5% of all other enterprises in C14 Apparel Textiles may use diisocyanates and that 15% of employees at these enterprises may be exposed.

In Eurostat, in 2019, for C14.11 Manufacture of leather clothes and C14.19 Manufacture of other wearing apparel and accessories there were 2,095 and 23,666 enterprises respectively and 7,220 and 81,480 employees.

In total the study team estimates that a total of 7,538 enterprises use diisocyanates and 7,475 employees might be occupationally exposed to diisocyanates, this includes around 210 enterprises and 204 employees from C14.11 and 2,367 enterprises and 2,291 employees from C14.19 (once 6.25% of no occupational asthma cases are excluded).

The study team assumptions on the total number of enterprises with exposure to diisocyanates across the whole of the sector might overestimate the number of enterprises with exposure. This estimate results in around 1 employee (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. CEPE were only aware of one enterprise laying PU prints on leather, so the assumed number of enterprises using diisocyanates might be an overestimate. When only C14.11 and C14.19 are considered, there would be also be around 1 worker exposed per enterprise.

4.6.6.3 C15 Leather

In Eurostat, in 2018, there are 36,776 enterprises in sector C15 Leather and these enterprises had 407,681 employees. In C15 Leather, the only source of occupational exposure to diisocyanates is expected to be C15.20 Manufacture of footwear.

In the consultation survey, there were no responses from leather companies. Occupational exposure to diisocyanates in C15.20 is expected to be related to the use of adhesives in shoe manufacturing. FEICA agreed with this suggestion and estimate that the vast majority of enterprises will use sealants in the manufacture of footwear and that around half of all employees are likely to be exposed. in the shoe manufacturing sector sealants that do not contain diisocyanates might be used by some enterprises and in some applications physical methods (i.e. shoe tacks/nails) might be used instead of a chemical sealant. The study team have assumed that 95% of all enterprises will use diisocyanates and that 50% of employees may be occupationally exposed.

In Eurostat, in 2018, for C15.20 Manufacture of footwear there were 19,700 enterprises and 256,000 employees. In total the study team estimates that a total of 18,715 enterprises use diisocyanates and 114,000 employees might be occupationally exposed to diisocyanates (once 6.25% of no occupational asthma cases are excluded).

This estimate results in around 6.1 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. The study team believes this might be realistic, especially considering the high proportion of small enterprises in the sector.

4.6.6.4 C16 Wood

In Eurostat, in 2018, there are 160,000 enterprises in sector C16 Wood and these enterprises had 800,000 employees. In C16 Wood, three specific sectors are expected to be sources of diisocyanate exposure, these are:

- C16.21 Manufacture of veneer sheets and wood-based panels;
- C16.22 Manufacture of assembled parquet floors; and
- C16.29 Manufacture of other products of wood; manufacture of articles of cork, straw and plaiting materials.

In the consultation questionnaire, there were 12 responses, representing six enterprises (some enterprises completed the questionnaire for several sites and processes). All respondents indicated that their use of diisocyanates was in relation to C16.21. These enterprises employee around 5,422 workers and indicated that around 468 workers were occupationally exposed to diisocyanates. The average ratio of employees to those occupationally exposed at these companies was 13.9%.

The European Federation of the Parquet Industry and FEICA also provided information on the use of adhesive in the wood industry. The use in this sector is presented in Table 4-20. The numbers provided by FEICA are in most cases higher than the average ratio provided in response to the consultation activity, therefore, these values have been used for these specific sectors.

Based on information from Eurostat, in 2018, the study team estimates 3,085 enterprises use diisocyanates and 14,427 employees might be occupationally exposed to diisocyanates (once 6.25% of no occupational asthma cases are excluded).

This estimate results in around 4.7 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. The study team believes this might be realistic, especially as diisocyanate use might be restricted to a specific part of the production process and considering the high proportion of small enterprises in the sector.

Table 4-20 Summary of exposed workers in C16 sectors

Sector	C16.10 Sawmilling and planing of wood	C16.21 Manufacture of veneer sheets and wood-based panels	C16.22 Manufacture of assembled parquet floors	C16.23 Manufacture of other builders' carpentry and joinery	C16.24 Manufacture of wooden containers	C16.29 Manufacture of other products of wood; manufacture of articles of cork, straw and plaiting materials	C16 Total
Diisocyanate use	No	Yes	Yes	No	No	Yes	-
Enterprises (Eurostat)	-	2,074	1,118	-	-	29,916	33,108
Employees (Eurostat)	-	96,626	15,000*	-	-	80,495**	192,121
% of enterprises using diisocyanates	-	75%	3%	-	-	5%	-
Number of enterprises with exposed workers	-	1,555	34	-	-	1496	3,085
% of workers in these companies that are exposed	-	20%	20%	-	-	20%	-
Number of exposed workers	-	14,494	90	-	-	805	15,389
% exposed workers in NACE code	-	18%	0.6%	-	-	1%	-
Number of exposed workers (excluding 6.25% with existing asthma)	-	13,588	84	-	-	755	14,427

*Source: Eurostat (2018), *2015, ** 2017*

4.6.6.5 C20 Chemicals

In Eurostat, in 2018, there are 27,986 enterprises in sector C20 Chemicals and in 2017 (the latest year data is available) these enterprises had 1,100,000 employees. In C20 Chemicals, six specific sectors are expected to be sources of diisocyanate exposure, these are:

- C20.14 Manufacture of other organic basic chemicals
- C20.16 Manufacture of plastics in primary forms
- C20.17 Manufacture of synthetic rubber in primary forms
- C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics
- C20.52 Manufacture of glues
- C20.60 Manufacture of man-made fibres

In the consultation survey, there were 105 responses, representing 73 enterprises (in some cases individual entities completed the survey and in other cases enterprises completed the questionnaire for several sites and processes), with approximately 7,500 exposed workers in companies with a total of 58,750 workers. The average ratio of employees to those occupationally exposed at all these companies is around 13%, while the geometric mean of all the responses provided by enterprises is around 25%.

CEPE and FEICA highlighted the use of that diisocyanates in the manufacturing of C20.14 Manufacture of other organic basic chemicals, C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics, and C20.52 Manufacture of glues. Although the study team believes that there are additional uses of diisocyanates in the manufacturing of other chemical products, they believe that these are the most important uses.

The study team's assumptions are shown in Table 4-21. Based on the information in Eurostat the study team estimates that 1,472 enterprises use diisocyanates and 13,722 employees are exposed to diisocyanates (once 6.25% of no occupational asthma cases are excluded).

This estimate results in around 9.3 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. The study team believes this might be realistic, especially as diisocyanate exposure might be restricted to a specific part of the production process, the closed systems in place.

Table 4-21 Summary of exposed workers in C20 sectors

Sector	C20.14 Manufacture of other organic basic chemicals	C20.16 Manufacture of plastics in primary forms	C20.17 Manufacture of synthetic rubber in primary forms	C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	C20.52 Manufacture of glues	C20.60 Manufacture of man-made fibres	C20 Total
Diisocyanate use	Yes	Yes	Yes	Yes	Yes	Yes	-
Enterprises (Eurostat)	1,885	2,263	179	3,356	481	260	8,424
Employees (Eurostat)	223,030	131,254	7,179*	147,718	13,720	28,149	551,050
% of enterprises using diisocyanates	20%	10%	20%	20%	20%	25%	-
Number of enterprises with exposed workers	377	226	36	671	97	65	1,472
% of workers in these companies that are exposed	15%	15%	15%	15%	10%	15%	-
Number of exposed workers	6,691	1,969	215	4,432	274	1,056	14,637
% exposed workers in NACE code	3%	1.5%	3%	3%	2%	3.75%	-
Number of exposed workers (excluding 6.25% with existing asthma)	6,273	1,846	201	4,155	257	990	13,722

*Source: Eurostat (2018); * Eurostat (2017)*

4.6.6.6 C22 Plastics/Rubber

In Eurostat, in 2017, there are 54,662 enterprises in sector C22 Plastics/Rubber and in 2018, these enterprises had 1,628,724 employees. In C22 Plastics/Rubber two significant uses of diisocyanates were highlighted to the study team, these were the use of diisocyanates in the manufacture of rigid foams (C22.21) and flexible foams (C22.29).

EUROPUR, the European Association of Flexible Polyurethane Foam Block Manufacturers, indicate that the production of flexible polyurethane foam blocks in the European Economic Area is around 1.3 million tonnes per year. EUROPUR indicate that foam blocks are used mainly in the production of upholstered furniture (±50%), mattresses (±35%) and the automotive sector (±10%).

EURO-MOULDERS, the European Association of Manufacturers of Moulded Polyurethane Parts for the Automotive Industry, estimate that 342,000 tonnes of moulded flexible polyurethane foam were produced in the European Economic Area in 2018 and most automotive foam use was for seating.

EUROPUR and EURO-MOULDERS suggest that their use accounts for around 88% and 9% of TDI and MDI use within Europe. Furthermore, based on what they know of their members and the sector, they estimate that there are:

- For polyurethane slabstock, around 105 sites and 125 lines in the EU27, UK, Switzerland and Norway, 7 sites and 7 lines less if the UK, Switzerland and Norway are removed
- For polyurethane moulded parts for the automotive sector, around 42 sites and 53 lines in the EU27 and UK, there are no such plants in Switzerland or Norway. There are two sites and two lines less if the UK is removed
- For moulded polyurethane intended for furniture, there are an estimated 35 sites in for EU 27, UK, Switzerland and Norway. This is an estimate since these are not in the scope of EUROPUR or EURO-MOULDERS

Based on an extrapolation EUROPUR and EURO-MOULDERS estimated that about 30,000 people work in foam production (polyurethane slabstock production and moulded polyurethane production for the automotive sector, excluding moulded polyurethane for furniture) and that of those about 8,000 (26%) are working in areas where diisocyanates are used. EUROPUR and EURO-MOULDERS believe these numbers to be credible compared with the typical total "FTE vs under medical surveillance" numbers and the ratio that they see in their annual occupational asthma surveys.

In the consultation survey, there were 76 responses, representing 60 companies (some companies completed the questionnaire for several sites and processes) across the whole of C22 Plastics/Rubber.

In the consultation, those enterprises indicating that their relevant sector is C22.21 Rigid Foam indicated that an average of 25% of their employees might be exposed to diisocyanates. In C22.29 Flexible Foam enterprises indicated that an average of 20% of their employees might be exposed to diisocyanates.

EUROPUR and EURO-MOULDERS, Flexible Packaging Europe (FPE), FEICA, and PU Europe provided information on the use of diisocyanates in their relevant sectors. EUROPUR and EURO-MOULDERS represent the majority of flexible foaming enterprises within Europe, in addition to this they commissioned a study into the flexible and rigid foam industrial sectors. The study team believes that the industry association’s views and the independent report present a realistic picture of the number of employees in the sector included those that might be exposed. FPE gave relatively high estimate of the numbers of workers that might be exposed, the study team have no reason to doubt the figures.

The study team suggest that in:

- C22.21 Rigid Foam there are 143 enterprises and 4,969 employees who are occupationally exposed to diisocyanates;
- C22.29 Flexible Foam there are 234 enterprises and 9,750 employees who are occupationally exposed to diisocyanates; and
- C22 Other there are 6,983 enterprises and 39,169 employees who are occupationally exposed to diisocyanates

This estimate results in around 34.7, 41.7 and 5.6 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed in C22.21 Rigid foam, C22.29 Flexible foam and C22 Other. The study team believes this might be realistic, much of C22 Plastic/Rubber concerns the manufacturing of plastics not manufactured using diisocyanates. If it is assumed that 10% of all enterprises in C22 Plastic/Rubber use diisocyanates and 25% of these employees are occupationally exposed, then this would equate to 38,175 occupationally exposed workers (once 6.25% of no occupational asthma cases are excluded). The study team estimates that 53,888 might be occupationally exposed in C22 Plastic/Rubber.

4.6.6.7 C26 Computers

In Eurostat, in 2018, there are 36,417 enterprises in sector C26 Computer and these enterprises had 1,000,000 employees. In this sector some of the processes are automated and take place in closed systems.

The associations approached indicated that they were not aware of diisocyanates being used in C26 Computers. In the consultation survey, there was a single response from an enterprise that classified themselves as being a computer company. The enterprises activities included the dispending and curing of polyurethanes. In some electronic equipment small amounts of adhesives and sealants might also be used. Small amounts of occupational exposure are therefore expected in the sector, however, the total enterprises and workers exposed is likely to overestimate the exposure within the sector since many processes are expected to take place in closed systems with few opportunities for exposure.

The one respondent to the consultation survey indicated that around 13% of their workforce are occupationally exposed to diisocyanates. The study team have assumed that 25% of all enterprises in C26 Computer will use diisocyanates and that 10% of employees may be occupationally exposed.

The study team estimates that a total of 9,104 enterprises use diisocyanates and 23,438 employees might be occupationally exposed to diisocyanates (once 6.25% of no occupational asthma cases are excluded).

This estimate results in around 2.6 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. The study team believes this might be realistic when all enterprises in C26 Computer are considered, especially as the number of enterprises using diisocyanates might have been overestimated.

4.6.6.8 C27 Electrical equipment

In Eurostat, in 2018, there are 42,350 enterprises in sector C27 Electrical equipment and these companies had 1,439,860 employees. In this sector some of the processes are automated and take place in closed systems.

FEICA suggested that diisocyanates are used in C27.31 Manufacture of fibre optic cables (where only 10% of enterprise us diisocyanates) and C27.51 Manufacture of electric domestic appliances. It is also clear that some domestic appliances are injected with insulating foams as part of the manufacturing process. Although domestic appliances are often painted/coated on site as part of the manufacturing process, not all of the paints/coatings contain diisocyanates.

The one respondent to the consultation survey indicated that around 6% of their workforce are occupationally exposed to diisocyanates. The study team have assumed that 20% of all enterprises in C27 Electrical equipment will use diisocyanates and that 5% of employees may be occupationally exposed.

The study team estimates that a total of 9,441 enterprises use diisocyanates and 19,990 employees might be occupationally exposed to diisocyanates (once 6.25% of no occupational asthma cases are excluded).

This estimate results in around 2.1 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. The study team believes this might be realistic when all enterprises in C27 Electrical equipment are considered.

4.6.6.9 C28 Machinery

In Eurostat, in 2018, there are 80,000 enterprises in sector C28 Machinery and these enterprises have 3,000,000 employees.

The use of diisocyanates in this sector is likely to be similar to that in C26 Computers, where small amounts of occupational exposure are expected in the sector from using adhesives/sealants and in some cases the painting/coating of machinery. FEICA suggested that diisocyanates are used in C28.25 Manufacture of non-domestic cooling and ventilation equipment and C28.30 Manufacture of agricultural and forestry machinery. FEICA suggested in C28.25 30% of enterprise may use diisocyanates, with 5% of employees exposed and in C28.30 20% of enterprise may use diisocyanates and 20% employees might be occupationally exposed.

In the consultation survey, there were no responses from the machinery industry. The study team have used FEICA's estimates of diisocyanate use and employee exposure. In addition to this, as a precaution to include the possible use of diisocyanates in other parts of the machinery industry, it has been assumed that 5% of all other enterprises in C28 Machinery may use diisocyanates and that 5% of employees at these enterprises may be exposed.

The study team estimates that a total of 6,770 enterprises use diisocyanates and 16,226 employees might be occupationally exposed to diisocyanates (once 6.25% of no occupational asthma cases are excluded). This might overestimate the number of enterprises with exposure.

This estimate results in around 2.4 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. The study team believes this might be realistic for C28 Machinery, although the number of enterprises in the sector might slightly underestimate the number of exposed workers per enterprise.

4.6.6.10 C29 Motor vehicles

In Eurostat, in 2018, there are 17,000 enterprises in sector C29 Motor vehicles and these enterprises have 2,556,478 employees. Diisocyanates are expected to be used quite widely across the motor vehicle industry.

In the consultation survey, there were five responses, representing five enterprises (two enterprises complete the questionnaire for two different legal entities), with a combined total of 3000 workers at the enterprises with a total of 140 workers occupationally exposed to diisocyanates workers, around 5% (a geometric mean of around 10% when considering individual enterprises)

FEICA suggested that diisocyanate containing adhesives and sealants are used in all parts of the sector and CEPE suggested that diisocyanate coatings are used in all parts of the sector expect for C29.31 Manufacture of electrical and electronic equipment for motor vehicles. EUROPUR and EURO-MOULDERS indicated that only a few companies in C29 Motor vehicles manufacture their own foam. This exception is relevant to C29.32 Manufacture of other parts and accessories for motor vehicles, where a few enterprises manufacture acoustic insulation parts or car seats on site rather than purchasing these through a foam related business (C22.29).

The study team suggestions are combined with those of FEICA and CEPE in Table 4-22. In total the study team estimates that a total of 14,292 enterprises use diisocyanates and 166,373 employees might be occupationally exposed to diisocyanates (once 6.25% of no occupational asthma cases are excluded). This estimate results in around 11.6 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. The study team believes this might be realistic for C29 Motor vehicles, although the number of enterprises in the sector might slightly underestimate the number of healthy workers exposed per enterprise.

Table 4-22 Summary of exposed workers in C29 sectors

Sector	C29.10 Manufacture of motor vehicles	C29.20 Manufacture of bodies (coach-work) for motor vehicles; manu-facture of trailers and semi-trailers	C29.31 Manufacture of electrical and electronic equip-ment for motor vehicles	C29.32 Manufacture of other parts and accessories for motor vehicles	C29 Total
Diisocyanate use	Yes	Yes	Yes	Yes	-
Enterprises (Eurostat)	1,800	6,247	1,500	7,500*	17,047
Employees (Eurostat)	1,114,365	154,966	246,969	1,040,181	2,556,481
% of enterprises using diisocyanates	90%	90%	20%	90%	-
Number of enterprises with exposed workers	1,620	5,622	300	6,750	14,292
% of workers in these companies that are ex-posed	10%	20%	5%	5%	-
Number of exposed workers	100,293	27,894	2,470	46,808	166,373
% exposed workers in NACE code	9%	18%	0.01%	4.5%	-
Number of exposed workers (excluding 6.25% with existing asthma)	94,025	26,150	2,316	43,882	166,373

*Source: Eurostat (2018), *2017*

4.6.6.11 C30 Transport

In Eurostat, in 2018, there are 13,487 enterprises in sector C30 Transport and these enterprises had 687,812 employees. Like C29 Motor vehicles, diisocyanates are expected to be widely used in C30 Transport. The uses include coatings applied on the outside of transport and the use of adhesives and sealants with transport.

In the consultation survey, there was a response from a company who self-classified themselves as being a transport company, however, upon review the response was reclassified as being relevant to C22.29.

CEPE suggest that coatings containing diisocyanate are used in all parts of the sector and FEICA expect that adhesives and sealants containing diisocyanate would be used in most parts C30 Transport, with exceptions including C30.91 Manufacture of motorcycles and C30.92 Manufacture of bicycles and invalid carriages. The majority, perhaps all enterprises, are expected to purchase foam seating through a foam enterprise (C22.29).

The study team suggestions are combined with those of CEPE and FEICA in Table 4-23. In total the study team estimates that a total of 12,137 enterprises use diisocyanates and 58,034 employees might be occupationally exposed to diisocyanates (once 6.25% of no occupational asthma cases are excluded). This estimate results in around 4.8 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. The study team believes this might be realistic for C30 Transport, although the assumed number of enterprises in the sector using diisocyanates might slightly underestimate the number of workers exposed per enterprise.

The International Council of Marine Industry Associations (ICOMIA) provided information on the number of known enterprises within the EU and other countries around the world, see Table 4-24. The number of boat building enterprises within 14 EU Member States known by ICOMIA (3,011) is similar to Eurostat with the EU-27 (4,066). The other enterprises exist in other sectors.

Table 4-23 Summary of exposed workers in C30 sectors

Sector	C30.11 Building of ships and floating structures	C30.12 Building of pleasure and sporting boats	C30.20 Manufacture of railway locomotives and rolling stock	C30.30 Manufacture of air and spacecraft and related machinery	C30.40 Manufacture of military fighting vehicles	C30.91 Manufacture of motorcycles	C30.92 Manufacture of bicycles and invalid carriages	C30.99 Manufacture of other transport equipment n.e.c.	C30 Total
Diisocyanate use	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	-
Enterprises (Eurostat)	3,775	4,066	743	1,350	34	933	2,107	478	13,486
Employees (Eurostat)	107,109	43,024	112,860	354,936	11,731	20,991	32,817	4,344	687,812
% of enterprises using diisocyanates	90%	90%	90%	90%	90%	90%	90%	90%	-
Number of enterprises with exposed workers	3,397	3,659	668	1,215	31	840	1,897	430	12,137
% of workers in these companies that are exposed	10%	10%	10%	10%	10%	10%	10%	10%	-
Number of exposed workers	9,640	3,873	10,158	31,945	1,056	1,890	2,954	391	61,907
% exposed workers in NACE code	9%	9%	9%	9%	9%	9%	9%	9%	-
Number of exposed workers (excluding 6.25% with existing asthma)	9,037	3,630	9,523	29,948	990	1,771	2,769	366	58,034

Source: Eurostat (2018)

Table 4-24 Enterprise figures from ICOMIA Recreational Boating Industry Statistics 2019

Country	Boat builders	Engine manufacturers	Boat accessory & marine equipment manufacturers	Service providers	TOTAL
Croatia					
Czech Republic					
Denmark	213		179		392
Estonia	350				350
Finland					2,500
France	10,328	975	3,339	22,748	37,390
Germany					20,000
Greece	600		150	9,500	10,250
Italy	16,480	780	6,980		24,240
Netherlands					23,000
Poland	45,030		6,170		51,200
Spain	550	70	660	16,000	17,280
Sweden	1,000	200	2,000		3,200
EU (14) total	3,011	43	1,229	12,680	16,963
Rest of the world					
Australia	175	79	87	1,625	1,966
Brazil	58		14	58	130
Canada	396		127	4,105	4,628
Israel					
Japan	25	10			35
New Zealand	160		120	900	1,180
Norway	150	50	200	1,800	2,200
South Africa	14		6	40	60
Sri Lanka	30		8	22	60
Turkey	190	2	75	950	1,217
UK	351	5	550	4,899	5,805
USA	925				35,277
Rest of world total	**2,324**	**96**	**987**	**12,599**	**50,358**

Source: ICOMIA Recreational Boating Industry Statistics 2019

4.6.6.12 C31 Furniture

In Eurostat, in 2018, there are 120,000 enterprises in sector C31 Furniture and in 2017 these enterprises had 826,729 employees.

In the consultation survey there were no response from furniture enterprises.

EUROPUR and EURO-MOULDERS indicated that only a small part of furniture is upholstered and that most furniture enterprises will buy foam from a foam manufacture. Although approximately 90% of furniture enterprises may use premade foams, it was suggested that some companies do manufacture their own foam, however, the number of enterprises doing this is low. FEICA indicated that adhesives and sealants might be used throughout the sector and CEPE indicated that polyurethane paints/coatings are occasional used in C31.02 Manufacture of kitchen furniture.

The study team suggestions are combined with those of CEPE, EUROPUR and EURO-MOULDERS, and FEICA in Table 4-25. In total, the study team estimates that a total of 17,494 enterprises use diisocyanates and 16,918 employees might be occupationally exposed to diisocyanates (once 6.25% of no occupational asthma cases are excluded). This estimate results in around 0.97 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. The study team believes the number of exposed workers might be realistic for C31 furniture, however, the large number of enterprises in the sector might slightly underestimate the number of workers exposed per enterprise. An association indicated that in most cases manufactured items are not coated with a polyurethane coating, however, for those items requiring a coating this activity was normally conducted by an individual in an LEV booth. The number of enterprises using diisocyanates might be overestimated, particularly in C31.01 and C31.09.

Table 4-25 Summary of exposed workers in C31 sectors

Sector	C31.01 Manufacture of office and shop furniture	C31.02 Manufacture of kitchen furniture	C31.03 Manufacture of mattresses	C31.09 Manufacture of other furniture	C31 Total
Diisocyanate use	Yes	Yes	Yes	Yes	-
Enterprises (Eurostat)	20,447	17,858	2,000	82,056	122,361
Employees (Eurostat)	173,667	89,506	40,000	546,858	850,031
% of enterprises using diisocyanates	10%	40%	5%	10%	-
Number of enterprises with exposed workers	2045	7144	100	8,206	17,495
% of workers in these companies that are exposed	10%	30%	5%	10%	-
Number of exposed workers	1,736	10,740	100	5,468	18,044
% exposed workers in NACE code	8.5%	12%	0.25%	1%	-
Number of exposed workers (excluding 6.25% with existing asthma)	1,628	10,069	94	5,127	16,918

Source: Eurostat (2018)

4.6.6.13 C33 Machinery repair

In Eurostat, in 2018, there are 200,000 enterprises in sector C33 Machinery repair and these companies have 1,000,000 employees.

In the consultation survey, there were no responses from C33 Machinery repair companies.

CEPE and FEICA indicated that there is use in three of the nine NACE divisions, the four relevant ones being:

- C33.15 Repair and maintenance of ships and boats
- C33.16 Repair and maintenance of aircraft and spacecraft
- C33.17 Repair and maintenance of other transport equipment

In these divisions the use of diisocyanates includes paints, coatings, adhesives and sealants as part of re-spraying and other repairing and maintenance operations.

The study teams assumptions for the sector have considered the views proposed by CEPE, FEICA and ICOMIA. The study team has assumed that 20% of enterprises in C33.15 Repair and maintenance of ships and boats use diisocyanates and 35% of enterprises in C33.16 Repair and maintenance of aircraft and spacecraft and C33.17 Repair and maintenance of other transport equipment use diisocyanates. It is assumed that 20% of all employees in these enterprises are exposed to diisocyanates.

In total the study team estimates that a total of 5,240 enterprises use diisocyanates and 10,899 employees might be occupationally exposed to diisocyanates (once 6.25% of no occupational asthma cases are excluded). This estimate results in around 2 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. The study team believes the number of exposed workers might be realistic for C33 Machinery repair due to the large number of small companies operating in the sector. In Eurostat, 88.3% of enterprise in the sector consist of 0-9 employees. The study team believes that the highest exposure and risk to employees in the sector comes from respraying operations, however, these operations are highly controlled to meet the required technical specifications. Furthermore, access to the respraying areas is normally restricted and RPE and PPE is worn by employees.

4.6.6.14 F41.2 Construction

In Eurostat, in 2018, there are 677,446 enterprises in sector F41.20 Construction and these enterprises had 2,325,033 employees. Diisocyanate containing products are expected to be used as part of several construction activities.

In the consultation survey, there were three responses, representing three construction enterprises, however, these enterprises are more relevant to the sectors F42 Civil engineering and F43 Specialised construction.

In this sector the study team has assumed that 90% of enterprises use diisocyanates and that 50% of employees are potentially occupationally exposed.

In total the study team estimates that a total of 609,701 enterprises use diisocyanates and 1,304,561 employees might be occupationally exposed to diisocyanates (once 6.25% of no occupational asthma cases are excluded and 33% self-employed workers are considered). The estimate results in around 2.1 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. On construction sites large numbers of employees are expected to be working in the vicinity of diisocyanates but not all employees might be directly working with them. Therefore, most employees might be at low risk from occupational exposure.

4.6.6.15 F42 Civil engineering

In Eurostat, in 2018, there are 85,210 enterprises in sector F42 Civil engineering and these enterprises had 1,331,914 employees.

In the consultation survey, there were three responses, representing three construction enterprises, one of these enterprises was a civil engineering enterprise. The enterprise indicated that they employ 21 employees and 5 are occupationally exposed to diisocyanates, around 23.8% of the enterprise are occupationally exposed.

In this sector the study team has assumed that 90% of enterprises in F42.12 Construction of railways and underground railways and F42.13 Construction of bridges and tunnels use diisocyanates and that 20% of employees at these enterprises are exposed to diisocyanates. As a precaution, to include the possible use of diisocyanates in other parts of the civil engineering industry, it has been assumed that 5% of all other enterprises in F42 Civil engineering may use diisocyanates and that 5% of employees at these enterprises may be exposed.

In total the study team estimates that a total of 4,301 enterprises use diisocyanates and 29,990 employees might be occupationally exposed to diisocyanates (once 6.25% of no occupational asthma cases are excluded and 33% self-employed workers are considered). The estimate results in around 6.97 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. The study team believes the number of exposed workers is realistic for F42 Civil engineering and the one consultation response supported this.

4.6.6.16 F43 Specialised construction

In Eurostat, in 2018, there are 2,191,277 enterprises in sector F43 Specialised construction and these enterprises had 5,669,588 employees. The decision was taken to treat the division F43.29 Other construction installation, different from F43 Specialised construction. This decision was based on the use of diisocyanates in this division as part of spray foams compared with adhesives, sealants and coatings in the rest of the sector. The number of enterprises offering spray foam services is expected to make up a small proportion of the entire employee exposure in the sector and this would have overestimated the risk in the sector.

The specialised construction sector is different to some of the other sectors. In this sector the activity undertaken by an employee might not directly involve the use of diisocyanates but the employee might be occupationally exposed from an activity taking place within the vicinity. Therefore, in some sectors where there might not be any use of diisocyanates the study team have assumed that employees might be occupationally exposed.

In the consultation survey, there were three responses, representing three construction enterprises, two of these enterprises were specialised construction enterprises. One enterprise employing 250 employees indicated that all employees are occupationally exposed to diisocyanates, the other enterprise employing 120 employees indicated 25 employees (20.8%) are occupationally exposed to diisocyanates.

The study team suggestions are combined with those of CEPE and FEICA in Table 4-26. The study team have assumed that employees in F43.11 Demolition, F43.12 Site preparation and F43.13 Test drilling and boring are not occupationally exposed to diisocyanates and these have not been included in Table 4-26.

In total the study team estimates that a total of 1,284,501 enterprises use diisocyanates and 1,408,207 employees might be occupationally exposed to diisocyanates (once 6.25% of no occupational asthma cases are excluded and 33% self-employed workers are considered). The estimate results in around 1.46 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. The study team believes the number of exposed workers is realistic for F43 Specialised construction as more than 90% of enterprises in Eurostat in this sector consist of enterprises with 0-9 employees. However, the assumed total number of enterprises and employees with occupational exposure might be overestimated for the reason described.

Table 4-26 Summary of exposed workers in F43 divisions

Sector	F43.21 Electrical installation	F43.22 Plumbing, heat and air conditioning installation	F43.29 Other construction installation	F43.31 Plastering	F43.32 Joinery installation	F43.33 Floor and wall covering	F43.34 Painting and glazing	F43.39 Other building completion and finishing	F43.91 Roofing activities	F43.99 Other specialised construction activities n.e.c.	F43 Total
Diisocyanate use or otherwise occupationally exposed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	-
Enterprises (Eurostat)	344,137	348,954	99,570	94,033*	276,978	170,130	240,214	244,028	116,843	256,390	2,186,460
Employees (Eurostat)	1,209,416	1,063,606	382,713	143,435*	476,790	276,082	410,306	225,896	338,190	775,515	4,919,236
% of enterprises using or otherwise exposed to diisocyanates	50%	50%	50%	50%	80%	95%	50%	50%	75%	50%	-
Number of enterprises with exposed workers	172,068	174,477	49,785	47,016	221,582	161,624	120,107	122,014	87,633	128,195	1,284,501
% of workers in these companies that are exposed	50%	10%	75%	75%	80%	95%	25%	50%	75%	25%	-
Number of exposed workers	302,354	53,181	143,518	53,789	305,146	249,164	51,289	56,474	190,232	96,940	1,502,087
% exposed workers in NACE code	25%	5%	37.5%	37.5%	64%	90.3%	12.5%	25%	56.3%	12.5%	-
Number of exposed workers (excluding 6.25% with existing asthma)	283,457	49,857	134,548	50,427	286,075	233,591	48,084	52,944	178,343	90,881	1,408,207

*Source: Eurostat (2018); *Eurostat (2017)*

4.6.6.17 F43.29 Other installation

In Eurostat, in 2018, there are 99,570 enterprises in sector F43.29 Other installation and these enterprises had 382,713 employees.

In the consultation survey, there were no responses from F43.29 Other installation enterprises.

The study team have assumed that a small part of those enterprises in F43.29 are those that use spray foams containing diisocyanates. Through discussions with chemical enterprises in the spray foam sector, the study team estimates that there might be around 5,000 enterprises and most of these will be micro and small enterprises. The study team assume that 75% of the employees working for each enterprise are exposed (13,333 employees) and in total 12,469 employees might be occupationally exposed to diisocyanates (once 6.25% of no occupational asthma cases are excluded and 33% self-employed workers are considered).

The estimate results in around 2.49 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. The study team believes the number of exposed workers is realistic for F43.29 Other installation.

4.6.6.18 G45 Vehicle repair

In Eurostat, in 2018, there are 818,660 enterprises in sector G45 Wholesale and retail trade and repair of motor vehicles and motorcycles, and these enterprises had 2,823,932 employees. However, the most relevant sector for diisocyanate exposure is G45.20 Maintenance and repair of motor vehicles. In Eurostat, in 2018, there are 452,830 enterprises in the sector G45.20 and in 2017 these enterprises had 994,874 employees. A small amount of exposure may take place in G45.40 Sale, maintenance and repair of motorcycles and related parts and accessories. In Eurostat, in 2018, there are 262 enterprises in the sector G45.40 and these enterprises had 63,000 employees.

In the consultation survey, there were no responses from G45 Vehicle repair enterprises. CEPE and FEICA indicated their awareness of CASE products being used in the sector.

The study team have assumed that 95% of enterprises in G45.20 and G45.40 use diisocyanates and that 50% of employees are occupationally exposed.

In total the study team estimates that a total of 430,437 enterprises use diisocyanates and 471,085 employees might be occupationally exposed to diisocyanates (once 6.25% of non-occupational asthma cases are excluded). The estimate results in around 1.1 employees (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. The study team believes the number of exposed workers is realistic for G45 Vehicle repair as more than 96% of enterprises in Eurostat in this sector consist of enterprises with 0-9 employees. However, the assumed total number of enterprises with occupational exposure might be overestimated as not all enterprise might over respraying services. Both the enterprises and employees exposed might be significantly overestimated as within Europe CEPE suggest there are about 80,000 spraying booths and an estimated workforce of 120,000 workers, this would suggest there are 1.5 workers exposed for each spray booth (CEPE, 2021).

4.6.6.19 S95 Repairs

In Eurostat, in 2018, there are 16,196 enterprises in S95.23 Repair of footwear and leather goods and these enterprises had 7,806 employees. In Eurostat there were less employees than enterprise. In Eurostat, in 2018, there are 269 enterprises in S95.24 Repair of furniture and home furnishings and these enterprises had 11,049 employees.

In the consultation survey, there were no responses from S95 Repair enterprises. FEICA indicated their awareness of CASE products being used in the sector.

The study team have assumed that 95% of enterprises in S95.23 and S95.24 use diisocyanates and that 95% of employees are occupationally exposed.

In total the study team estimates that a total of 31,981 enterprises use diisocyanates and 15,954 employees might be occupationally exposed to diisocyanates (once 6.25% of non-occupational asthma cases are excluded). However, as there are twice as many enterprises as employees the study team have set all enterprises to equal employees, reducing enterprises rather than increased employees is more conservative as it will reduce the cost benefit ratio. This results in 15,954 employees and enterprises.

The estimate results in around 1 employee (excluding non-occupational asthma cases) per enterprise using diisocyanates that are exposed. The study team believes the number of exposed workers is realistic for S95 Vehicle repair as more than 99.8% of enterprises in Eurostat in this sector consist of enterprises with 0-9 employees (the majority of enterprise have 0-1 employee).

4.6.7 Comparison of workers exposed from different sources

In Table 4-27, the estimates from four sources and the study team estimates described in section 4.6.6 are compared for all sectors. Data is also available from the SUMER database (2020) but cannot easily be allocated to the sectors. The total estimated number of exposed workers is 4,226,582.

The study team's estimates are used for the remainder of the analysis because the estimates are based upon the best available data.

In section 4.8.4, there is further discussion about the numbers of exposed workers and number of companies with exposed workers estimated by the study and by industry associations.

Table 4-27 Summary of estimated number of EU workers exposed to diisocyanates in key sectors

<table>
<tr><th>NACE</th><th>CAREX Canada</th><th>UK HSE</th><th>SUMER France</th><th>REACH restriction</th><th>Study estimates</th></tr>
<tr><td>C13 Textiles</td><td></td><td></td><td>2,700 (Manufacture of textiles, clothing industries, leather industry and shoe) (2.2%)</td><td rowspan="13">1.6 million (Other sectors*)
1.8 million (construction chemicals)
1.8 million (automotive repair)</td><td>4,225</td></tr>
<tr><td>C14 apparel</td><td></td><td></td><td>2,700 (Manufacture of textiles, clothing industries, leather industry and shoe) (2.2%)</td><td>7,475</td></tr>
<tr><td>C15 Leather</td><td></td><td></td><td>2,700 (Manufacture of textiles, clothing industries, leather industry and shoe) (2.2%)</td><td>114,000</td></tr>
<tr><td>C16 Wood</td><td></td><td></td><td>4,900 (Woodworking, paper industries and printing) (2.1%)</td><td>14,427</td></tr>
<tr><td>C20 Chemicals</td><td></td><td></td><td>2000 (1.3%)</td><td>13,722</td></tr>
<tr><td>C22.21 Rigid foam</td><td rowspan="3">7,400 (14%)</td><td rowspan="3"></td><td rowspan="3">9,700 (4.1%)</td><td>4,969</td></tr>
<tr><td>C22.29 Flexible foam</td><td>9,750</td></tr>
<tr><td>C22 Other</td><td>39,169</td></tr>
<tr><td>C26 Computers</td><td></td><td></td><td>2,200 (2.3%)</td><td>23,438</td></tr>
<tr><td>C27 Electrical equipment</td><td></td><td></td><td>2,400 (3.1%)</td><td>19,990</td></tr>
<tr><td>C28 Machinery</td><td></td><td></td><td>4,100 (2.1%)</td><td>16,226</td></tr>
<tr><td>C29 Motor vehicles</td><td>1,900 (<5%)</td><td></td><td>8,200 (Manufacture of transport equipment) (1.7%)</td><td>166,373</td></tr>
<tr><td>C30 Transport</td><td></td><td></td><td>8,200 (Manufacture of transport equipment) (1.7%)</td><td>58,034</td></tr>
</table>

NACE	CAREX Canada	UK HSE	SUMER France	REACH restriction	Study estimates
C31 Furniture	1,500				16,918
C33 Machinery repair			13,600 (Other manufacturing industries; repair and installation of machinery and equipment) (4.6%)		10,899
F41.20 Construction			90,700 (construction) (6.6%)		1,304,561
F42 Civil engineering			90,700 (construction) (6.6%)		29,990
F43 Specialised construction			90,700 (construction) (6.6%)		1,872,910
F43.29 Other installation					12,469
G45.2 Vehicle repair	3,100 (<5%)	46,225	36,300 (1.1%)		471,085
S95 Repair					15,953
Total	**24,000**		**232,700**	**5.2 million**	**4,226,583**

Sources: (CAREX, no date), (HSE, 2005), (SUMER, 2020), (ECHA, 2018a), Study team estimates based upon Eurostat, survey and industry data
**Estimated exposed workers for the REACH Restriction background*

The SUMER (2020) report describes the type of professions and activities where occupational exposure to diisocyanates may occur, these are shown in Table 4-28.

Table 4-28 Professional users with the highest and greatest number of exposed employees in France

Professional users with the highest proportion of exposed employees		
Profession	**Workforce**	**Percentage exposed**
Qualified construction workers	60,100	13,3%
Skilled workers in public works, concrete and mining.	12,000	10,0%
Unqualified mechanical workers	6,700	9,2%
Skilled mechanical workers	7,800	7,8%
Skilled auto repair workers	16,500	6,8%
Qualified maintenance workers	6,900	4,7%
Skilled workers working by forming metal	4,200	3,8%
Skilled workers in the structural work of the building	8,500	3,2%
Skilled workers in process industries	12,000	3,1%
Professional users with the greatest number of employees exposed		
Profession	**Workforce**	**Percentage exposed**
Qualified construction workers	60,100	13,3%
Skilled auto repair workers	16,500	6,8%
Skilled workers in process industries	12,000	3,1%
Skilled workers in public works, concrete and mining	12,000	10,0%
Skilled workers in the structural work of the building	8,500	3,2%
Skilled mechanical workers	7,800	7,8%
Qualified maintenance workers	6,900	4,7%
Unqualified mechanical workers	6,700	9,2%
Skilled workers working by forming metal	4,200	3,8%

Sources: (SUMER, 2020)

4.6.8 Trends

The use of diisocyanates is expected to steadily increase in the future across many sectors, however, there is also a continual trend to automate industrial processes, particularly those with higher potential for exposure, and therefore the number of exposed workers is expected to be static in future years.

4.6.9 Exposed workers: conclusion

The data collected through consultation for this study provides evidence of approximately 4,226,583 workers currently exposed to diisocyanates. This is shown by key sectors in Table 4-29, the table excludes 6.25% of non-occupational asthma cases.

Table 4-29 Estimated number of EU workers exposed to diisocyanates in key sectors (excluding 6.25% of non-occupational asthma cases)

Sector	Estimated exposed workers
C13 Textiles	4,225
C14 Apparel	7,475
C15 Leather	114,000
C16 Wood	14,427
C20 Chemicals	13,722
C22.21 Rigid foam	4,969
C22.29 Flexible foam	9,750
C22 Other	39,169
C26 Computers	23,438
C27 Electrical equipment	19,990
C28 Machinery	16,226
C29 Motor vehicles	166,373
C30 Transport	58,034
C31 Furniture	16,918
C33 Machinery repair	10,899
F41.2 Construction	1,304,561
F42 Civil engineering	29,990
F43 Specialised construction	1,872,910
F43.29 Other installation	12,469
G45.2 Vehicle repair	471,085
S95 Repairs	15,953
Total	**4,226,583**

Source: Study team

4.7 Current risk management measures

This section starts out with an overall description of risk management measures followed by sector specific descriptions.

4.7.1 Overall description of RMMs

The recommended risk management measures extracted from REACH CSRs supplied by ISOPA/ALIPA are as follows:

Engineering and ventilation controls: Basic aspects of equipment and facility design should be such that lead emissions that may contribute to occupational exposures are minimised. Such measures may include enclosure of process equipment such that sources of dust or aerosol emissions are minimised, negative draft exhaust systems to reduce emissions from enclosures and/or local exhaust ventilation installed at unavoidable sources of process emissions. The design characteristics of any local exhaust ventilation (e.g. exhaust hoods) will be specific to the emission source being controlled. Area ventilation should also be balanced such that air flow within a work area moves from areas of low to high exposure potential. Air captured by ventilation controls may require treatment to minimise toxic substances prior to discharge or recirculation.

Cleaning: Ensure general shop cleanliness is maintained by frequent washing/vacuuming. Clean every workplace at the end of every shift.

Personal protective equipment: Assess the need to wear respiratory protective equipment (RPE) in production areas. Consider using effective masks accompanied by a compliance policy (ensure proper shaving; ensure workers do not remove RPE in production areas in order to communicate).

Where masks are used, employ formal mask cleaning and filter changing strategies; for workers in areas of significant exposure, provide sufficient working clothes to enable daily change into clean clothes. In such cases, all work clothing should be cleaned by the employer on a daily basis and not permitted to leave the work site.

Personal hygiene: Ensure workers follow simple hygiene rules (e.g. do not bite nails and keep them cut short, avoid touching or scratching face with dirty hands or gloves); ensure workers do not wipe away sweat with hands or arms, e.g. by providing disposable perspiration towels; ensure workers use disposable tissues rather than a handkerchief; prohibit drinking, eating and smoking in production areas; prevent access to eating and non-production areas in working clothes; ensure workers as a minimum wash hands, arms, faces and mouths (but preferably shower) and change into personal clothing (or clean coveralls provided by the company) before entering eating areas; for high exposure workplaces, at the end of a shift, workers may need to pass through a room containing washbasins for the cleaning of hands, followed by a 'dirty' room for the removal of working clothes, then through showers into a 'clean' room for changing into personal clothing; ensure workers handle dirty working clothes with care; consider making showering obligatory at the end of a shift, and provide towels and soap; allow no personal belongings to be taken into production areas, and allow no items that have been used in production areas to be taken home.

Creating a culture of safety: Define and communicate a clear policy for controlling occupational exposure to diisocyanates; ensure managers set the example in terms of personal protection and hygiene; where possible involve occupational physicians in making workers take control of their own diisocyanate exposure; consider making low diisocyanate exposure a condition of employment, with disciplinary action taken where protective equipment and hygiene procedures are not followed; involve managers when workers' diisocyanate exposure levels exceed action levels; consider publicising company diisocyanate exposure performance to workers via notices and briefings to ensure the topic remains a key priority;

provide detailed training for new personnel on the risks of diisocyanate exposure and the procedures for protection; provide instruction on specific diisocyanate exposure risks for workers undertaking new tasks; provide regular refresher courses for all employees on the risks of diisocyanate exposure and the procedures for protection; involve worker representatives.

4.7.2 Types of RMMs

Table 4-30 provides the details of RMMs currently used in each sector obtained from the consultation survey. Companies provided information from a variety of different sectors which were reviewed for accuracy and relevance to the study. Responses that provided incorrect NACE codes were corrected, and responses from sectors not relevant to the study were omitted. In total the consultation received legitimate responses from 11 different sectors which have been included in the analysis.

Companies were invited to provide up to four processes for each questionnaire submission, with several companies providing more than one questionnaire submission to account for facilities with more than four activities with exposure to diisocyanate compounds. Respondents were also encouraged to provide additional questionnaire submissions in the event of a company having multiple facilities. Some companies provided submissions with up to seven processes.

Table 4-30 and Table 4-31 (two parts of the same table) below provide an overview of the RMMs currently being used by consultation respondents in each of the 12 sectors. The majority of responses were provided from companies operating in C16 Wood, C20 Chemicals, C22 Rubber and plastics, and C22.21 Rigid foams. As shown, companies across the sectors are primarily using a mixture of RMMs, noting that partially closed, open hood systems, and general dilution ventilation are prevalent amongst most sectors. Closed systems are not commonly used by respondents in any given sector. RPE has a lower level of usage than expected, however this is accounted for by respondents use of local exhaust ventilation which reduces the need for RPE to be work by workers. However, in a significant proportion of sectors full and half-facemasks are commonly used as a primary RMM. Enclosed systems are not commonly used in any sector given the percentages of RMMs below. Occupational health/organisational measures regarding the cleaning of machines, facilities and/or instruments, and training of staff are commonly used as a RMM for activities using diisocyanates in all sectors. Furthermore, personal protective equipment (PPE) is also commonplace.

Table 4-30 Companies current use of RMMs for individual processes by sector (part 1 of 2)

Sector	Reduced amount of substance used	Reduced number of workers exposed	Rotation of the workers exposed	Redesign of work processes	Closed systems	Partially closed systems	Open hoods over equipment or local extraction ventilation	General ventilation	Pressurised or sealed control cabs	Simple enclosed control cabs	Self-contained breathing apparatus	Powered air-purifying respirators	Half and full face-masks (negative pressure respirators)	Disposable respirators (FFP masks)	Face screens, face shields, visors	Safety spectacles, goggles	Total number of processes analysed in sector
C15	0%	100%	100%	0%	0%	0%	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	1
C16	44%	67%	67%	0%	25%	47%	53%	94%	17%	6%	0%	3%	75%	42%	8%	97%	36
C20	12%	42%	32%	22%	17%	37%	62%	64%	5%	5%	9%	8%	36%	10%	22%	79%	337
C22.21	6%	56%	15%	31%	10%	54%	37%	54%	0%	6%	2%	6%	15%	19%	6%	83%	52
C22.29	9%	50%	36%	33%	12%	59%	69%	76%	2%	19%	15%	21%	52%	11%	16%	79%	170
C22	0%	9%	18%	9%	18%	45%	64%	55%	0%	0%	0%	0%	9%	18%	0%	91%	11
C26	25%	75%	0%	25%	0%	50%	75%	25%	0%	0%	0%	0%	100%	0%	0%	100%	4
C27	25%	50%	50%	50%	0%	75%	50%	75%	0%	50%	0%	0%	50%	0%	0%	100%	4
C29	10%	40%	30%	20%	10%	10%	30%	60%	20%	0%	50%	20%	20%	30%	0%	90%	10
F42	0%	0%	0%	0%	0%	0%	67%	33%	0%	0%	0%	0%	100%	0%	0%	100%	3
F43	0%	0%	0%	14%	14%	0%	29%	43%	0%	0%	14%	0%	29%	0%	0%	71%	7

Source: Consultation survey

Table 4-31 Companies current use of RMMs for individual processes by sector (part 2 of 2)

NACE Code	Gloves	Gloves with a cuff, gauntlets and sleeving covering the arm	Safety boots and shoes	Rubber boots	Conventional or disposable overalls, boiler suits, aprons	Coveralls/hazardous materials suits	Training and education	REACH Restriction training (future)	Cleaning	Provision of separate storage facilities for work clothes	Formal/external RPE cleaning and filter changing regime	Continuous measurement to detect unusual exposures	Partial substitution of diisocyanates used in this activity in the past	Discontinuation of part of the activity using diisocyanates	Other	Total number of processes analysed in sector
C15	100%	0%	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	1
C16	94%	17%	97%	31%	61%	11%	97%	89%	81%	86%	92%	11%	3%	0%	0%	36
C20	84%	31%	93%	5%	46%	20%	95%	45%	80%	91%	48%	9%	12%	1%	27%	337
C22.21	75%	46%	98%	6%	25%	23%	96%	71%	81%	50%	8%	4%	2%	0%	8%	52
C22.29	79%	42%	96%	11%	48%	31%	100%	67%	95%	75%	70%	45%	2%	2%	26%	170
C22	91%	0%	91%	0%	9%	0%	82%	64%	55%	64%	0%	9%	0%	0%	9%	11
C26	100%	0%	100%	0%	100%	0%	100%	100%	0%	100%	0%	25%	0%	25%	0%	4
C27	100%	25%	100%	0%	25%	0%	100%	100%	100%	50%	50%	0%	0%	0%	0%	4
C29	90%	70%	100%	30%	40%	40%	100%	80%	100%	40%	50%	0%	10%	0%	0%	10
F42	67%	0%	100%	0%	100%	0%	33%	0%	0%	0%	0%	0%	0%	0%	0%	3
F43	71%	0%	14%	0%	43%	0%	29%	29%	29%	71%	43%	0%	0%	0%	0%	7

Source: Consultation survey

4.7.3 Specific risk management measures

The following section includes information on RMMs applied for the specific exposure scenarios in relation to specific diisocyanates. As regards the organisational RMMs, the tables do not list the general RMMs described above.

Table 4-32: RMMs applied for Adhesives and Sealants relating to 4,4-MDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Industrial Spraying	Areas where gloves are required identified by management. Worker training on how and where to use gloves. Control measures are regularly inspected and maintained.	Usage should be in a predominantly closed system with local exhaust ventilation required	Not required	Protective gloves, Eye protection
Low energy manipulation of substances in materials and/or articles		None required	None required	
Mixing or blending in batch processes (multistage and/or significant contact)		Variations	Variations	
Non Industrial Spraying		Discrepancies	Discrepancies	
Production of preparations or articles by tabletting, compression, extrusion, pelletisation		None required	None required	
Roller application or brushing		None required	None required	
Transfer of chemicals from/to vessels/ large containers at dedicated facilities		None required	None required	
Transfer of chemicals from/to vessels/ large containers at non dedicated facilities		None required	None required	
Transfer of chemicals into small containers (dedicated filling line)		Local exhaust ventilation required	None required	

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Treatment of articles by dipping and pouring		None required	None required	
Use in batch and other process (synthesis) where opportunity for exposure arises		Variations	Variations	
Use in closed batch process (synthesis or formulation)		None required	None required	
Use in closed, continuous process with occasional controlled exposure		None required	None required	
Use of laboratory reagents in small scale laboratories		Variations	Variations	

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-33: RMMs applied for adhesives and sealants in industrial and professional use relating to TDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Open batch/continuous processes with opportunity for exposure	Clean spills/contamination immediately, Basic employee training on preventing/minimising exposures and reporting skin contact issues. Wash skin contamination immediately	Local exhaust ventilation required	None required	Protective gloves, Eye protection, Coveralls
Tabletting, compression, extrusion, pelletisation		Local exhaust ventilation required	Full face respirator conforming to EN147 with a type A or better filter is required	

Source: REACH CSRs supplied by ISOPA/ALIPA

Table 4-34: RMMs applied for cleaning relating to 4,4-MDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Mixing or blending in batch processes (multistage and/or significant contact)	Areas where gloves are required identified by management. Worker training on how and where to use gloves. Control measures are regularly inspected and maintained.	Local exhaust ventilation required	None required	
Roller application or brushing		Local exhaust ventilation required	Respirator of 90% efficiency required if LEV not available	
Transfer of chemicals from/to vessels/ large containers at non dedicated facilities		Local exhaust ventilation required	Respirator of 90% efficiency required if LEV not available	
Treatment of articles by dipping and pouring		Local exhaust ventilation required	Respirator of 90% efficiency required if LEV not available	
Use in batch and other process (synthesis) where opportunity for exposure arises		Local exhaust ventilation required	None required	
Use in closed batch process (synthesis or formulation)		None required	None required	
Use in closed process, no likelihood of exposure		Variations	None required	
Use of laboratory reagents in small scale laboratories		Local exhaust ventilation required	Respirator of 90% efficiency required if LEV not available	

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-35: RMMs applied for coatings, industrial and professional use relating to TDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Dipping	Clean spills/contamination immediately, Basic employee training on preventing/minimising exposures and reporting skin contact issues. Wash skin contamination immediately.	Use in fume cupboard with extract ventilation	None required	Protective gloves, Eye protection, Coveralls
Enclosed batch processes with occasional exposure		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter required if LEV not available	
Enclosed continuous processes with occasional exposure		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter required if LEV not available	
Enclosed continuous processes with occasional exposure		Local exhaust ventilation required	None required	
Filling operations with small containers		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter required if LEV not available	
Industrial spraying		Local exhaust ventilation required	Full face respirator conforming to EN147 with type A filter or better required	
Laboratory use		Use in fume cupboard with extract ventilation	None required	
Not enclosed dedicated transfer of chemicals		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter required if LEV not available	

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Not enclosed transfer of chemicals		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter required if LEV not available	
Open batch/continuous processes with opportunity for exposure		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter required if LEV not available	
Open processes (mixing)		Local exhaust ventilation required	Full face respirator conforming to EN147 with type A filter or better required	
Rolling or brushing (large scale >20 m2)	Clean spills/contamination immediately, Basic employee training on preventing/minimising exposures and reporting skin contact issues. Wash skin contamination immediately. Ensure good natural ventilation.	Ventilate room by a mix of natural ventilation and controlled ventilation measures (i.e. fan/ air removal)	Respirator conforming to EN1140 with type A/P2 filter required if LEV not available	
Rolling or brushing (small scale <10m2)	Clean spills/contamination immediately, Basic employee training on preventing/minimising exposures and reporting skin contact issues. Wash skin contamination immediately.	Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter required if LEV not available	

Source: REACH CSRs supplied by ISOPA/ALIPA

Table 4-36: RMMs applied for coatings relating to 4,4-MDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Industrial spraying	Areas where gloves are required identified by management. Worker training on how and where to use gloves. Control measures are regularly inspected and maintained.	Local exhaust ventilation required	None required	Protective gloves, Eye protection
Low energy manipulation of substances in materials and/or articles		None required	None required	
Mixing or blending in batch processes (multistage and/or significant contact)		Local exhaust ventilation required	Respirator conforming to EN140 with efficiency greater than 90% required if LEV not available	
Non industrial spraying		Variations	Variations	
Roller application or brushing		None required	None required	
Transfer of chemicals from/to vessels/ large containers at dedicated facilities		None required	None required	
Transfer of chemicals from/to vessels/ large containers at non dedicated facilities		None required	None required	
Transfer of chemicals into small containers (dedicated filling line)		Local exhaust ventilation required	None required	
Treatment of articles by dipping and pouring		None required	None required	
Use in batch and other process (synthesis) where opportunity for exposure arises		Local exhaust ventilation required	Respirator conforming to EN140 with efficiency greater than 90% required if LEV not available	

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Use in closed batch process (synthesis or formulation)		None required	None required	
Use in closed process, no likelihood of exposure		None required	None required	
Use in closed, continuous process with occasional controlled exposure		None required	None required	
Use of laboratory reagents in small scale laboratories		Local exhaust ventilation required	None required	

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-37: RMMs applied for Composite Materials Based on Wood/Man-Made/Mineral/Natural Fibres relating to 4,4-MDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
High (mechanical) energy work-up of substances bound in materials and/or articles - pt > mp - High Fugacity	Areas where gloves are required identified by management. Worker training on how and where to use gloves. Control measures are regularly inspected and maintained.	None required	Variations	Protective gloves, Eye protection
Industrial spraying		Local exhaust ventilation required	Respirator conforming to EN140 with efficiency greater than 90% required if LEV not available	
Mixing or blending in batch processes (multistage and/or significant contact)		Local exhaust ventilation required	None required	
Production of preparations or articles by tabletting, compression, extrusion, pelletisation		Local exhaust ventilation required	Respirator conforming to EN140 with efficiency greater than 90% required	
Roller application or brushing		None required	Respirator conforming to EN140 with efficiency greater than 90% required	
Transfer of chemicals from/to vessels/ large containers at dedicated facilities		None required	None required	
Use in closed batch process (synthesis or formulation)		None required	None required	
Use in closed process, no likelihood of exposure		None required	None required	
Use in closed, continuous process with occasional controlled exposure		Variations	Variations	
Use of laboratory reagents in small scale laboratories		Local exhaust ventilation required	None required	

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-38: RMMs applied for elastomers, TPU, polyamide & synthetic fibres & manufacturing of other polymers relating to 4,4-MDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Industrial spraying	Areas where gloves are required identified by management. Worker training on how and where to use gloves. Control measures are regularly inspected and maintained.	Local exhaust ventilation required	None required	Protective gloves, Eye protection
Low energy manipulation of substances in materials and/or articles		None required	None required	
Mixing or blending in batch processes (multistage and/or significant contact)		None required	None required	
Production of preparations or articles by tabletting, compression, extrusion, pelletisation		None required	None required	
Roller application or brushing		None required	None required	
Transfer of chemicals from/to vessels/ large containers at dedicated facilities		None required	None required	
Transfer of chemicals from/to vessels/ large containers at non dedicated facilities		None required	None required	
Transfer of chemicals into small containers (dedicated filling line)		Local exhaust ventilation required	None required	
Use in batch and other process (synthesis) where opportunity for exposure arises		Local exhaust ventilation required	None required	
Use in closed batch process (synthesis or formulation)		None required	None required	
Use in closed process, no likelihood of exposure		None required	None required	
Use in closed, continuous process with occasional controlled exposure		None required	None required	
Use of laboratory reagents in small scale laboratories		Local exhaust ventilation required	Respirator with minimum efficiency of 90% required if LEV not available	

Source: REACH CSRs supplied by ISOPA/ALIPA

Table 4-39: RMMs applied for ELASTOMERS, TPU, polyamide & synthetic fibres industrial use relating to TDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Enclosed batch processes with occasional exposure	Clean spills/contamination immediately, Basic employee training on preventing/minimising exposures and reporting skin contact issues. Wash skin contamination immediately.	Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	Protective gloves, Eye protection, Coveralls
Enclosed continuous processes with occasional exposure		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	
Enclosed processes & no likelihood of exposure		Local exhaust ventilation required	None required	
Filling operations with small containers		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	
Laboratory use		Use in a fume cupboard under extract ventilation	None required	
Not enclosed dedicated transfer of chemicals		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	
Open batch/continuous processes with opportunity for exposure		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	
Open processes (mixing)		Local exhaust ventilation required	Respirator TM3 conforming to EN147 with type A filter or better required	

Source: REACH CSRs supplied by ISOPA/ALIPA

Table 4-40: RMMs applied for flexible foam relating to 4,4-MDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Industrial spraying	Areas where gloves are required identified by management. Worker training on how and where to use gloves. Control measures are regularly inspected and maintained.	Local exhaust ventilation required	None required	Protective gloves, Eye protection
Low energy manipulation of substances in materials and/or articles		None required	None required	
Mixing or blending in batch processes (multistage and/or significant contact)		Local exhaust ventilation required	None required	
Production of preparations or articles by tabletting, compression, extrusion, pelletisation		Local exhaust ventilation required	None required	
Transfer of chemicals from/to vessels/ large containers at dedicated facilities		None required	None required	
Transfer of chemicals from/to vessels/ large containers at non dedicated facilities		None required	None required	
Use in batch and other process (synthesis) where opportunity for exposure arises		Local exhaust ventilation required	Variations	
Use in closed batch process (synthesis or formulation)		None required	None required	
Use in closed process, no likelihood of exposure		None required	None required	
Use in closed, continuous process with occasional controlled exposure		None required	None required	
Use of laboratory reagents in small scale laboratories		Local exhaust ventilation required	Respirator with minimum efficiency of 90% required if LEV not available	

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-41: RMMs applied for flexible foam industrial use relating to TDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Enclosed batch processes with occasional exposure	Clean spills/contamination immediately, Basic employee training on preventing/minimising exposures and reporting skin contact issues. Wash skin contamination immediately.	Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	Protective gloves, Eye protection, Coveralls
Enclosed continuous processes with occasional exposure		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	
Enclosed processes & no likelihood of exposure		Local exhaust ventilation required	None required	
Laboratory use		Use in a fume cupboard under extract ventilation	None required	
Not enclosed dedicated transfer of chemicals		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	
Open batch/continuous processes with opportunity for exposure		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	
Open processes (mixing)		Local exhaust ventilation required	Respirator TM3 conforming to EN147 with type A filter or better required	
Pressing		Local exhaust ventilation required	Respirator TM3 conforming to EN147 with type A filter or better required	
PU article treatment		Local exhaust ventilation required	Respirator conforming with EN140 with typeA-2 filter or better required	

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-42: RMMs applied for formulating, repackaging & distribution relating to TDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Enclosed batch processes with occasional exposure	Clean spills/contamination immediately, Basic employee training on preventing/minimising exposures and reporting skin contact issues. Wash skin contamination immediately.	Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	Protective gloves, Eye protection, Coveralls
Enclosed continuous processes with occasional exposure		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	
Enclosed processes & no likelihood of exposure		Local exhaust ventilation required	None required	
Laboratory use		Use in a fume cupboard under extract ventilation	None required	
Not enclosed dedicated transfer of chemicals		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	
Open batch/continuous processes with opportunity for exposure		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	
Open processes (mixing)		Local exhaust ventilation required	Respirator TM3 conforming to EN147 with type A filter or better required	
Transfer of substance or preparation into small containers		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-43: RMMs applied for formulation relating to HDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
None stated	Control staff entry in work area, employees with skin conditions or hypersensitivity not to work with product. All equipment to be well maintained. Regular cleaning of equipment and work area. Changing of contaminated clothes immediately. Regular washing of hands before breaks and at the end of shifts.	Local exhaust ventilation required. Substance should be subject to high level of containment in long term processes.	Respirator with carbon filter fitted required	Protective gloves, Eye protection

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-44: RMMs applied for formulation, including resin manufacturing, repackaging & distribution relating to 4,4-MDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Mixing or blending in batch processes (multistage and/or significant contact)		Local exhaust ventilation required	None required	
Transfer of chemicals from/to vessels/ large containers at dedicated facilities		None required	None required	
Transfer of chemicals from/to vessels/ large containers at non dedicated facilities		None Required	None required	
Transfer of chemicals into small containers (dedicated filling line)	Areas where gloves are required identified by management. Worker training on how and where to use gloves. Control measures are regularly inspected and maintained.	Local exhaust ventilation required	None required	
Use in batch and other process (synthesis) where opportunity for exposure arises		Local exhaust ventilation required	None required	Protective gloves, Eye protection
Use in closed batch process (synthesis or formulation)		None required	None required	
Use in closed process, no likelihood of exposure		None required	None required	
Use in closed, continuous process with occasional controlled exposure		None required	None required	
Use in closed, continuous process with occasional controlled exposure		Local exhaust ventilation required	Respirator with minimum efficiency of 90% required if LEV not available	

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-45: RMMs applied for foundry relating to 4,4-MDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Low energy manipulation of substances in materials and/or articles	Areas where gloves are required identified by management. Worker training on how and where to use gloves. Control measures are regularly inspected and maintained.	None required	None required	Protective gloves, Eye protection
Mixing or blending in batch processes (multistage and/or significant contact)		Local exhaust ventilation required	None required	
Production of preparations or articles by tabletting, compression, extrusion, pelletisation		Local exhaust ventilation required	Respirator with minimum efficiency of 90% required if LEV not available	
Transfer of chemicals from/to vessels/ large containers at dedicated facilities		None required	None required	
Transfer of chemicals from/to vessels/ large containers at non dedicated facilities		None required	None required	
Use in batch and other process (synthesis) where opportunity for exposure arises		Local exhaust ventilation required	None required	
Use in closed batch process (synthesis or formulation)		None required	None required	
Use in closed process, no likelihood of exposure		None required	None required	
Use in closed, continuous process with occasional controlled exposure		None required	None required	
Use of laboratory reagents in small scale laboratories		Local exhaust ventilation required	Respirator with minimum efficiency of 90% required if LEV not available	

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-46: RMMs applied for industrial use as an intermediate/monomer relating to HDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
None stated	Control staff entry in work area, employees with skin conditions or hypersensitivity not to work with product. All equipment to be well maintained. Regular cleaning of equipment and work area. Changing of contaminated clothes immediately. Regular washing of hands before breaks and at the end of shifts.	Local exhaust ventilation required. Substance should be subject to high level of containment in long term processes.	Respirator with carbon filter fitted required	Protective gloves, Eye protection

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-47: RMMs applied for manufacture relating to HDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
None stated	Control staff entry in work area, employees with skin conditions or hypersensitivity not to work with product. All equipment to be well maintained. Regular cleaning of equipment and work area. Changing of contaminated clothes immediately. Regular washing of hands before breaks and at the end of shifts.	Local exhaust ventilation required. Substance should be subject to high level of containment in long term processes.	Respirator with carbon filter fitted required	Protective gloves, Eye protection

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-48: RMMs applied for manufacture relating to 4,4-MDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
High (mechanical) energy work-up of substances bound in materials and/or articles - pt < mp - Low Fugacity	Areas where gloves are required identified by management. Worker training on how and where to use gloves. Control measures are regularly inspected and maintained.	None required	Full face respirator conforming to EN136 with minimum efficiency of 97.5% required	Protective gloves, Eye protection
Transfer of chemicals from/to vessels/ large containers at dedicated facilities		None required	Full face respirator conforming to EN136 with minimum efficiency of 97.5% required	
Transfer of chemicals from/to vessels/ large containers at non dedicated facilities		None required	Full face respirator conforming to EN136 with minimum efficiency of 97.5% required	
Use in batch and other process (synthesis) where opportunity for exposure arises		None required	Full face respirator conforming to EN136 with minimum efficiency of 97.5% required	
Use in closed batch process (synthesis or formulation)		None required	Full face respirator conforming to EN136 with minimum efficiency of 97.5% required	
Use in closed process, no likelihood of exposure		None required	None required	
Use in closed, continuous process with occasional controlled exposure		None required	Full face respirator conforming to EN136 with minimum efficiency of 97.5% required	
Use of laboratory reagents in small scale laboratories		Local exhaust ventilation required	None required	

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-49: RMMs applied for manufacture relating to TDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Enclosed batch processes with occasional exposure	Clean spills/contamination immediately, Basic employee training on preventing/minimising exposures and reporting skin contact issues. Wash skin contamination immediately.	Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	Protective gloves, Eye protection, Coveralls
Enclosed continuous processes with occasional exposure	Clean spills/contamination immediately, Basic employee training on preventing/minimising exposures and reporting skin contact issues. Wash skin contamination immediately.	Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	Protective gloves, Eye protection, Coveralls
Enclosed processes & no likelihood of exposure	Clean spills/contamination immediately, Basic employee training on preventing/minimising exposures and reporting skin contact issues. Wash skin contamination immediately.	Local exhaust ventilation required	None required	Protective gloves, Eye protection, Coveralls
Laboratory use	Clean spills/contamination immediately, Basic employee training on preventing/minimising exposures and reporting skin contact issues. Wash skin contamination immediately.	Use in fume cupboard under extract ventilation	None required	Protective gloves, Eye protection, Coveralls
Not enclosed dedicated transfer of chemicals	Clean spills/contamination immediately, Basic employee training on preventing/minimising exposures and reporting skin contact issues. Wash skin contamination immediately.	Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	Protective gloves, Eye protection, Coveralls
Open batch/continuous processes with opportunity for exposure	Clean spills/contamination immediately, Basic employee training on preventing/minimising exposures and reporting skin contact issues. Wash skin contamination immediately.	Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	Protective gloves, Eye protection, Coveralls

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-50: RMMs applied for manufacture of other substances relating to TDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Enclosed batch processes with occasional exposure	Clean spills/contamination immediately, Basic employee training on preventing/minimising exposures and reporting skin contact issues. Wash skin contamination immediately.	Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	Protective gloves, Eye protection, Coveralls
Enclosed continuous processes with occasional exposure		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	
Enclosed processes & no likelihood of exposure		Local exhaust ventilation required	None required	
Laboratory use		Use in fume cupboard under extract ventilation	None required	
Not enclosed dedicated transfer of chemicals		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	
Open batch/continuous processes with opportunity for exposure		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	
Open processes (mixing)		Local exhaust ventilation required	Respirator TM3 conforming to EN147 with type A filter or better required	
Transfer of substance or preparation into small containers		Local exhaust ventilation required	Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available	

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-51: RMMs applied for manufacture of other substances relating to 4,4-MDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Mixing or blending in batch processes (multistage and/or significant contact)	Areas where gloves are required identified by management. Worker training on how and where to use gloves. Control measures are regularly inspected and maintained.	Local exhaust ventilation required	None required	Protective gloves, Eye protection
Transfer of chemicals from/to vessels/ large containers at dedicated facilities		None required	None required	
Transfer of chemicals from/to vessels/ large containers at non dedicated facilities		None required	None required	
Transfer of chemicals into small containers (dedicated filling line)		Local exhaust ventilation required	None required	
Use in batch and other process (synthesis) where opportunity for exposure arises		Local exhaust ventilation required	Respirator conforming to EN140 with minimum efficiency of 90% required	
Use in closed batch process (synthesis or formulation)		None required	None required	
Use in closed process, no likelihood of exposure		None required	None required	
Use in closed, continuous process with occasional controlled exposure		None required	None required	
Use of laboratory reagents in small scale laboratories		Local exhaust ventilation required	Respirator with minimum efficiency of 90% required if LEV not available	

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-52: RMMs applied for other composite material relating to 4,4-MDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Industrial Spraying	Areas where gloves are required identified by management. Worker training on how and where to use gloves. Control measures are regularly inspected and maintained.	Local exhaust ventilation required	None required	Protective gloves, Eye protection
Low energy manipulation of substances in materials and/or articles		None required	None required	
Mixing or blending in batch processes (multistage and/or significant contact)		Local exhaust ventilation required	None required	
Production of preparations or articles by tabletting, compression, extrusion, pelletisation		None required	None required	
Roller application or brushing		None required	None required	
Transfer of chemicals from/to vessels/ large containers at dedicated facilities		None required	None required	
Transfer of chemicals from/to vessels/ large containers at non dedicated facilities		None required	None required	
Treatment of articles by dipping and pouring		None required	None required	
Use in batch and other process (synthesis) where opportunity for exposure arises		Local exhaust ventilation required	None required	
Use in closed batch process (synthesis or formulation)		None required	None required	
Use in closed process, no likelihood of exposure		None required	None required	
Use in closed, continuous process with occasional controlled exposure		None required	None required	
Use of laboratory reagents in small scale laboratories		Local exhaust ventilation required	Respirator with minimum efficiency of 90% required if LEV not available	

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-53: RMMs applied for other composite material industrial and professional use relating to TDI

<table>
<tr><th>Scenario</th><th>Organisational RMMs</th><th>Technical RMMs</th><th>RPE*</th><th>Other PPE</th></tr>
<tr><td>Dipping</td><td rowspan="10">Clean spills/contamination immediately, Basic employee training on preventing/minimising exposures and reporting skin contact issues. Wash skin contamination immediately.</td><td>Use in fume cupboard under extract ventilation</td><td>None required</td><td rowspan="10">Protective gloves, Eye protection, Coveralls</td></tr>
<tr><td>Enclosed batch processes with occasional exposure</td><td>Local exhaust ventilation required</td><td>Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available</td></tr>
<tr><td>Enclosed continuous processes with occasional exposure</td><td>Local exhaust ventilation required</td><td>Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available</td></tr>
<tr><td>Enclosed processes & no likelihood of exposure</td><td>Local exhaust ventilation required</td><td>None required</td></tr>
<tr><td>Laboratory use</td><td>Use in fume cupboard under extract ventilation</td><td>None required</td></tr>
<tr><td>Not enclosed dedicated transfer of chemicals</td><td>Local exhaust ventilation required</td><td>Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available</td></tr>
<tr><td>Not enclosed transfer of chemicals</td><td>Local exhaust ventilation required</td><td>Respirator TM3 conforming to EN147 with type A filter or better required</td></tr>
<tr><td>Open batch/continuous processes with opportunity for exposure</td><td>Local exhaust ventilation required</td><td>Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available</td></tr>
<tr><td>Open processes (mixing)</td><td>Local exhaust ventilation required</td><td>Respirator TM3 conforming to EN147 with type A filter or better required</td></tr>
<tr><td>Transfer of substance or preparation into small containers</td><td>Local exhaust ventilation required</td><td>Respirator conforming to EN1140 with type A/P2 filter or better required if LEV not available</td></tr>
</table>

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

Table 4-54: RMMs applied for rigid foam relating to 4,4-MDI

Scenario	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Industrial Spraying	Areas where gloves are required identified by management. Worker training on how and where to use gloves. Control measures are regularly inspected and maintained.	Local exhaust ventilation required	None required	Protective gloves, Eye protection
Low energy manipulation of substances in materials and/or articles		None required	None required	
Mixing or blending in batch processes (multistage and/or significant contact)		Local exhaust ventilation required	Respirator conforming to EN140 with minimum efficiency of 90% required	
Non industrial spraying		Variations	Variations	
Roller application or brushing		None required	None required	
Transfer of chemicals from/to vessels/ large containers at dedicated facilities		None required	None required	
Transfer of chemicals from/to vessels/ large containers at non dedicated facilities		None required	None required	
Transfer of chemicals into small containers (dedicated filling line)		Local exhaust ventilation required	None required	
Use in batch and other process (synthesis) where opportunity for exposure arises		Local exhaust ventilation required	Respirator conforming to EN140 with minimum efficiency of 90% required	
Use in closed batch process (synthesis or formulation)		None required	None required	
Use in closed process, no likelihood of exposure		None required	None required	
Use in closed, continuous process with occasional controlled exposure		None required	None required	
Use of laboratory reagents in small scale laboratories		Local exhaust ventilation required	Respirator with minimum efficiency of 90% required if LEV not available	

Source: REACH CSRs supplied by ISOPA/ALIPA
Notes: Variations means some CSRs require these RMMs for this activity and others do not.

4.8 Market analysis

4.8.1 Sources of data on enterprises with exposed workers

The main source of data about enterprises for all key sectors was Eurostat along with assumptions about the proportion of enterprises using diisocyanates.

In some key sectors industry associations have estimated the total number of enterprises with exposure.

4.8.2 Study team analysis of Eurostat, survey and industry data

For key sectors the number of enterprises with exposed workers is investigated more thoroughly, using similar thinking as for exposed workers in section 4.6.6. Each sector is considered in turn following discussions with industry associations and companies in the sector to develop either an estimate based upon one of the following methods:

- Defining a NACE code into which the sector falls and estimating the percentage of companies within that sector that will use diisocyanates under the scope of the CMD, which when multiplied by the number of companies in that NACE code gives the number of enterprises with exposed workers.
- Defining the actual companies operating in the sector (where the number is small). As values for small, medium and large companies are also required, the calculations may need to be adjusted because in some sectors there might not be any large enterprises with exposed workers, for example S95 repair.

Note that due to rounding, there are small differences between the total number of enterprises and the total number of enterprises split by small, medium and large enterprises.

4.8.2.1 C13 Textiles

In Eurostat, in 2018, there are 58,878 enterprises in sector C13 Textiles. In total, the study team estimates that 2,982 enterprises across the whole of C13 Textiles use diisocyanates, including 77 enterprises in C13.95.

The study team's estimate is based on conversations with trade associations that suggested a small amount of use in the sector. The study team estimates that 10% of enterprises in C13.95 use diisocyanates and 5% of all other enterprises in C13 also use diisocyanates.

The split of enterprises by size is challenging to estimate. The study team used Eurostat's 2018 enterprise figures as a basis to calculate the percentages of small, medium and large enterprises as being: 96.5%, 3% and 0.5% respectively in C13. The spilt is also identical for C13 Textiles and results in around 2,880, 88 and 14 small, medium and large enterprises respectively.

In the consultation survey, there were no responses from the textile industry.

4.8.2.2 C14 Apparel

In Eurostat, in 2018, there are 125,000 enterprises in sector C14 Apparel. In total, the study team estimates that a total of 7,538 enterprises use diisocyanate, including 210 enterprises in C14.11 and 2,367 enterprises in C14.19.

The study team's estimate is based on conversations with trade associations that suggested a small amount of use in the sector. The study team estimates that 10% of enterprises in C14.11 and C14.19 use diisocyanates and 5% of all other enterprises in C14 also use diisocyanates.

The split of enterprises by size is challenging to estimate. According to Eurostat, in 2018 the percentages of small, medium and large enterprises are: 97.5%, 2% and 0.5% respectively in C14 Apparel. The split results in there being around 7,350, 151 and 38 small, medium and large enterprises respectively. Most small enterprises in the sector are micro enterprises.

In the consultation survey, there were no responses from the apparel industry.

4.8.2.3 C15 Leather

In Eurostat, in 2018, there are 36,776 enterprises in sector C15 Leather. In total, the study team estimates that a total of 18,715 enterprises use diisocyanates and the exposure is restricted to C15.2.

The study team's estimate is based on conversations with trade associations that suggested the wide use of sealants in the sector. The study team estimates that 95% of enterprises in C15.2 use diisocyanates.

The split of enterprises by size is challenging to estimate. According to Eurostat, in 2018 the percentages of small, medium and large enterprises are: 95%, 5% and 0% (no large manufactures) respectively in C15.20 Manufacture of footwear. However, in 2018 the percentages of small, medium and large enterprises for C15 are 96.10%, 3.42% and 0.48%. Using the data for C15 the split results in 17,985, 640 and 90 small, medium and large enterprises respectively.

In the consultation survey there was a response from one leather enterprise, a medium sized enterprise employing 60 employees.

4.8.2.4 C16 Wood

In Eurostat, in 2018 there are 160,000 enterprises in sector C16 Wood. The study team estimates 3,085 enterprises use diisocyanates in C16.21, C16.22 and C16.29.

The study team's estimate is based on conversations with trade associations. The study team estimates that 75% of enterprises in C16.21 use diisocyanates and 3% and 5% of enterprises in C16.22 and C16.29 respectively use diisocyanates.

The split of enterprises by size is challenging to estimate, however, most enterprises are expected to operate in C16.21 and C16.29. The study team used Eurostat's 2018 enterprise figures as a basis to calculate the percentages of small, medium and large enterprises as being: 97.5%, 1.5% and 1% respectively in C16.2. The split results in there being around 3,008, 46 and 31 small, medium and large enterprises respectively. Around 92% of enterprises in the sector are micro enterprises.

In the consultation questionnaire, there were 12 responses, representing six enterprises (some enterprises completed the questionnaire for several sites and processes). Five of the enterprises were large enterprises and one of the responses was by a small enterprise. The large enterprises employed a different number of employees across their different manufacturing sites. Four respondents indicated employee numbers of ≥500 employees at their sites (with ≤10% of employees at the sites being exposed to diisocyanates).

The industry association Euro panels confirm use of diisocyanates was most likely to take place C16.21 and C16.29, however, they could not comment on the numbers of enterprises or the likely split between small medium and large enterprises.

4.8.2.5 C20 Chemicals

In Eurostat, in 2018, there are 27,986 enterprises in sector C20 Chemicals. The study estimates 1,472 enterprises use or produce diisocyanates. These includes enterprises in C20.14, C20.16, C20.17, C20.30, C20.52 and C20.60.

The study team's estimate is based on conversations with trade associations. The study team estimates that 20%, 10%, 20%, 20%, 20% and 25% of enterprises in C20.14, C20.16, C20.17, C20.30, C20.52 and C20.60 respectively use diisocyanates.

The split of enterprises by size is challenging to estimate. According to Eurostat, in 2018 the percentages of small, medium and large enterprises are: 88%, 9% and 3% respectively in C20 Chemicals. The split results in there being around 1,295, 132 and 44 small, medium and large enterprises respectively.

In the consultation survey, there were 105 responses, representing 73 enterprises (in some cases individual entities completed the survey and in other cases enterprises completed the questionnaire for several sites and processes). Out of the 105 responses, 23, 55 and 24 enterprises could be classified as a small, medium and large enterprises. Three responses did not provide an indication of their number of employees.

Industry associations confirmed that diisocyanates are used in C20.14, C20.30 and C20.52 and other sectors including those outside of C20 chemicals. CEPE estimate that their membership consists of approximately 250 enterprises and their members have around 100,000 customers.

4.8.2.6 C22.21 Rigid foam

In Eurostat, in 2017 there are 54,662 enterprises in sector C22 Plastics/Rubber. The study team estimates up to 143 enterprises use diisocyanates in C22.21 Rigid Foam.

The study team's estimate is based on conversations with trade associations and an independent report produced by TRISKELION (2021). EUROPUR and EURO-MOULDERS indicated that their memberships cover approximately 70% of all European foam manufactures and these participated in the TRISKELION study which provide a number of the total rigid foam manufactures. Therefore, the total number of rigid foam manufactures was increased by 30%.

Eurostat does not break down the divisions into a sufficient level of detail that will allow an in-depth analysis of the split of enterprises by size. The split of enterprises by size is challenging to estimate. The study team used Eurostat's 2018 enterprise figures as a basis to calculate the percentages of small, medium and large enterprises as being: 53%, 35% and 12% respectively in C22.21 rigid foam. The split results in there being around 76, 50 and 17 small, medium and large enterprises respectively.

In the consultation survey, there were 21 responses, representing 18 enterprises (in some cases individual entities completed the survey and in other cases enterprises completed the questionnaire for several sites and processes). Out of the 21 responses, ten, seven and four enterprises could be classified as a small, medium and large enterprises respectively.

Industry associations suggest the total number of rigid foam produces is around 143, this estimate is based on their knowledge of the sector.

4.8.2.7 C22.29 Flexible foam

In Eurostat, in 2017 there are 54,662 enterprises in sector C22 Plastics/Rubber. The study team estimates up to 234 enterprises use diisocyanates in C22.29 Flexible Foam.

The study team's estimate is based on conversations with trade associations and an independent report produced by TRISKELION (2021). EUROPUR and EURO-MOULDERS indicated that their memberships cover approximately 70% of all European foam manufactures and these participated in the TRISKELION study which provide a number of the total flexible foam manufactures. Therefore, the total number of flexible foam manufactures was increased by 30%.

Eurostat does not break down the divisions into a sufficient level of detail that will allow an in-depth analysis of the split of enterprises by size. The split of enterprises by size is challenging to estimate. The study team used Eurostat's 2018 enterprise figures as a basis to calculate the percentages of small, medium and large enterprises as being: 53%, 35% and 12% respectively in C22 flexible foam. The split results in there being around 124, 82 and 28 small, medium and large enterprises respectively.

In the consultation survey, there were 64 responses, representing 22 enterprises (in some cases individual entities completed the survey and in other cases enterprises completed the questionnaire for several sites and processes). Out of the 64 responses, 7, 42 and 15 enterprises could be classified as a small, medium and large enterprises respectively.

Industry associations suggest the total number of flexible foam produces is around 234, this estimate is based on their knowledge of the sector.

4.8.2.8 C22 Other

In Eurostat, in 2017 there are 54,662 enterprises in sector C22 Plastics/Rubber. The study team estimates 6,983 enterprises use diisocyanates in C22. Other, this includes use in C22.11, C22.19, C22.21, C22.22, C22.23 and C22.29 but excludes rigid and flexible foam.

The study team's estimate is based on conversations with trade associations. The study team estimates that 90%, 90%, 7.5%, 20%, 90% and 7.5% of enterprises in C20.14, C20.16, C20.17, C20.30, C20.52 and C20.60 respectively use diisocyanates, excluding those rigid and flexible foam manufactures described in sections 4.8.2.6 and 4.8.2.7.

Eurostat does not break down the divisions into a sufficient level of detail that will allow an in-depth analysis of the split of enterprises by size. The split of enterprises by size is challenging to estimate. According to Eurostat, in 2018 the percentages of small, medium and large enterprises are: 87%, 9% and 4% respectively in C22 Plastic. The split results in there being around 4,543, 465 and 95 small, medium and large enterprises respectively.

In the consultation survey, there were six responses, representing five enterprises and an association. Of the five enterprise responses, two could be classified as being small enterprise, one is a medium enterprise and two are large enterprises.

4.8.2.9 C26 Computers

In Eurostat, in 2018, there are 36,417 enterprises in sector C26 Computer. The study team estimates that a total of 9,104 enterprises use diisocyanates across the whole of C26 Computer.

The study team's estimate is based on conversations with trade associations. The study team estimates that 25% of enterprises in C26 use diisocyanates

The split of enterprises by size is challenging to estimate. The study team used Eurostat's 2018 enterprise figures as a basis to calculate the percentages of small, medium and large enterprises as being: 92%, 6% and 2% respectively. The split results in there being around 8,376, 546 and 182 small, medium and large enterprises respectively.

In the consultation survey, there was a single response from one large enterprise.

4.8.2.10 C27 Electrical equipment

In Eurostat, in 2018, there are 42,350 enterprises in sector C27 Electrical equipment. The study team estimates that a total of 9,441 enterprises use diisocyanates across the whole of C27 Electrical equipment.

The study team's estimate is based on conversations with trade associations. The study team estimates that 10% and 75% of enterprises in enterprises in C27.31 and C27.51 respectively use diisocyanates and 25% of all other enterprises in C27 also use diisocyanates.

The split of enterprises by size is challenging to estimate. According to Eurostat, in 2018 the percentages of small, medium and large enterprises are: 86%, 10% and 4% respectively in C27 Electrical equipment. The split results in there being around 8,120, 944 and 378 small, medium and large enterprises respectively.

In the consultation survey, there was a single response from one large enterprise.

4.8.2.11 C28 Machinery

In Eurostat, in 2018 there are 80,000 enterprises in sector C28 Machinery. The study team estimates that a total of 6,770 enterprises use diisocyanates across the whole of C28 Machinery.

The study team's estimate is based on conversations with trade associations. The study team estimates that 30% and 20% of enterprises in enterprises in C28.25 and C28.30 respectively use diisocyanates and 5% of all other enterprises in C28 also use diisocyanates.

The split of enterprises by size is challenging to estimate. According to Eurostat, in 2018 the percentages of small, medium and large enterprises are: 93%, 6% and 1% respectively in C28 Machinery. The split results in there being around 6,304, 406 and 61 small, medium and large enterprises respectively.

In the consultation survey, there were no responses from the machinery industry.

4.8.2.12 C29 Motor vehicles

In Eurostat, in 2018 there are 17,000 enterprises in sector C29 Motor vehicles. In total the study team estimates that a total of 14,292 enterprises use diisocyanates across the whole of C29 Motor vehicles.

The study team's estimate is based on conversations with trade associations. The study team estimates that 90%, 90% 20% and 90% of enterprises in enterprises in C29.10, C29.20, C29.31 and C29.32 respectively use diisocyanates.

The split of enterprises by size is challenging to estimate. According to Eurostat, in 2018 the percentages of small, medium and large enterprises are: 83%, 10% and 7% respectively in C29 Motor vehicles. The sector has the largest proportion of large and medium sized enterprises. The split results in there being around 11,863, 1,429 and 1,000 small, medium and large enterprises respectively.

In the consultation survey, there were responses from three medium and three large enterprises.

4.8.2.13 C30 Transport

In Eurostat, in 2018, there are 13,487 enterprises in sector C30 Transport. In total the study team estimates that a total of 12,137 enterprises use diisocyanates across the whole of C30 Transport.

The study team's estimate is based on conversations with trade associations. The study team estimates that 90% of enterprises in enterprises in C30.11, C30.12, C30.20, C30.30, C30.40, C30.91, C30.92 and C30.99 respectively use diisocyanates.

The split of enterprises by size is challenging to estimate. According to Eurostat, in 2018 the percentages of small, medium and large enterprises are: 92%, 6% and 2% respectively in C30 Transport. The split results in there being around 11,166, 728 and 243 small, medium and large enterprises respectively.

In the consultation survey, there was a response from one small enterprise.

4.8.2.14 C31 Furniture

In Eurostat, in 2018, there are 120,000 enterprises in sector C31 Furniture. In total the study team estimates that a total of 17,494 enterprises use diisocyanates across the whole of C31 Furniture.

The study team's estimate is based on conversations with trade associations. The study team estimates that 10%, 40%, 5% and 10% of enterprises in enterprises in C31.01, C31.02, C31.03 and C31.09 respectively use diisocyanates.

The split of enterprises by size is challenging to estimate. The study team used Eurostat's 2018 enterprise figures as a basis to calculate the percentages of small, medium and large enterprises as being: 97.87%, 1.8% and 0.33% respectively in C31 Furniture. The split results in there being around 17,120, 315 and 58 small, medium and large enterprises respectively.

In the consultation survey, there were one response from a medium sized enterprise.

4.8.2.15 C33 Machinery repair

In Eurostat, in 2018 there are 200,000 enterprises in sector C33 Machinery repair. In total the study team estimates that a total of 5,240 enterprises use diisocyanates across the whole of C33 Machinery repair.

The study team's estimate is based on conversations with trade associations. The study team estimates that 20%, 35% and 35% of enterprises in enterprises in C33.15, C33.16 and C33.17 respectively use diisocyanates.

The split of enterprises by size is challenging to estimate. According to Eurostat, in 2018 the percentages of small, medium and large enterprises are: 98.25%, 1.5% and 0.25% respectively in C33 Machinery repair. The split results in there being around 5,148, 79 and 13 small, medium and large enterprises respectively.

In the consultation survey, there were no responses from the machinery repair industry.

4.8.2.16 F41.2 Construction

In Eurostat, in 2018, there are 677,446 enterprises in sector F41.20 Construction. In total the study team estimates that a total of 609,701 enterprises use diisocyanates across the whole of F41.20 Construction, however, there is a crossover with F43 Specialised construction and F43.29 Other installation.

The study team's estimate is based on conversations with trade associations. The study team estimates that 90% of enterprises in enterprises in F41.20 respectively use diisocyanates.

The split of enterprises by size is challenging to estimate. According to Eurostat, in 2018 the percentages of small, medium and large enterprises are: 99%, 1% and <0.1%

respectively in F41.20 Construction. The split results in there being around 604,909, 4,433 and 360 small, medium and large enterprises respectively.

In the consultation survey, there were no responses from the construction industry.

The German insurance association, BG BAU, suggested there are between 100,000 and 200,000 construction enterprises (covering all construction activity) with diisocyanate exposure in Germany.

4.8.2.17 F42 Civil engineering

In Eurostat, in 2018, there are 85,210 enterprises in sector F42 Civil engineering. In total the study team estimates that a total of 4,301 enterprises use diisocyanates across the whole of F42 Civil engineering.

The study team's estimate is based on conversations with trade associations. The study team estimates that 90% of enterprises in enterprises in F41.20 respectively use diisocyanates.

The split of enterprises by size is challenging to estimate. The study team used Eurostat's 2018 enterprise figures as a basis to calculate the percentages of small, medium and large enterprises as being: 95%, 4% and 1% respectively in F42 Civil engineering. The split results in there being around 4,086, 172 and 43 small, medium and large enterprises respectively.

In the consultation survey, there was a response from one small enterprise.

4.8.2.18 F43 Specialised construction

In Eurostat, in 2018, there are 2,191,277 enterprises in sector F43 Specialised construction. In total the study team estimates that a total of 1,284,501 enterprises use diisocyanates across the whole of F43 Specialised construction (not including F43.29 Other installation).

The study team's estimate is based on conversations with trade associations. The study team estimates that 50% of enterprises in enterprises in F43.21, F43.22, F43.29, F43.31, F43.32, F43.33, F43.34, F43.39, F43.91 and F43.99 respectively use diisocyanates.

The split of enterprises by size is challenging to estimate. According to Eurostat, in 2018 the percentages of small, medium and large enterprises are: 99.5%, 0.4% and <0.1% respectively in F43 Specialised construction. The split results in there being around 1,284,501, 5,138 and 514 small, medium and large enterprises respectively.

In the consultation survey, there were responses from one small, one medium and one large enterprise.

4.8.2.19 F43.29 Other installation

In Eurostat, in 2018, there are 99,570 enterprises in sector F43.29 Other installation. In total the study team estimates that a total of 5,000 enterprises use diisocyanates as part of foaming activity in F43.29 Other installation.

The study team's estimate is based on conversations with trade associations.

The split of enterprises by size is challenging to estimate. The study team used Eurostat's 2018 enterprise figures as a basis to calculate the percentages of small, medium and large enterprises as being: 99.4%, 0.55% and <0.0% respectively in F43.29 Other installation. The split results in there being around 4,970, 28 and 3 small, medium and large enterprises respectively.

In the consultation survey, there were no responses from other installation enterprises.

4.8.2.20 G45 Vehicle repair

In Eurostat, in 2018, there are 818,660 enterprises in sector G45 Wholesale and retail trade and repair of motor vehicles and motorcycles. In total the study team estimates that a total of 430,437 enterprises use diisocyanates.

The study team's estimate is based on conversations with trade associations. The study team estimates that 95% of enterprises in enterprises in G45.20 and G45.40 respectively use diisocyanates.

The split of enterprises by size is challenging to estimate. According to Eurostat, in 2018 the percentages of small, medium and large enterprises are: 99.8%, 0.2% and <0.0% respectively in G45 Wholesale and retail trade and repair of motor vehicles and motorcycles. The split results in there being around 429,577, 732 and 129 small, medium and large enterprises respectively.

In the consultation survey, there were no responses from other vehicle repair enterprises.

4.8.2.21 S95 Repairs

In Eurostat, in 2018, there are 17,048 enterprises in S95.23 Repair of footwear and leather goods and S95.24 Repair of furniture and home furnishings. In total the study team estimates that a total of 15,954 enterprises use diisocyanates.

The study team's estimate is based on conversations with trade associations. The study team estimates that 95% of enterprises in enterprises in S95.23 and S95.24 respectively use diisocyanates. However, as there are twice as many enterprises as employees the study team have set all enterprises to equal employees, reducing enterprises rather than increased employees is more conservative as it will reduce the cost benefit ratio. This results in 15,954 employees and enterprises.

The split of enterprises by size is challenging to estimate. According to Eurostat, in 2018 the percentages of small, medium and large enterprises are: 99.9%, <0.1% and <0.0% respectively in S95.23 Repair of footwear and leather goods and S95.24 Repair of furniture and home furnishings. The split results in there being around 15,942, 10 and 2 small, medium and large enterprises respectively.

In the consultation survey, there were no responses from repair enterprises.

4.8.3 Summary of enterprises with exposed workers

The study team's estimate of enterprises with exposed workers by sector is summarised in Table 4-55, a more detailed breakdown appears in Annex 5.

Comparing Table 4-29 showing the number of exposed workers with the Table 4-55 which shows the number of enterprises with exposed workers, it is clear that in some sectors such as construction and vehicle repair the average number of workers per enterprise is low (less than 2). Some of these micro companies will be one person enterprises, but some will be inactive. Therefore, as the costs are related to the number of enterprises it is possible that the costs are overestimated, however, the study team has no data to estimate the number of inactive micro companies.

Table 4-55 Estimated EU enterprises with workers exposed to diisocyanates using Eurostat, survey and industry data

NACE Sector	Number of enterprises in EU (Eurostat)	% of enterprises with exposed workers	Estimated enterprises with exposed workers in EU
C13 Textiles	58,878	5-10	2,982
C14 Apparel	125,000	5-10	7,538
C15.20 Leather	36,776	95	18,715
C16 Wood	160,000	3-75	3,085
C20 Chemicals	27,986	10-25	1,472
C22 Plastics/Rubber	54,662*	7.5-90	7,360
C26 Computers	36,417	25	9,104
C27 Electrical equipment	42,350	10-75	9,441
C28 Machinery	80,000	5-30	6,770
C29 Motor vehicles	17,000	20-90	14,292
C30 Transport	13,487	90	12,137
C31 Furniture	120,000	5-40	17,494
C33 Machinery repair	200,000	20-35	5,240
F41.2 Construction	677,446	90	609,701
F42 Civil engineering	85,210	5-90	4,301
F43 Specialised construction	2,191,277	50-95	1,284,501
F43.29 Other installation	99,570	-	5,000
G45 Vehicle repair	818,660	95	430,437
S95 Repairs	31,981	95	15,954
TOTAL	**4,822,038**	**-**	**2,466,524**

*Source: Eurostat (2018), consultation (*Eurostat 2017)*

4.8.4 Enterprises with exposed workers by sector by size of enterprise

Table 4-56 shows the percentage of enterprises in key sectors that are small, medium or large sized enterprises and Table 4-57 show the total number of enterprises in key sectors that are small, medium or large sized enterprises. It is based upon the proportions for small, medium and large from Eurostat data for enterprises at the NACE code.

Table 4-56 Distribution of EU enterprises with exposed workers by size of enterprise by sector (percentages)

NACE - Sector	Number of enterprises			
	Small	Medium	Large	Total
C13 Textiles	96.56%	2.96%	0.48%	100%
C14 Apparel	97.50%	2.00%	0.50%	100%
C15 Leather	96.10%	3.42%	0.48%	100%
C16 Wood	97.50%	1.50%	1.00%	100%
C20 Chemicals	88.00%	9.00%	3.00%	100%
C22.21 Rigid foam	53.00%	35.00%	12.00%	100%
C22.29 Flexible foam	87.00%	9.00%	4.00%	100%
C22 Other	53.00%	35.00%	12.00%	100%
C26 Computers	92.00%	6.00%	2.00%	100%
C27 Electrical equipment	86.00%	10.00%	4.00%	100%
C28 Machinery	93.00%	6.00%	1.00%	100%
C29 Motor vehicles	83.00%	10.00%	7.00%	100%
C30 Transport	92.00%	6.00%	2.00%	100%
C31 Furniture	97.87%	1.80%	0.33%	100%
C33 Machinery repair	98.25%	1.50%	0.25%	100%
F41.2 Construction	99.21%	0.73%	0.06%	100%
F42 Civil engineering	95.00%	4.00%	1.00%	100%
F43 Specialised construction	99.56%	0.40%	0.04%	100%
F43.29 Other installation	99.39%	0.55%	0.06%	100%
G45.2 Vehicle repair	99.80%	0.17%	0.03%	100%
S95 Repairs	99.93%	0.06%	0.01%	100%

Source: Eurostat (2018), consultation

Table 4-57 Distribution of EU enterprises with exposed workers by size of enterprise by sector (numbers)

NACE - Sector	Number of enterprises			
	Small	Medium	Large	Total
C13 Textiles	2,880	88	14	2,982
C14 Apparel	7,350	151	38	7,538
C15 Leather	17,985	640	90	18,715
C16 Wood	3,008	46	31	3,085
C20 Chemicals	1,295	132	44	1,472
C22.21 Rigid foam	76	50	17	143
C22.29 Flexible foam	124	82	28	234
C22 Other	6,075	628	279	6,983
C26 Computers	8,376	546	182	9,104
C27 Electrical equipment	8,120	944	378	9,441
C28 Machinery	6,296	406	68	6,770
C29 Motor vehicles	11,863	1,429	1,000	14,292
C30 Transport	11,166	728	243	12,137
C31 Furniture	17,120	315	58	17,494
C33 Machinery repair	5,148	79	13	5,240
F41.2 Construction	604,909	4,433	360	609,701
F42 Civil engineering	4,086	172	43	4,301
F43 Specialised construction	1,278,849	5,138	514	1,284,501
F43.29 Other installation	4,970	28	3	5,000
G45.2 Vehicle repair	429,577	732	129	430,437
S95 Repairs	15,942	10	2	15,954
Total	2,465,525	16,778	3,533	2,465,525

Source: Eurostat (2018), consultation

4.8.5 Trends

The market demand for diisocyanates (along with other substances) is expected to have been impacted by the Covid-19 global pandemic, however, demand for diisocyanates is predicted to increase. As shown in Figure 4-3, the global demand for TDI in 2017 was estimated to be 2.28 million tons, and it is forecasted to increase to 2.77 million tons by 2022. In the EU, demand/consumption of MDI and pMDI has increased from 267,000 tonnes in 1980 to an estimate 1,341,700 tonnes in 2016 (Danish Environmental Protection Agency, 2014), as shown in Figure 4-4. An increase in demand for other diisocyanates is also anticipated. Globally, the compound annual growth rate of TDI and MDI is estimated to be greater than 5% (Market Data Forecast, 2020). The global consumption of TDI and MDI are shown in Figure 4-5.

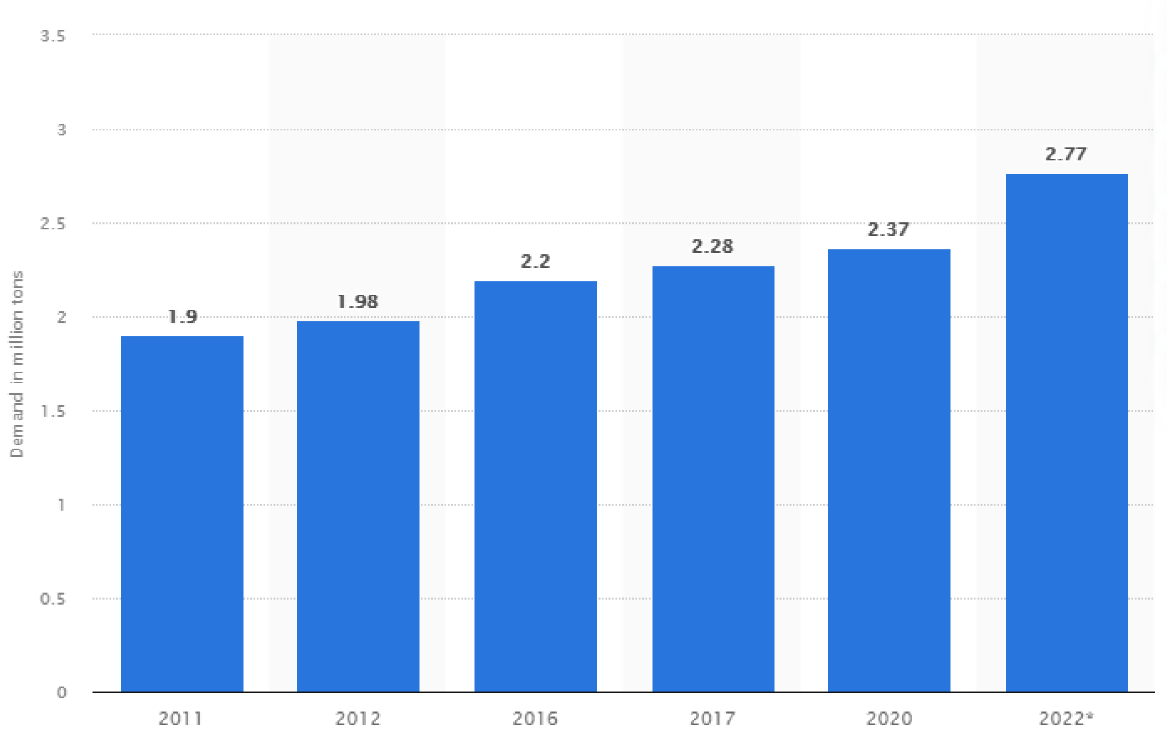


Figure 4-3 TDI demand worldwide from 2011 to 2020 with a forecast for 2022
Source: Statista (2021)

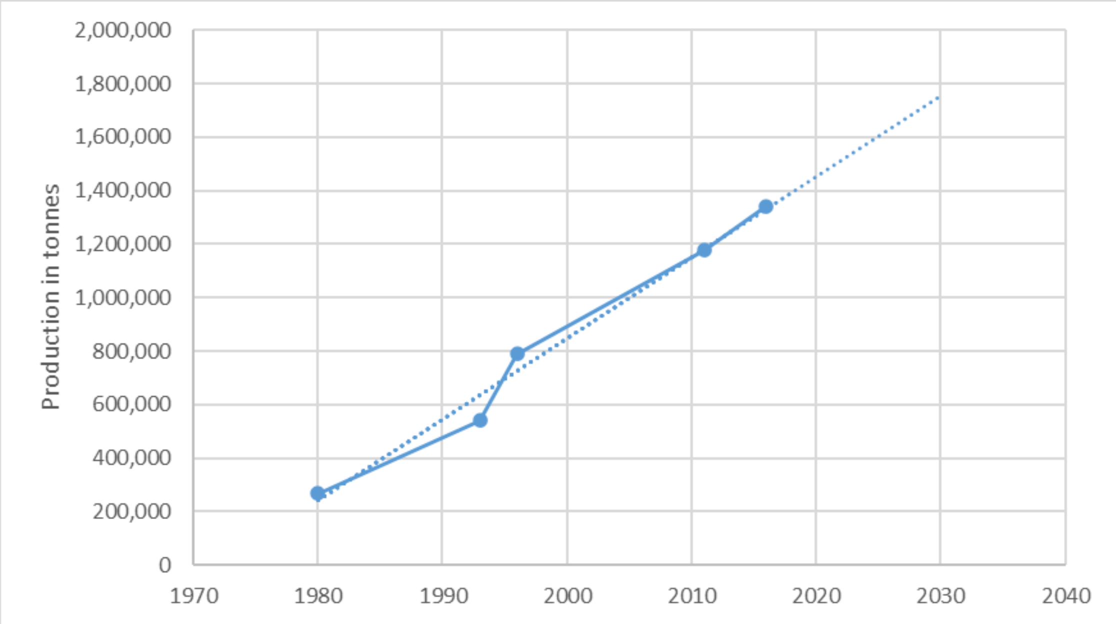


Figure 4-4 EU production/consumption demand of MDI and pMDI from 1980 to 2016 and a linear trend projecting demand to 2030
Source: Study team calculation based on Danish Environmental Protection Agency (2014)

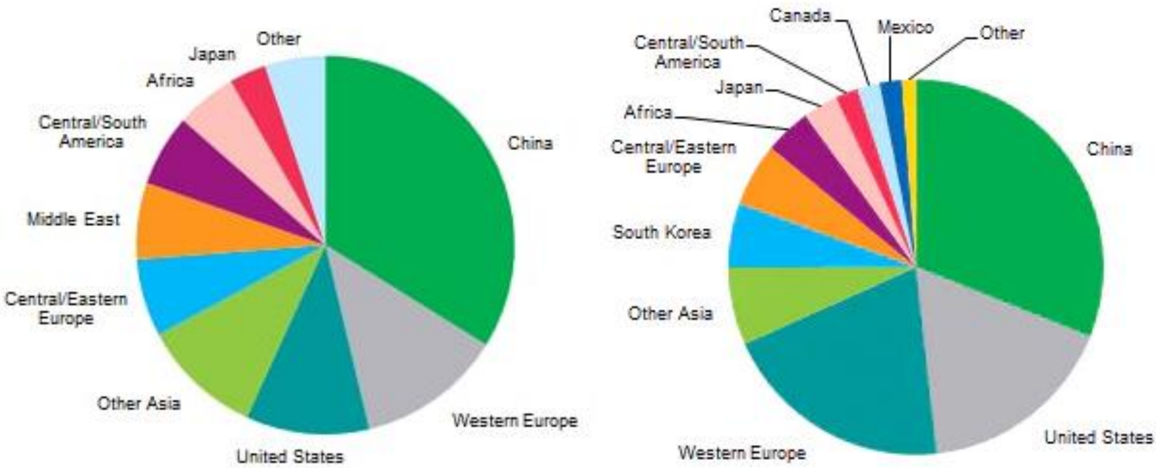


Figure 4-5 World consumption of TDI (2017) (left), world consumption of MDI (2017) (right)
Source: IHS Markit (2018)

A contributing factor in the growth in demand for diisocyanates in Europe and globally is their wide use across a number of sectors. Another factor is that several of the end products produced using or containing diisocyanates are purchased and used by consumers and both the European population continues to grow (European Commission, 2021e) and gross household adjusted disposable income per inhabitant has increased in both nominal and real terms in both the EU and the euro area since 2013 (European Commission, 2021d).

Information on market trends is provided below for the key sectors.

4.8.5.1 C13 Textiles, C14 Apparel, C15 Leather

Although a significant amount of clothing and footwear are imported into the EU, the sectors have radically changed in recent years to maintain competitiveness by moving towards high value-added products and more specialised products.

Demand for goods in Europe is strong and the market is continuously growing, therefore, diisocyanate use may continue to grow in these sectors. The growth in diisocyanate use and the growth of the market sectors might be balanced by efforts to improve the circular economy within the sectors.

4.8.5.2 C16 Wood

The wood sector is an important European sector and will help the EU towards meeting the objectives of the European Green Deal. About 70% of the wood in the EU is used in construction and furnishings. The properties of wood make it suitable for a range of applications in the construction industry, it has an energy saving potential through its natural thermal insulation properties as well as the sequestration and storage of carbon. These properties are particularly favourable compared with the energy and emissions required to produce cement and steel.

The demand for diisocyanates in the wood sector may increase significantly in the coming years due to regulatory pressures on existing substances used as wood adhesives, such as formaldehyde. There may also not be enough pMDI available on the market to replace the amount of formaldehyde used.

4.8.5.3 C20 Chemicals

The chemicals sector is one of the largest manufacturing sectors in Europe. The EU27 is the second largest region in terms of chemical sales in the world, however, the market share of the EU27 has fallen (Cefic, 2021). There are several diisocyanate manufactures and product formulators in Europe. The proximity of manufactures and formulators to customers is beneficial in offering security of supply chains. This is particularly important to customers requiring regular deliveries of diisocyanates, for example, foam producers and formulators.

Durable and high-performance polyurethane coating and resin solutions are already used to protect motor vehicles and other forms of transport, but they may also be increasingly used to protect wind farms and cable systems.

As several markets are expanding the chemicals market is also expected to expand in to meet the demand.

4.8.5.4 C22.21 Rigid foam, C22.29 Flexible foam C22 Other

The European foam market helps to meet the demands of end users in several sectors including construction, bedding and furniture, motor vehicles and public transport. The Covid-19 global pandemic will have temporarily reduced the demand in these sectors but the demand is likely to return and grow in the coming years. Increase in the demand for foams in the construction industry will also be driven by European Green Deal and light weight foams will also be used in modern electric vehicles.

The close proximity of foam manufactures is important to the supply chains. Some foam customers are based on the just-in-time production principle and slabstock foams are big and bulky which makes them unsuitable for transporting long distances.

Similarities exist in the rest of the plastic and rubber sector. The demand for plastic and rubber is also expected to be maintained while the EU's adoption of a European strategy for plastics in January 2018 forms part of the EU's circular economy action plan and builds on existing EU measures to reduce plastic waste. The plastics strategy is a key element of Europe's transition towards a carbon neutral and circular economy.

4.8.5.5 C26 Computers, C27 Electrical equipment, C28 Machinery

The overall market demand for electronics and electrical equipment continues to grow in Europe and globally. Therefore, as diisocyanates are used in the manufacture of these sectors, this market trend will cause demand for diisocyanates to increase. In terms of electrical equipment such as refrigeration units, the market is moving towards demanding more energy efficient products. The diisocyanate used in these products help maintain strong seals and thus provide high levels of energy efficiency. This market trend would thus again cause demand for diisocyanates to increase to meet production demand of appropriate consumer and industrial products.

Production of renewable energy is becoming the growing market trend in the energy sector; this push would include the creation and expansion of off-shore wind farm sites that require additional underwater electrical cables. Polyurethanes are one of the substances used to manufacture underwater cables. The push for green energy would therefore increase demand.

New EU rules which demand manufacturers and importers make their goods repairable for 10 years after being placed on the market have a slightly blurred potential to impact demand for these chemicals. There is the reasonable potential that new designs and cost saving approaches may be taken by manufactures following the introduction of these rules meaning less items such as adhesives or sealants are used in goods; also extending the life span of electrical products means less over time will be demanded, causing a fall in demand for diisocyanates. Counteractively however, it could be argued that the need for manufactures to now supply a stock of replacement parts may result in more products containing diisocyanates needing to be manufactured

4.8.5.6 C29 Motor vehicles, C30 Transport

The EU is a world leader in the production of motor vehicles and other transport including aircraft, trains and marine vessels. Diisocyanates and parts made using diisocyanates are widely used in the sector presently.

Demand for lower emissions and more sustainable transport is leading to lighter transportation and polyurethanes are being used to help achieve this. The transition to more sustainable transport will likely see demands for diisocyanates maintained or increase as new generations of vehicles are produced including hybrid and electrical vehicles across all sectors. In some cases where welding once took place in the manufacturing of motor vehicles this activity has been replaced with using adhesives as they offer additional advantages.

4.8.5.7 C31 Furniture

There are several mattress and furniture manufactures located in the EU. Foams, coatings and adhesives are used in other types of furniture by manufactures in the EU. Furniture market demand is typically driven by consumer demand and the housing renovation and increasing demand for residential dwelling has helped to maintain the market demand for furniture. As part of the Green Deal, furniture manufacture is becoming more circular, promoting remanufacturing and repair over new production.

4.8.5.8 F41.2 Construction, F42 Civil engineering, F43 Specialised construction, F43.29 Other installation

The construction sectors will all play an important role towards the EU meeting the objectives of the European Green Deal. More energy efficient residential and non-residential buildings will be built and existing buildings may be renovated. Several CASE related products or products manufactured with diisocyanates (e.g. insulated sandwich panels) are used as part of the construction process. Insulating foams can quickly and conveniently be sprayed into existing buildings. Light density foams can be produced with enough strength to be used in the civil engineering sector. Wood and adhesives can also replace some uses of steel and cement.

The market demand for diisocyanates in the construction sector is expected to increase.

4.8.5.9 C33 Machinery repair, G45 Vehicle repair, S95 Repairs

The market demand of diisocyanates is expected to follow market trends. Polyurethane coatings offer a high level of protection, however, if assisted or fully automated driving becomes more common within Europe the demand for repairs may decrease.

Again, the right to repair may also see some products re-designed and less diisocyanates being used.

4.9 Alternatives

Due to the wide-ranging uses of isocyanates in the production of polyurethane products, adhesives, sealants and coatings, it is a significant challenge to find alternatives which are as versatile and pose lower risks to human health. This view is echoed in the background document to the REACH Restriction on diisocyanates:

Based on the analysis of alternatives for diisocyanates and the feedback from stakeholders, a major shift towards the use of isocyanate free products is not foreseen anytime soon. Therefore, such effects have not been taken into account (ECHA, 2018d).

Some possible alternatives are outlined below for the major uses of diisocyanates, together with their associated issues.

Overall, non-chemical cost, adhesive and sealant alternatives are scarce, the possibility of solutions depends on which type of material or combination is used in the application and whether the product is to be used for renovation or new installations (The Danish Environmental Protection Agency, 2015).

4.9.1 Coatings

Epoxy resins are considered an alternative to diisocyanates for coating purposes, especially in electronics and metal coating. These resins have useful anticorrosive properties and a greater temperature resistance than diisocyanate based polyurethane coatings and can be used as a replacement for MDI/TDI based products. Epoxies are also widely available on the market. Despite these factors, epoxy resins are not seen as a suitable alternative as some ingredients required to manufacture them pose a risk of skin sensitisation that is more widespread than that of respiratory sensitisation from diisocyanates. This concern was raised by BG BAU who suggested that in Germany the cases of occupational disease from diisocyanates was low (0-6 per year) compared with epoxy resins and case of skin sensitisation would increase with the substitution of diisocyanates. Alongside this, epoxies also degrade under ultraviolet light more readily than diisocyanates and often require a topcoat of diisocyanate based materials.

In the vehicle refinish sector, there are some primers which do not contain diisocyanates, these are claimed to be an alternative where there is a 'lower performance demand'. However, almost all topcoats contain diisocyanates.

Without protective coatings, surfaces would be less resistance to abrasion and weathering which would significantly shorten the time between painting cycles and in the transport sector it might risk the durability of transport like aircraft.

Many of the alternatives mentioned below also have potential as alternative coatings.

4.9.2 Adhesives

Alternatives for adhesives are largely the same as those identified for alternative coatings with the potential for epoxies and hybrid non-isocyanate polyurethane products to replace existing diisocyanate based polyurethane adhesives. Non-isocyanate polyurethane (NIPU) products are also a potential substitute. The production route associated with NIPU products eliminates exposure to isocyanates but entails exposure risk from cyclic polycarbonates and primary amines. These substances have their own human health risks and so NIPU alternatives may not provide a safer alternative to isocyanate based polyurethane adhesives. The use of hybrid non-isocyanate polyurethane products may be considered a way of avoiding the risk posed by potentially harmful monomers, however these products also require the use of hazardous substances in their manufacture. NIPU substances also have slower reaction times, lower elasticity and greater susceptibility to water than isocyanate-based products.

The study by Solt *et al.* (2019) investigated alternatives to formaldehyde in the particle board industry this included alternative aldehydes, sugar based, epichlorohydrin, reactive polymers derived from the paper industry, epoxy resins, polyacids and diisocyanates. With the exception of pMDI-based systems, most of the alternative adhesives were identified as being considerably less reactive and that this would result in dramatically higher production costs.

Formaldehyde users in several sectors are waiting for details of a new REACH Restriction (ECHA, 2021c), which if it requires a new low limit, may cause them to switch to MDI.

4.9.3 Sealants

The epoxy resins described above could be used as a replacement for diisocyanates in sealants, although there are some disadvantages. Another potential substitute is hybrid non isocyanate polyurethanes (HNIPU) including modified silanes. Modified silanes are well established for use in the construction industry and would be readily available for use, they may also be suitable for some wood adhesive applications. These compounds are currently relatively unexplored in use as replacement sealants however from a toxicological point of view their component substances pose less severe toxicity than diisocyanates. However, primary amines used in production do pose significant alternative risks from their classification as corrosive and respiratory sensitisers. There are also concerns regarding the release of methanol from modified silanes in final articles which may pose a human health risk in confined spaces. Furthermore, it has previously been suggested that silanes might be 3-4 times more expensive than diisocyanate based products (Christensen *et al.*, 2014).

4.9.4 Elastomers

The alternatives available for elastomers are largely the same as those stated above with modified silanes and NIPU products showing potential for use as alternatives. Despite these products being technically feasible for replacement of elastomers, they are not recommended due to lower elasticity, which is a key requirement in elastomer products.

4.9.5 Foam

Both TDI and MDI are used in the manufacture of foams. TDI is typically used to manufacture flexible foams for use in transportation, furniture, bedding, carpet underlay, packaging and MDI is typically used to manufacture rigid foams for us in sandwich insulation panels. Alternatives to flexible polyurethane foams produced with TDI are natural latex foam, polyester fill, cotton, down, wool and other similar materials. Although these alternatives are able to replace the use of flexible polyurethane foams is some sectors, it is unlikely these will be suitable for all sectors. Market availability of the alternatives may also be a challenge and the costs might be more expensive than diisocyanate based products. Some of the alternatives have other disadvantages depending on the application and some individuals are allergic to some of the alternatives.

In the construction sector, it is important that efficient insultation can be added to buildings quickly. This is a key factor in achieving the objectives of the EU Green Deal. MDI spray foam insulation is efficient and can be applied quickly to both new and older buildings whereas alternatives typically take longer to install. Spray foam achieves better air tightness in buildings and is easier to apply in hard-to-treat locations such as complex corners and angles. Wood panel insultation can be difficult to install and it is difficult to prevent gaps. Mineral wool has fibres that are hazardous for workers' health. Polystyrene is good for some types of external insulation, however, because it has a lower performance, a much bigger volume is required. Wood fibre insultation is a natural source but it also has a lower insulation performance than spray foams.

4.10 Voluntary industry initiatives

ISOPA members developed a program called Walk the Talk (ISOPA, no date b) nearly 20 years ago aimed at improving safety, health and environmental standards across the European polyurethanes industry and internationally. It is available in almost 30 languages and has been promoted by experts from ISOPA membership companies through face-to-face visits to their customers.

ISOPA also runs a driver training programme (ISOPA, no date a) in close cooperation with the member companies and a logistics provider. This specifically trains drivers who transport diisocyanates.

ALIPA promotes a similar programme "We care that you care" (ALIPA, no date). ALIPA member companies developed the programme of information packages with recommendations and measures regarding safe handling of aliphatic isocyanates. The presentations available focus on the safe use of aliphatic diisocyanate monomers and aliphatic polyisocyanates in spray applications.

EUROPUR, (European Association of Flexible Polyurethane Foam Blocks Manufacturers), and EURO-MOULDERS, (European Association of Manufacturers of Moulded Polyurethane Parts for the Automotive Industry) promotes another programme with their "Guidelines for the Establishment of a Safety Management System in a Flexible Polyurethane Foam Plant." (Europur and Euromoulders, no date). This guide was drafted by the joint Plant and Workers Issues Working Group of both associations, to improve levels of safety and environmental care for the handling of diisocyanates and other chemicals in flexible polyurethane foam production (both slabstock and moulded).

Consultation feedback indicates that approximately half of all respondents are aware of such voluntary initiatives. Although, of the 99 questionnaire responses that stated "yes", 70 were from eight organisations and of these, 70% operate in C20 Chemicals, 23% operate in C22.21 Rigid foam, and 7% in C22.29 Flexible foam. Responses from C20 Chemicals primarily concern product steward programmes, including “Walk the Talk”, “We care that you care”, and “Truck driver training”.

As Table 4-58 suggests, respondents were primarily aware of and participating in ISOPA/ALIPA and EUROPUR initiatives. No other initiatives were cited. During the site visits, both the Truck Driver training and Tanker Assessment training were mentioned.

Table 4-58 Are you aware of any voluntary industry initiatives to reduce exposure to diisocyanates (Product Stewardships or Social Partner Agreements) (n= 210)

Response	Frequency
Yes	47% (99)
No	53% (111)

Source: Consultation survey

Table 4-59 Voluntary initiatives consultation respondents knew about (n= 210)

Voluntary initiatives	Frequency
ISOPA Walk the Talk (A)	31% (65)
ISOPA Truck driver training (B)	13% (27)
ALIPA We care that you care (C)	12% (26)
ISOPA/ALIPA Tank farm assessments (D)	11% (24)
ISOPA Logistic Guidelines (E)	5% (11)
ISOPA Product Stewardships programme (not identified) (F)	5% (11)
EUROPUR Safety Guidelines	2% (4)
ISOPA One step ahead	4% (9)
ISOPA/ALIPA inspections (not identified)	1% (2)
Other unclassified responses	10% (21)

Source: Consultation survey

*Notes: Total does not equal 100% due to rounding. Respondents were able to provide multiple responses to the questionnaire (i.e. one for each facility in their organisation). These percentages include multiple responses from the same respondent. *A: 61 responses were provided by different plants from nine (9) organisations; *B: 17 responses from one organisation; *C: 24 from two organisations; *D: all responses from two organisations; *E: all responses from three organisations; *F: all responses from two organisations*

4.11 Best practice

There are several areas of best practice:

- Continuous monitoring
- Screening
- Medical surveillance
- Removal of workers with sensitisation
- Ionisation
- Risk management measures and protocols

4.11.1 Continuous monitoring

The use of continuous monitoring equipment is a widespread best practice, particularly for foam manufacturers using TDI: one of the diisocyanates sites visited as part of the study had continuous monitoring. Usually at the first level of detection, the systems give a warning; at the next threshold, they sound an evacuation alarm. Each facility should develop and implement an alarm procedure that requires the evacuation of the immediate area and a plan for subsequent investigation during a monitor alarm situation must be in place.

This provides better protection for workers because an 8-hour TWA can easily include short significant peaks and it is the peaks that cause the highest likelihood of sensitisation or irritation.

Currently, the limit of detection of this equipment is normally 1 ppb for diisocyanates and the resolution is 1 ppb (i.e. if the devices show 1 ppb, this means 1 ppb ±50%).

However, if the short-term limit value approaches these limits, it becomes difficult to continue using this equipment as there tends to be frequent false alarms. Companies may choose to stop continuous monitoring and rely on annual measurements of 15 min peaks and 8-hour TWA taken as part of their compliance with STELs/OELs. There are concerns that an OEL below 10 µg NCO/m^3 could lead some companies to remove continuous monitoring, which is expensive, if the warnings cannot be set much below the OEL.

The company at one site visit used continuous monitoring extensively, with 12 monitors around the production processes most likely to cause exposure to diisocyanates. The monitoring devices cost approximately €5,000. This company provided their view of the most likely actions and equipment requirements at the various OEL options, and these are shown in Table 4-60. The company thought that it could continue continuous monitoring using the same equipment at an OEL of 8.5 µg NCO/m^3 and a STEL of 34 µg NCO/m^3. At and below an OEL of 6 µg NCO/m^3, new equipment would probably be required, and definitely below an OEL of 3 µg NCO/m^3. However, this company and the study team are not aware of any continuous devices that would operate at these lower levels.

Table 4-60 Impact on continuous monitoring of various OEL options

	Current monitor limits	Better equipment needed
Current limits (5 PPB / 20PPB 17 µg NCO/m³ / 68 µg NCO/m³ HSE limit 20 / 70 µg NCO/m³	Warn at 5 Evacuate at 20	No
Estimated best limit with existing equipment (2.5 PPB / 10 PPB) 8.5 µg NCO/m³ / 34 µg NCO/m³	Warn at 2 Evacuate 5	No
6 µg NCO/m³ = 1.75 ppb	Warn at 2 Evacuate 5	Possibly
3 µg NCO/m³ = 0.88 ppb	Warn at 2 Evacuate 5	Yes
1 µg NCO/m³ = 0.29 ppb	Warn at 2 Evacuate 5	Yes

Source: Survey consultation – site visit

4.11.2 Screening

When recruiting staff or if an external contractor is required to visit a site and they are at risk of being exposed to diisocyanates, individuals may be screened.

The screening step may involve new starters taking a medical and contractors/site visitors providing confirmation that they do not suffer from a range of chronic lung diseases. Regular contractors could also be subject to the same type of medical and medical surveillance activities as employees.

This screening step helps to protect susceptible individuals from developing occupational asthma. In the foam sectors, a pre-placement medical examination must be completed, and the results documented to establish whether the person is fit to do a certain job.

EUROPUR and EURO-MOULDERS indicate that the minimum requirements for all jobs on site are:

- Medical history and questionnaire
- Physical examination
- Contra indications for the job function

Additionally, the minimum requirements for jobs in a production plant are:

- Medical history and questionnaire
- Physical examination with an emphasis on the back, arms and shoulders
- Audiogram
- Respiratory examination, including a Pulmonary Function Test (PFT)
- Contra indications for the job function

- Additional examinations may be required for forklift truck drivers, emergency response team members, maintenance personnel, machine operators with safety function or performing critical tasks or any other function as defined by the risk assessment.

4.11.3 Medical surveillance

A further area of best practice is medical surveillance (otherwise known as health surveillance) because if workers are identified as being sensitised or irritated as early as possible, they can be removed from tasks with potential exposure to diisocyanates and this has been shown to reduce the likelihood of occupational asthma.

There are two broad methods in which medical surveillance can be administered:

- Using questionnaire that asks if a worker has symptoms and taking action if they do
- Performing regular medical checks such as lung capacity measurement, urine test and dermal observations.

The first questionnaire-based process usually broadly follows these steps:

- Use of a questionnaire that asks if a worker has symptoms and whether those go away during weekends/holidays; in practice in the UK (HSE, 2011).
    - Negative result --> no occupational asthma related to diisocyanates
    - Positive result --> go to next step
- Specific IgE test for human serum albumin (HSA) conjugated with the diisocyanates.
    - Negative result --> no occupational asthma related to the diisocyanates
    - Positive result --> go to next step
- Perform serial peak flow (PEF) measurement or specific inhalation challenge (SIC). SIC is the golden standard, but not available in all countries.
    - Negative --> sensitisation without occupational asthma related to diisocyanates
    - Positive --> sensitisation with occupational asthma related to diisocyanates

An alternative questionnaire based approach for evaluating diisocyanate exposed workers for occupational asthma is described by Bernstein (2017) who suggests occupational asthma due to respiratory sensitisation to diisocyanates is one of several potential causes of work-related lower respiratory symptoms. The following steps are described:

- Obtain a medical and occupational history of work-related asthma
- Spirometry testing-pre/post bronchodilator to confirm the presence of asthma
- Workplace monitoring by serial monitoring of lung function (i.e. FEV1 and/or peak expiratory flow rate [PEFR]), four weeks consisting of two weeks at work and two weeks away
- Methacholine inhalation test testing after two weeks at work

There are five possible outcomes of the monitoring and methacholine testing, and interventions are suggested.

The details about the medical checks process are given in section 6.9.2, where an approximate cost of implementing medical surveillance over 40 years is estimated. Further work on medical surveillance is beyond the scope of this study.

Several enterprises completing the consultation questionnaire or participating in site visits indicated that they conducted medical surveillance, and this gave them confidence that they had no cases of occupational asthma. They usually conducted annual medical examinations including serial peak flow measurement.

In addition to limit values, the Chemicals Agents Directive (CAD) contains provisions for appropriate medical surveillance of workers at a national level. Medical surveillance can also be mandated at an EU level under the CAD: it is already mandated for lead. According to several stakeholders, industry had expected medical surveillance for workers to be introduced as part of the REACH Restriction, see 2.1.3.

4.11.4 Removal of workers with sensitisation

Where medical surveillance or another means has detected that a worker is developing sensitisation, best practise is to remove the worker from the source of exposure. Trade associations highlighted the fact that redeployed workers with symptoms have been able to recover. In some cases, this practice prevents workers who show initial symptoms from deteriorating and developing lasting damage and irreversible forms of asthma.

There are two scenarios where workers can be removed from exposure:

- Their employers recognise they have some symptoms and move them to a role without exposure.
- The worker has to leave their job because they cannot continue in their role.

ECHA's calculations for the costs and benefits of the REACH Restriction take into consideration income loss (ECHA, 2018d). However, the RPA/COWI benefits model has never included these costs as they are not a cost to society (unlike healthcare, caring costs, unemployment, paid time off sick and employers' costs).

4.11.5 Ionisation

Another relatively recent development used to reduce the level of diisocyanates in the breathing zone is ionisation of the air within a spray booth. Used in the marine industry, both to ensure low levels of diisocyanates and to reduce dust particles which can be caught in the paint and reduce the quality of the paint finish, this risk management measure has the advantage of improving quality of the product as well as improving safety.

4.11.6 Risk management measures - safe urethane guidelines

The Finnish National Institute of Occupational Health (no date) provide information to help minimise health hazards and occupational exposure to diisocyanates. These include the following:

- Good working practises:
  - Spraying work, such as coating, varnishing, open foaming, is carried out in the intended space or deliberately outside normal working hours to avoid unnecessary exposure to other workers.
  - Automatic dispensers are recommended instead of taps and weighing whenever possible, and especially when isocyanates are used extensively.
  - When the raw materials are mixed with a hand-held machine, the risk of splashing is reduced by filling the container up to halfway and with a rack placed on the container.

- The use of pre-weighed doses of hardener and pulp reduces the risk of exposure during the dosing phase.
- The raw materials for HDI coatings are metered and mixed in a fume hood or in a well-ventilated, vacuum room.
- Reduce the need to wash tools with solvents using disposable tools.
- Tools should be cleaned without touching the polyurethane or washing solutions, even with gloves.
- Lid-lined, waste disposal containers for isocyanate wastes containing solvents are used. Dispose of excess hardener by adding sufficient resin / mass.
- Freshly painted pieces are dried in a separate, well-ventilated room.
- The freshly cured polyurethane product is not touched with bare hands.
- Urethane-based paints, varnishes, adhesives, putties and sealants are removed mechanically, not by heating.
- Processing temperatures above 150°C, whether polyurethane material or not, should be avoided.
- Emergency and accident situations are prepared in advance.
- Attention is paid to the public order and cleanliness of the workplace. Uncured isocyanate that has come into contact with protective equipment, surfaces or tools increases the risk of skin sensitization by direct contact with exposed skin. Passageways are considered to be unobstructed to reduce the risk of tripping, as tripping is especially dangerous when workers transport freshly mixed urethane to the point of use.

• Ventilation:

- In addition to efficient general ventilation, well-functioning local exhaust is provided during high-risk work phases. Despite local exhaust, there may be harmful concentrations of isocyanate in the breathing air, e.g. in spray painting.
- Ensure that spaces designed to be under pressure remain under pressure.
- Preferably use tools with built-in local removal.
- Ensure proper maintenance of air conditioners. Replace the ventilation filters frequently enough for the air to change as planned.
- Ensure the adequacy of the replacement air and its correct orientation.
- Return air is not used in isocyanate work.

• Personal protective equipment overview

- Despite the introduction of personal protective equipment, effective ventilation and the avoidance of chemical contact are not neglected.
- Protective equipment is used at all times when exposure to other measures is not sufficiently reduced.
- The protective equipment is stored, maintained and decommissioned in accordance with their operating instructions. Dirty and poorly maintained protective equipment may expose you more than working without protective equipment.
- Eye or face protection should be worn if there is a risk of splashing at work.

- Chemical protective clothing must be worn for work where diisocyanates or freshly mixed polyurethane mass is splashed on clothing. Isocyanates are absorbed into ordinary clothing and the skin is exposed through clothing.
- Exposure to bare skin must be prevented.
- Chemical protective gloves are always required for handling isocyanates. Used gloves should be stored on the outside of clothing and not in pockets.

- Respirators

- When a respirator is used as a risk management measure, it shall be selected so that the protective capacity is sufficient to reduce the respirable pollutants to less than 0.1 µg NCO/m^3. The protection factor often required for spray painting is 100 or more. The face part of the protector should also protect the eyes.
- Only a compressed air hose device is well suited as an effective respirator. For example, a type 3A device according to EN 14594 has a protection factor of 200 and a type 4A device has a protection factor of 2000. As these are difficult to install in all work sites, filter protectors with a fan are also used. TM3A2P class or TH3A2P class devices are recommended as a filter protector with a fan. These practical protection factors are 1000 (TM3) and 200 (TH3). The filter must bear an SL marking. The filter fills up when in use and diisocyanates cannot be smelled, so the filter must be replaced every day unless the change interval can be estimated. If the polyurethane or diisocyanates are heated above 150°C, the filter must be A2B2E2K2P SL.

- Guidance is also available for non-respirable exposure routes:
- Clothing and protective gloves for HDI spray painting and other HDI coating
- Clothing and protective gloves for MDI ion work (without solvents)

4.12 Standard monitoring methods/tools

4.12.1 Standard for monitoring compliance with OELs and STELs

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

As concerns the monitoring of substances in the workplace, guidelines may refer to two European standards:

- EN 482:2012+A1:2015: Workplace exposure. General requirements for the performance of procedures for the measurement of chemical agents (European Standards, 2016)
- EN 689:2018: Workplace exposure. Measurement of exposure by inhalation to chemical agents. Strategy for testing compliance with occupational exposure limits (European Standards, 2020)

An increasing number of Member States rely upon EN689.

The strategy described in EN 689:2018, see Figure 4-6, 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.

In the standard, compliance with an OEL is determined by either a screening test or a test of compliance.

Screening test

The **screening test** requires three to five exposure measurements on workers belonging to a SEG.

a) If all results are below:

- 1) 0.1 * OEL for a set of three exposure measurements or,
- 2) 0.15 * OEL for a set of four exposure measurements or,
- 3) 0.2 * OEL for a set of five exposure measurements

then it is considered that the OEL is respected: **Compliance**.

b) If one of the results is greater than the OEL, it is considered that the OEL is not respected: **Non-compliance.** In case that the first measurement result is above the OEL, it is not necessary to perform any additional measurements.

c) If all the results are below the OEL and a result above 0.1 * OEL (set of three results) or 0.15 * OEL (set of four results) or 0.2 * OELV (set of five results) it is not possible to conclude on compliance with the OELV. **No-decision.** In this situation additional exposure measurements shall be carried out in order to apply the test based on the calculation of the confidence interval of the probability of exceeding the OELV, as specified below.

Test of compliance with the OELV

According to the standard, the appraiser shall select a statistical test of whether the exposures in a Same Exposure Group (SEG) comply with the OEL. The test shall measure, with at least 70 % confidence, whether less than 5 % of exposures in the SEG exceed the OEL.

Figure 4-6 Summary of the approach in EN689
Source: EN689 (European Standards, 2020)

To undertake the screening tests, ideally an analytical method with a limit of quantification (LOQ) at 0.1 times the OEL would be required; otherwise more tests are necessary and the costs of monitoring increases.

In the consultation survey, respondents were asked if they have to comply with the European standard on testing compliance under EN 689 and approximately 60% of the companies that know indicated that they do, see Table 4-61.

Table 4-61 Do you have to comply with the European standard on testing compliance with occupational exposure limit values EN 689? (n= 209)

Sector	Yes	No	Don’t know
C15 Leather	0.0% (0)	0.0% (0)	0.6% (1)
C16 Wood	5.5% (10)	0.0% (0)	0.0% (0)
C20 Chemicals	20.4% (37)	14.9% (27)	7.2% (13)
C22.29 Rigid foams	16.6% (30)	13.8% (25)	2.8% (5)
C22.21 Flexible foams	2.2% (4)	3.9% (7)	3.9% (7)

Sector	Yes	No	Don't know
C22 Other	0.6% (1)	0.6% (1)	2.2% (4)
C26 Computers	0.0% (0)	0.0% (0)	0.6% (1)
C27 Electrical equipment	0.0% (0)	0.6% (1)	0.0% (0)
C29 Motor vehicles	0.6% (1)	0.6% (1)	1.1% (2)
C30 Transport	0.0% (0)	0.0% (0)	0.0% (0)
F42 Civil engineering	0.0% (0)	0.0% (0)	0.0% (0)
F43 Specialised construction	0.6% (1)	0.0% (0)	0.6% (1)
Total	**46.4% (84)**	**34.3% (62)**	**19.3% (35)**

Source: Consultation survey

4.12.2 Available analytical standards for monitoring diisocyanates in air

A list of relevant analytical standards is shown in Table 4-62 on the basis of lists provided by the 'GESTIS - Analytical methods' database. All methods use an inhalable sampler and consequently measure the inhalable fraction.

The GESTIS database contains validated lists of methods from various EU Member States, the USA and Canada described as suitable for the analysis of chemical agents at workplaces with a ranking of the methods. An 'A' ranking indicates that all or most of the requirements of EN 482 are met, while a 'B' ranking indicates incomplete validation data, but a potential to meet the requirements of EN 482. Methods ranked 'C' in the original evaluation are not considered to be able to meet the requirements of the norm and are often not included in the 'method sheets'. The GESTIS - Analytical methods' database contains eight standards for analysis of diisocyanates. Only the five methods with the Category A rating "*the methods meet all or most of the requirements of the EN 482 (1999)*" are shown in Table 4-62.

The RAC opinion on diisocyanates, ECHA (2020c), lists seven standards for analysis of diisocyanates and this table is replicated in Table 4-63. Several of these standards are updates of the standards listed on GESTIS and some are more recent than any on GESTIS.

In Table 4-63, the LOD for ISO 17734-1: 2013 of LOD: 0.02 ng/m^3 for TDI and 0.6 ng/m^3 for HDI seemed a big step down from the LOD/LOQs for all the other analytical methods listed. The study team contacted the International Organization for Standardization (ISO) for clarification, and it confirmed (personal communication, 2021) that it:

> *"would expect to see a LOQ of 0.33 ug/m^3 for a 15-L sample with MDI. The limit of detection can be considerably lower than this due to the instrumental detection limit however in real life the LOD is often higher than the theoretical value for the equipment. Overall however the currently stated values in ISO 17734 of 0.02 ng/m^3 for TDI and 0.6 ng/m^3 for HDI are unlikely to be accurate due to the scale of the difference."*

Adding that:

> *"adjustments may need to be made in the scope of the ISO 17734."*

In addition, ISOPA/ALIPA highlight several further methods standards for analysis of diisocyanates:

- Annual repeated measurements during standard operation by ISO TR 17737 (CEN - EN 689)

- ISO 14382:2012 Workplace air quality for isocyanates: TDI vapor using 1,2-MP coated GFF and analysis via HPLC UV and fluorescence
- ISO 17734-2:2013 Determination of organonitrogen compounds in air using liquid chromatography and mass spectrometry -- Part 2: Amines and aminoisocyanates using dibutylamine and ethyl chloroformate derivatives
- ISO 17734-2:2013 Workplace air quality for isocyanates: Impinger/filter or tube/filter containing, impregnated or coated with DBA and ECF using HPLC/MS analytics
- NIOSH 5521 Workplace air quality for isocyanates: Impinger -1,2MP toluene (suitable for total isocyanates)
- OSHA 42 & OSHA 47 Workplace air quality for isocyanates: 1,2-PP coated GFF
- National methods developed on the basis of these ISO methods, such as the Institut für Arbeitsschutz der deutschen gesetzlichen Unfallversicherung (IFA) in Germany and their method 7120.

Table 4-62 Standard analytical methods for diisocyanates – GESTIS A rated

No	Source and method name	Lang	Year ***	Principle of the method	Flow rate (Recommended air volume; time)	Limit of quantification (LOQ) Validated working range (WR) ****	Rating **	Remarks
1	MTA/MA-034/A95 Determination of organic isocyanates (2,6 and 2,4-toluene diisocyanate, hexamethylene diisocyanate, 4,4'- diphenylmethane diisocyanate) in air – Derivatisation and double detection method by ultraviolet and electrochemical detection / High performance liquid chromatography	ES	1995	Impinger containing an absorption solution of 0.2 mM 1-2MP reagent in toluene. After sampling, unreacted reagent is acetylated, solvent is evaporated and the residue dissolved in 1 ml of acetonitrile/acetic anhydride (95.5/0.5). Analysis by HPLC/UV or HPLC/ECHD.	1 l/min 30 l	WR: 0.005-0.0125 mg/m³	A	
2	ISO 16702 Workplace air quality – determination of total isocyanate groups in air using 2-(1-methoxyphenylpiperazine and liquid chromatography	EN, FR	2001	25 mm GF filter impregnated with 1-2MP reagent and/or an impinger containing an absorption solution of 0.26 mM 1-2MP reagent in toluene. After sampling, unreacted reagent is acetylated, solvent is evaporated and the residue dissolved in 2 ml of acetonitrile. Analysis by HPLC/ UV or HPLC/ECHD	Filter: 1 l/min 20-900 l Impinger: 2 l/min	LOQ: 0.0003 mg/m³ 15 l (ECHD) WR: 0.002-0.04 mg/m³ 15 l (as total NCO)	A	Similar method described in MDHS 25/3 An updated version of this analytical method is available and can be seen in table 4-59 below.
3	MétroPol Fiche 004 Isocyanates monomères	FR	2003	Impinger containing a solution of 0.2 mM 1-2MP in xylene. Xylene is evaporated and the residue dissolved with 2 ml of acetonitrile (or THF). Analysis by HPLC/UV.	0.2-0.5 l/min	WR: 0.002-0.2 mg/m3	A	Sampling included in the method validation Method was developed before publication of EN 482
4	MDHS 25/3 Organic isocyanates in air – Laboratory method using sampling either onto 2-(1- methoxyphenylpiperazine coated glass fibre filters followed by solvent desorption or into impingers and analysis using	EN	1999	25 mm GF filter impregnated with 1-2MP reagent and/or an impinger containing an absorption solution of 0.26 mM 1-2MP reagent in toluene. After sampling, the excess of reagent is acetylated, solvent is evaporated and the residue dissolved in 2 ml of acetonitrile. Analysis by HPLC/UV or HPLC/ECHD.	Filter. 1 l/min 20-900 l Impinger: 2 l/min	LOQ: 0.0003 mg/m³ 15 l (ECHD) WR: 0.002-0.04 mg/m³ 15 l (as total NCO)	A	Filter only analysis An updated version of this analytical method is

No	Source and method name	Lang	Year ***	Principle of the method	Flow rate (Recommended air volume; time)	Limit of quantification (LOQ) Validated working range (WR) ****	Rating **	Remarks
	high performance liquid chromatography							available and can be seen in table 4-59 below.
5	BIA 7670 Isocyanat	DE	2004	Double GF filter impregnated with nitro reagent. Desorption with 2 ml CH2Cl2, the excess of reagent is hydrolysed. Analysis by HPLC/UV.	1.66 l/min 200 l	LOQ 0.002 mg/m^3 (as total NCO)	A	Method evaluated for analysis of polymeric isocyanates Parallel determination of the free isocyanate content in the used material

**   Indicated in the Gestis database as methods for HDI, TDI and MDI. All methods are applicable to the diisocyanates listed.*
***   Category A rating "the methods meets all or most of the requirements of the EN 482 (1999)"*
**** Checked in this study for newest versions of standards. Year of newest version and review data has been obtained from standard organisations*
***** Values are given based on TDI.*
Source: Gestis database. (DGUV, no date)

Table 4-63 Air monitoring methods for the most common diisocyanate monomers and for their polymeric isocyanates ECHA (2020c)

Method	Suitable for	Sampler	Derivatising agent	Analytical technique	Sample flow rate, volume, time	LOD/LOQ/range 15 L (corresponds to STEL)	LOD/LOQ/range 240 L (corresponds to 8-hr TWA OEL)
ISO 17734-1: 2013*	Gas and vapour phase isocyanates; monomers, prepolymers and oligomers	Impinger/filter or tube/filter (solvent-free sampling)	DBA	HPLC MS/CLND	1 l/min and 30 min or 0.2 l/min and even > 8 h	LOD: 0.02 ng/m3 for TDI and 0.6 ng/m3 for HDI LOQ***: 0.1 ng/m3 for TDI and 3.0 ng/m3 for HDI See note **** Range: 0.001-200,000 µg/m3 for TDI (5 l)	LOD: 0.001 ng/m3 for TDI and 0.04 ng/m3 for HDI LOQ***: 0.005 ng/m3 for TDI and 0.18 ng/m3 for HDI
ISO 17735: 2019	Vapours and aerosols; monomers, prepolymers	Reagent impregnated filters and/or impinger samples	MAP	HPLC UV/FL (LC MS-MS)	1 -960 l; 1 or 2 l/min	LOD: 0.7 – 1.4 µg monomer/m3 for filters and 2.0-5.3 monomer µg/m3 for impingers LOQ***: 2.9 – 5.7 µg monomer/m3 for filters and 8.2 – 21.6 µg monomer/m3 for impingers	LOD: 0.04 – 0.08 µg monomer /m3 for filters; 0.13 – 0.3 µg monomer/m3 for impingers LOQ***: 0.18 – 0.36 µg monomer /m3 for filters and 0.59 – 1.35 µg monomer/m3 for impingers
ISO 17736: 2010 **	Vapours and aerosols; monomers, prepolymers and oligomers	Douple filters	MAMA	HPLC UV/FL/DAD	1 l/min; for short-term exposure, but if only vapour form the sampling can be extended to 8 hour;	Range: 0.67 – 140 µg NCO/m3	
ISO 16702 2007	Vapours and aerosols; Any product containing free isocyanate groups. Primarily MDI, HDI and TDI both monomers and their oligomers and polymers	Chemically treated filters or impinger/ filters	1,2-MP	LC-UV/EC/(DAD)	0.5 min to 8 hour	LOD: 0.07 µg NCO/m3 LOQ: 0.3 µg NCO/m3 Range: 0.1 – 140 µg/m3	LOD: 0.004 µg NCO/m3 LOQ: 0.019 µg NCO/m3
MDHS 25/4	Vapours and aerosols; monomers and prepolymers	Glass fibre filters (vapours); impinger + glass	1,2-MP	HPLC-UV/ EC/(MS/MS)	Vapours 2 l/min and 20-900 l; Aerosols 1 l/min and 15-480 l	LOD: 0.07 µg NCO/m3 (EC) LOQ: 0.27 µg NCO/m3 (EC)	LOD: 0.004 µg NCO/m3 (EC) LOQ: 0.017 µg NCO/m3 (EC)

Method	Suitable for	Sampler	Derivatising agent	Analytical technique	Sample flow rate, volume, time	LOD/LOQ/range 15 L (corresponds to STEL)	LOD/LOQ/range 240 L (corresponds to 8-hr TWA OEL)
		fibre filters (aerosols)					
NIOSH 5522 (1998)	Vapours and aerosols; only for area samples monomer (TDI, MDI, HDI) and estimate oligomer; not for mixtures of different isocyanates	Impinger	Tryptamine/DMSO	HPLC-FL/EC	15-360 l; 1-2 l/min	Range: 10 – 250 µg/m3 for TDI (50 l);	
NIOSH 5525 (2003)	Vapour, aerosols and condensation aerosols; monomeric and oligomeric isocyanates	Glass fibre filters; impinger; impinger + glass fibre filters	MAP	HPLC-UV/FL	1-500 l; 1-2 l/min	LOD: 1.1 µg/m3 for HDI LOQ***: 4.5 µg/m3 for HDI Range: 1.4 – 840 µg NCO /m3;	LOD: 0.18 µg/m3 for HDI LOQ***: 0.81 µg/m3 for HDI Range: 0.1 – 52 µg NCO/m3;

**   Reviewed and confirmed in 2019.*
***   Reviewed and confirmed in 2016*
**** LOQ has been estimated (see explanatory paragraph below)*
***** LOD and LOQ in doubt following correspondence with ISO, see text.*
DBA = dibutylamine; 1,2-MP = 1-(2-methyoxyphenyl)piperazine; MAMA = 9-(methylaminomethyl)anthracene; DMSO = Dimethyl sulfoxide; MAP = 1-(9- anthracenylmethyl)piperazine
LOD limit of detection; LOQ limit of quantification
LC liquid chromatography; HPLC high pressure liquid chromatography; MS mass spectrometry; CLND = chemiluminescent nitrogen detection; UV ultraviolet detection; FL fluorescence detection; EC electrochemical detection; DAD diode array detector
Source: ECHA (2020c)

4.12.3 Limit of quantification

With many revisions and new standards for analysis for diisocyanates, it is not straightforward to establish the limit of quantification. As explained in section 4.12.1, for screening under EN689, ideally an analytical method with a limit of quantification (LOQ) at 10% the OEL is required; otherwise more tests are necessary and the costs of monitoring increases.

The LOQs of the standards mentioned in Table 4-63 are often not stated and as such some values have been estimated from the LOD. Using the standards where both the LOQ and LOD are known a factor of approximately five was estimated for both 15 litre and 240 litre methods.

The ISO 17734-1: 2013 method in Table 4-63 appears to have an LOD of: 0.001 ng/m^3 for TDI and 0.04 ng/m^3 for HDI, and an LOQ of 0.005 ng/m^3 for TDI and 0.18 ng/m^3. These are well below 10% of the lowest OEL option of 0.025 µg NCO/m^3. However, these levels are three orders of magnitude lower than any other LOD/LOQs given, and this seemed to be a big difference. The study team contacted the International Organization for Standardization (ISO) for clarification, as described in section 4.12.2, and found that this LOD/LOQ was likely to be much higher, probably closer to 0.3 µg NCO/m^3.

In Table 4-62 and Table 4-63, the lowest LOQs available (other than the ISO 17734-1: 2013 method) appear to be approximately 0.3 µg NCO/m^3 for a 15 Litre STEL measurement and approximately 0.02 µg NCO/m^3 for a 240 Litre 8-hour TWA OEL measurement. This implies that the lowest STEL that could currently be monitored is 3 µg NCO/m^3 and the lowest OEL is 0.2 µg NCO/m^3.

The study team asked a major European laboratory if it could sample to 0.025 µg NCO/m^3 and was told that it was possible using a sampling time of seven hours. The toluene would need to be refilled during the sampling period as it would evaporate. The laboratory had no experience of sampling for such long periods, (personal communication, European laboratory, 2021).

Increasing the sampling rate (litre per minute) to achieve a greater sampling volume in a shorter period of time is however problematic with these methods, as this may allow for diisocyanates to pass the sampling tube without being captured, (personal communication, European trade association, 2021).

4.13 Relevance of REACH Restrictions and Authorisation

The REACH Restriction that applies to training is discussed in section 4.17.

4.13.1 Possible REACH revisions

Two further REACH revisions under consideration could have a serious impact on some manufacturers using diisocyanates, in particular polyurethane manufacturers, these are the:

- Mixture assessment factor
- REACH registration obligations for polymers

The revisions of REACH are being considered as part of the next REACH revision.

4.13.1.1 Mixture assessment factor

Industry is concerned that a newly derived OEL value would mean the Risk Characterisation Ratio (RCR) and safety factor needed as part of the Mixture Assessment Factor (MAF) would be a double burden for industry. During the consultation, one industry stakeholder explained that a factor of ten was being discussed: this would effectively mean that any OELs/STELs for substances used in their mixtures would be divided by ten (personal communication; chemicals manufacturer 2021). In 2020, ECHA conducted an "indicative assessment" of the implications of applying a MAF of ten to 24 randomly selected substances registered under REACH (ECHA, 2020a). The study identified an occupational impact of an MAF of ten, there was a significant impact on 30% of the scenarios, a moderate impact on 60% of the scenarios and no impact in less than 10% of scenarios.

4.13.1.2 Obligations for polymers

The chemical manufacturing industry will also have to implement any decision on the REACH registration of polymers, for some chemicals companies that routinely develop customised polymers this could be a significant burden (personal communication; polyurethane manufacturer 2021). A CARACAL sub-group on polymers (CASG-Polymers) is advising the European Commission on how to best consider the outcomes of the recent polymers study in its development of a possible proposal for registration of certain types of polymers (European Commission, 2020). A recent study did not identify any red flags with the polymer grouping approach (Cefic-ECHA, 2021).

4.13.2 Other regulatory obligations

Most of the diisocyanates are also subject to other regulatory obligations, including:

- Cosmetic Products Regulation
- EU Ecolabel Regulation
- Plastic Materials and Articles Regulation
- Protection of Pregnant and Breastfeeding Workers Directive
- Protection of Young People Directive
- Safety and/or Health Signs at Work Directive
- WFD - Waste Framework Directive

4.14 Intermediate uses not covered by certain REACH procedures

Under REACH regulations, an intermediate is a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (REACH Article 3(15)). A wide variety of diisocyanates occur in intermediate use, as indicated in by those diisocyanates that are REACH registered as an intermediate and in diisocyanate REACH registration dossiers. Diisocyanates used as intermediates include:

- TDI
- 4,4'-MDI
- HDI

- 2,4'-MDI
- IPDI
- 4,4'-MDI (H12-MDI)
- 1,5-NDI
- 2,2'-MDI
- m-XDI
- m-TMXDI
- TMDI
- TODI
- PPDI

TMDI and PPDI are not substances included in the questionnaire/study.

4.15 Impact of Covid-19

The study team is not aware of any Covid-19 effects that are likely to have any significant impact upon this impact assessment. There are two types of likely impact:

- Factors that affect the conduct of the study and particularly the consultation
- Factors that will continue to affect the industrial sectors using diisocyanates post Covid-19.

The study was affected in several ways. As many operations were working differently, and, were often wearing more PPE than usual, several respondents supplied exposure data from 2019 rather than 2020. This is not expected to make any significant difference as the additional wearing of PPE because of Covid-19 is not expected to continue after the pandemic.

The survey asked respondents whether Covid-19 had had an impact on exposure levels of diisocyanates or the numbers of workers exposed to diisocyanates at this facility. The results are in Table 4-64. Most respondents (72%) state that Covid-19 had no impact on the exposure of their workers to diisocyanates with the remainder indicating relatively little impact. Thirteen percent (half of these responses originated from one company) stated that even with the increased RMMs and occupational health measures for Covid-19, Covid-19 had no impact on worker exposure (in other words, it did not lower it further). Overall, 85% of responses indicate Covid-19 had no impact on exposure levels. However, 7% of responses stated that Covid-19 resulted in lower demand for products containing diisocyanates which subsequently reduced worker exposure; it is assumed that this decrease is due to a general market decline during Covid-19 related lockdowns. Two percent of responses also state that monitoring ceased during Covid-19 either due to site personnel restrictions or due to the unsuitability of monitoring processes, for example occupational health testing (lung capacity measurement etc.).

Of the two responses (1%) that indicate an increase in exposure, the following reasons were provided: changes to shift working has resulted in more workers exposed; and to protect production against Covid-19, more employees were trained to work with chemicals. In both cases, it seems likely that the changes causing the increase in exposure will cease when Covid-19 is over.

Table 4-64 Estimated impact of Covid-19 on workplace exposure to diisocyanates (n= 210)

Response	Frequency
No impact	71% (149)
Increased RMM and occupational health measures to protect workers – no change in exposure *	13% (28)
Reduced demand of products – reduced exposure	7% (15)
Unknown – monitoring suspended during Covid	2% (5)
Reduced number of workers exposed	1% (2)
Factory closure	1% (2)
Increase in exposure	1% (2)
Reduced training sessions	0% (1)
Other unrelated comments	3% (6)

Source: Consultation survey

*Notes: Total does not equal 100% due to rounding. Respondents were able to provide multiple responses to the questionnaire (i.e. one for each facility in their organisation). These percentages include responses from the same respondent; *: refers to 17 responses provided from one organisation*

Site visits were more limited due to the travel restrictions, but some on-site and virtual site visits took place. However, the much greater familiarity that everyone now has with video conference calls using systems such as Microsoft Teams and Zoom meant that the interviews with trade associations and companies were considerably more effective than pre-Covid-19 telephone conference calls. In particular, it enabled an initial workshop with over 70 members of ISOPA/ALIPA members where the study team explained the survey: this probably contributed to the good response rate for the survey. Overall, the study team believes that Covid-19 probably improved the consultation process.

Some of the sectors included in the study saw a drop in the demand of their products and/or services due to the pandemic, in most cases, as the European economy reopens, the sectors are seeing demand pick up. In interviews and site visits, when asked about trends for their industry and the use of diisocyanates, no-one reported anticipated long-term changes in demand due to Covid-19.

4.16 Current disease burden (CDB)

The current burden of disease for both asthma and irritation is estimated using the data in the preceding sections for exposed workers, see Table 4-29 combined with data on exposure concentrations and the dose response relationship (DRR). The number of workers is adjusted to exclude workers who already have asthma (6.25% of the population, see section 4.6.4.

The exposure data used for the current burden of disease due to asthma (Table 4-14) is based upon data from approximately 1980 to present day, using the conservative (high), but realistic, exposure levels. To calculate the effects of asthma, the dose response relationship (DRR) is applied an estimated workforce of 4,226,583 exposed to concentrations identified from all publicly and non-publicly available data sources, including older studies that are likely to reflect historical exposure concentrations. As explained in section 4.8.5, the number of exposed workers is expected to be static in future years.

The current burden of disease due to irritation is based upon current data, see Table 4-15, as the likelihood of developing irritation is only dependent upon the current concentration and not affected by previous exposure.

The number of cases of asthma and irritation due to diisocyanates predicted for 2021 is shown below.

Table 4-65 Current burden of disease due to past exposure 5% turnover of workforce a year, static discount rate

Endpoint	Case over last 40 years	New cases per year (incidence) in 2021
Asthma	204,984	5,125
Irritation	52,597	1,315

Source: Study team

Several organisations have estimated the number of cases of asthma due to diisocyanates as shown in Table 4-66 and the estimates vary considerably. There are many challenges in identifying cases of occupational asthma in a uniform way. It can be difficult to identify accurately whether the onset of asthma is due to occupational factors and, if it is, whether diisocyanates is the cause. In section 4.6.4.1, several other sources of occupational asthma are indicated as also being common. There is also no consistency in registering cases of occupational asthma due to diisocyanates in the EU. Ideally, there would be a common EU approach to defining and registering cases.

The most comprehensive overall estimate from industry is that of ISOPA/ALIPA at 400-450 cases per year. As a reality check, the number of recognised cases is often thought to be just 10% of the reality. This has been verified by many studies. The current burden of disease in Table 4-65 would lead to a factor of 9%.

The RAC-SEAC Opinion on the Restriction (RAC SEAC, 2017) splits workers into two groups, high and low risk. The study team does not make this distinction, because the modelling allocates workers to a range of exposure levels from high to low. When all exposed groups in the RAC-SEAC Opinion are taken into consideration, the estimated cases are in the same range as the study team's estimates.

There has been an increase in the use of diisocyanates, but the total number of cases of diisocyanate-related occupational asthma has decreased in recent years. This could be due to medical surveillance and product stewardship to reduce exposure through better ventilation and RMM (Buyantseva et al., 2011).

Table 4-66 Estimates of new cases of occupational asthma per year due to diisocyanates

Source	Estimated cases
Annex XV dossier submitted by Germany in 2017 estimates of occupational asthmas due to diisocyanates (ECHA, 2017)	Over 5,000 (range 2,350 – 10,150/year)
Costs and benefits of REACH restrictions 2016-2020 (ECHA, 2021a)	6,500/year
RAC-SEAC Opinion on an Annex XV dossier proposing restrictions 470 – 10,150/year (three calculation approaches) (RAC SEAC, 2017)	470 – 10,150/year
ISOPA/ALIPA	400 – 450/year
BG BAU, German construction only – 5/year extrapolated to all sectors for EU-27 (note that the construction sector has relatively low exposure levels compared with several other sectors) (Personal communication, 2021)	35/year
Euromoulders/Europur (C22.29 flexible foam) – 2-5/year extrapolated to all sectors.	867 – 2,167/year

4.17 Future disease burden (FDB)

4.17.1 REACH Restriction

In August 2020, a new REACH Restriction was issued (EUROPEAN PARLIAMENT, 2020), which comes into effect in August 2023. The implications of the Restriction are explained in section 2.1.3 and the anticipated impacts are described in section 4.5.3.

The estimated reduction in the number of cases is between 50% and 70% after four years, or by 2027.

4.17.2 FBD before REACH Restriction

The future burden of disease before the REACH Restriction comes into effect is shown in Table 4-12, together with the present value of the healthcare costs over 40 years for both a static discount rate and a declining discount rate in Table 4-67 and Table 4-68.

These estimates assume that the number of workers exposed to diisocyanates is the same as for the current burden of disease, see Table 4-29. The exposure concentrations are based upon records from 2000 to present day, see *Source: Study team*

Table 4-15, and predicts the number of cases over the next 40 years. The estimates in the table below assume a workforce that turns over at 5% per year. This means that the entire workforce can be considered to have changed over a period of 20 years.

The predicted number of cases before the REACH Restriction comes into effect is 161,442 for asthma, and 52,597 for irritation over a 40-year period for a workforce of 4,226,583.

Table 4-67 Baseline future burden of disease (cases) before the REACH Restriction comes into effect, 5% turnover of workforce a year

Sector	**Number of cases over 40 years**	
	Asthma	**Irritation**
C13 Textiles	377	1,321
C14 Apparel	666	2,337
C15 Leather	3,727	-
C16 Wood	516	-
C20 Chemicals	604	856
C22.21 Rigid foam	179	-
C22.29 Flexible foam	442	291
C22 Other	1,439	-
C26 Computers	843	-
C27 Electrical equipment	776	387
C28 Machinery	616	265
C29 Motor vehicles	6,932	7,559
C30 Transport	2,499	2,797
C31 Furniture	636	160
C33 Machinery repair	550	1,550
F41.2 Construction	48,593	2,768
F42 Civil engineering	1,233	1,493
F43 Specialised construction	68,138	-
F43.29 Other installation	468	156
G45 Vehicle repair	21,687	30,658
S95 Repairs	522	-
Total	161,442	52,597

Source: Study team

Table 4-68 Baseline future burden of disease (PV40) before the REACH Restriction comes into effect, 5% turnover of workforce a year, static discount rate

Sector	PV40 over 40 years, static discount rate Range of Method 1 – Method 2		
	Asthma M1 – M2	Irritation M1 – M2	Total M1 – M2
C13 Textiles	€13,783,742 - €25,212,738	€967,936 - €1,360,139	€14,751,679 - €26,572,878
C14 Apparel	€24,386,829 - €44,607,533	€1,712,518 - €2,406,421	€26,099,347 - €47,013,954
C15 Leather	€136,423,855 - €249,541,732	€0 - €0	€136,423,855 - €249,541,732
C16 Wood	€18,873,166 - €34,522,134	€0 - €0	€18,873,166 - €34,522,134
C20 Chemicals	€22,109,511 - €40,441,942	€626,864 - €880,866	€22,736,375 - €41,322,808
C22.21 Rigid foam	€6,551,574 - €11,983,910	€0 - €0	€6,551,574 - €11,983,910
C22.29 Flexible foam	€16,181,170 - €29,598,029	€213,296 - €299,723	€16,394,466 - €29,897,751
C22 Other	€52,667,363 - €96,337,293	€0 - €0	€52,667,363 - €96,337,293
C26 Computers	€30,841,450 - €56,414,098	€0 - €0	€30,841,450 - €56,414,098
C27 Electrical equipment	€28,393,253 - €51,935,942	€283,347 - €398,158	€28,676,600 - €52,334,100
C28 Machinery	€22,545,115 - €41,238,735	€194,472 - €273,271	€22,739,588 - €41,512,006
C29 Motor vehicles	€253,713,222 - €464,083,328	€5,538,390 - €7,782,517	€259,251,612 - €471,865,845
C30 Transport	€91,470,605 - €167,314,822	€2,049,554 - €2,880,022	€93,520,158 - €170,194,844
C31 Furniture	€23,272,958 - €42,570,079	€117,075 - €164,513	€23,390,033 - €42,734,592
C33 Machinery repair	€20,139,413 - €36,838,309	€1,135,621 - €1,595,768	€21,275,034 - €38,434,077
F41.2 Construction	€1,778,561,864 - €3,253,282,993	€2,028,469 - €2,850,394	€1,780,590,333 - €3,256,133,387
F42 Civil engineering	€45,141,343 - €82,570,962	€1,093,762 - €1,536,949	€46,235,105 - €84,107,910
F43 Specialised con-struction	€2,493,963,495 - €4,561,870,570	€0 - €0	€2,493,963,495 - €4,561,870,570
F43.29 Other installation	€17,130,766 - €31,334,997	€114,275 - €160,579	€17,245,042 - €31,495,576
G45.2 Vehicle repair	€793,773,444 - €1,451,942,549	€22,463,209 - €31,565,184	€816,236,653 - €1,483,507,733
S95 Repairs	€19,090,963 - €34,920,520	€0 - €0	€19,090,963 - €34,920,520
Total	**€5,909,015,101 - €10,808,563,215**	**€38,538,788 - €54,154,504**	**€5,947,553,889 - €10,862,717,719**

Source: Study team
Notes: Static discount rate: 4% per year.
Range: For a description of methods 1 and 2, see section 3.5 of the methodological note.

Table 4-69 Baseline future burden of disease (PV40) before the REACH Restriction comes into effect, 5% turnover of workforce a year, declining discount rate

Sector	PV40 over 40 years, declining discount rate Range of Method 1 – Method 2		
	Asthma M1 – M2	**Irritation M1 – M2**	**Total M1 – M2**
C13 Textiles	€14,213,216 - €26,019,060	€997,781 - €1,401,624	€15,210,997 - €27,420,685
C14 Apparel	€25,146,673 - €46,034,115	€1,765,320 - €2,479,818	€26,911,994 - €48,513,933
C15 Leather	€140,674,544 - €257,522,263	€0 - €0	€140,674,544 - €257,522,263
C16 Wood	€19,461,215 - €35,626,177	€0 - €0	€19,461,215 - €35,626,177
C20 Chemicals	€22,798,398 - €41,735,305	€646,193 - €907,734	€23,444,591 - €42,643,039
C22.21 Rigid foam	€6,755,708 - €12,367,164	€0 - €0	€6,755,708 - €12,367,164
C22.29 Flexible foam	€16,685,342 - €30,544,596	€219,873 - €308,864	€16,905,215 - €30,853,460
C22 Other	€54,308,370 - €99,418,231	€0 - €0	€54,308,370 - €99,418,231
C26 Computers	€31,802,406 - €58,218,263	€0 - €0	€31,802,406 - €58,218,263
C27 Electrical equipment	€29,277,929 - €53,596,892	€292,083 - €410,302	€29,570,012 - €54,007,194
C28 Machinery	€23,247,575 - €42,557,580	€200,468 - €281,606	€23,448,044 - €42,839,186
C29 Motor vehicles	€261,618,407 - €478,925,059	€5,709,157 - €8,019,889	€267,327,565 - €486,944,947
C30 Transport	€94,320,642 - €172,665,675	€2,112,748 - €2,967,865	€96,433,390 - €175,633,539
C31 Furniture	€23,998,096 - €43,931,502	€120,685 - €169,531	€24,118,781 - €44,101,033
C33 Machinery repair	€20,766,916 - €38,016,425	€1,170,636 - €1,644,440	€21,937,552 - €39,660,866
F41.2 Construction	€1,833,978,219 - €3,357,325,406	€2,091,014 - €2,937,333	€1,836,069,232 - €3,360,262,739
F42 Civil engineering	€46,547,855 - €85,211,642	€1,127,487 - €1,583,827	€47,675,342 - €86,795,469
F43 Specialised construction	€2,571,670,303 - €4,707,762,588	€0 - €0	€2,571,670,303 - €4,707,762,588
F43.29 Other installation	€17,664,526 - €32,337,114	€117,799 - €165,477	€17,782,325 - €32,502,591
G45.2 Vehicle repair	€818,505,803 - €1,498,376,753	€23,155,827 - €32,527,943	€841,661,630 - €1,530,904,696
S95 Repairs	€19,685,798 - €36,037,304	€0 - €0	€19,685,798 - €36,037,304
Total	**€6,093,127,942 - €11,154,229,114**	**€39,727,071 - €55,806,253**	**€6,132,855,013 - €11,210,035,367**

Source: Study team
Notes: Declining discount rate: 4% per year for the first 20 years, 3% per year thereafter
Range: For a description of methods 1 and 2, see section 3.5 of the methodological note.

4.17.3 Baseline - FBD after REACH Restriction

The baseline future burden of disease including the impact of the REACH Restriction is estimated using the same method as the FBD except that the exposure levels in *Source: Study team*

Table 4-15 have all been reduced by 50%.

The number of cases for the baseline FBD including the impact of the REACH Restriction is shown in Table 4-69, together with the associated present value of the healthcare costs over 40 years for both a static discount rate and a declining discount rate in Table 4-70 and Table 4-71. These estimates assume that the number of workers exposed to diisocyanates is the same as for the current burden of disease, see Table 4-29. The exposure concentrations are based upon records since 2000, as shown in *Source: Study team*

Table 4-15, reduced by 50% to allow for the impact of the REACH Restriction. The estimates in the tables below assume a workforce that turns over at 5% per year. This means that the entire workforce can be considered to have changed over a period of 20 years.

The baseline predicted number of cases including the impact of the REACH Restriction comes into effect is 106,910 for asthma, and 10,099 for irritation over a 40-year period for a workforce of 4,226,582.

The REACH Restriction has the effect of reducing the number of asthma cases from by a third, whereas the cases of irritation are reduced by over 80%. This is because the threshold for irritation is relatively high at 2.3 µg/m³ and the reduction of the exposure levels by 50% effectively removes many workers from any excess risk.

Table 4-70 Baseline future burden of disease (cases) including the impact of the REACH Restriction, 5% turnover of workforce a year

Sector	Number of cases over 40 years	
	Asthma	Irritation
C13 Textiles	256	491
C14 Apparel	454	868
C15 Leather	2,481	-
C16 Wood	341	-
C20 Chemicals	402	177
C22.21 Rigid foam	118	-
C22.29 Flexible foam	298	-
C22 Other	957	-
C26 Computers	554	-
C27 Electrical equipment	513	-
C28 Machinery	405	-
C29 Motor vehicles	4,630	737

Sector	Number of cases over 40 years	
	Asthma	Irritation
C30 Transport	1,668	337
C31 Furniture	419	-
C33 Machinery repair	372	576
F41.2 Construction	32,144	-
F42 Civil engineering	819	198
F43 Specialised construction	44,974	-
F43.29 Other installation	308	-
G45.2 Vehicle repair	14,448	6,715
S95 Repairs	347	-
Grand Total	**106,910**	**10,099**

Source: Study team

Table 4-71 Baseline future burden of disease (PV40) including the impact of the REACH Restriction, 5% turnover of workforce a year, static discount rate

Sector	PV40 over 40 years, static discount rate Range of Method 1 – Method 2		
	Asthma M1 – M2	Irritation M1 – M2	Total M1 – M2
C13 Textiles	€9,382,782 - €17,162,656	€359,608 - €505,319	€9,742,390 - €17,667,976
C14 Apparel	€16,600,449 - €30,364,959	€636,235 - €894,034	€17,236,684 - €31,258,993
C15 Leather	€90,814,502 - €166,114,702	€0 - €0	€90,814,502 - €166,114,702
C16 Wood	€12,479,588 - €22,827,225	€0 - €0	€12,479,588 - €22,827,225
C20 Chemicals	€14,729,739 - €26,943,122	€129,589 - €182,098	€14,859,328 - €27,125,220
C22.21 Rigid foam	€4,326,186 - €7,913,307	€0 - €0	€4,326,186 - €7,913,307
C22.29 Flexible foam	€10,922,837 - €19,979,670	€0 - €0	€10,922,837 - €19,979,670
C22 Other	€35,030,863 - €64,077,226	€0 - €0	€35,030,863 - €64,077,226
C26 Computers	€20,262,583 - €37,063,607	€0 - €0	€20,262,583 - €37,063,607
C27 Electrical equipment	€18,792,325 - €34,374,262	€0 - €0	€18,792,325 - €34,374,262
C28 Machinery	€14,836,339 - €27,138,111	€0 - €0	€14,836,339 - €27,138,111

Sector	PV40 over 40 years, static discount rate Range of Method 1 – Method 2		
	Asthma M1 – M2	Irritation M1 – M2	Total M1 – M2
C29 Motor vehicles	€169,481,620 - €310,009,837	€540,186 - €759,066	€170,021,806 - €310,768,903
C30 Transport	€61,052,121 - €111,674,399	€247,257 - €347,444	€61,299,378 - €112,021,843
C31 Furniture	€15,344,278 - €28,067,216	€0 - €0	€15,344,278 - €28,067,216
C33 Machinery repair	€13,610,390 - €24,895,649	€421,789 - €592,696	€14,032,180 - €25,488,345
F41.2 Construction	€1,176,517,208 - €2,152,044,021	€0 - €0	€1,176,517,208 - €2,152,044,021
F42 Civil engineering	€29,970,062 - €54,820,186	€145,085 - €203,873	€30,115,147 - €55,024,059
F43 Specialised construction	€1,646,099,747 - €3,010,987,934	€0 - €0	€1,646,099,747 - €3,010,987,934
F43.29 Other installation	€11,261,003 - €20,598,232	€0 - €0	€11,261,003 - €20,598,232
G45.2 Vehicle repair	€528,825,649 - €967,309,332	€4,920,167 - €6,913,793	€533,745,815 - €974,223,125
S95 Repairs	€12,708,454 - €23,245,858	€0 - €0	€12,708,454 - €23,245,858
Total	**€3,913,048,725 - €7,157,611,512**	**€7,399,916 - €10,398,324**	**€3,920,448,642 - €7,168,009,835**

Source: Study team
Notes: Static discount rate: 4% per year
Range: For a description of methods 1 and 2, see section 3.5 of the methodological note.

Table 4-72 Baseline future burden of disease (PV40) including the impact of the REACH Restriction, 5% turnover of workforce a year, declining discount rate

Sector	PV40 over 40 years, declining discount rate Range of Method 1 – Method 2		
	Asthma M1 – M2	Irritation M1 – M2	Total M1 – M2
C13 Textiles	€9,675,131 - €17,711,531	€370,696 - €520,732	€10,045,826 - €18,232,263
C14 Apparel	€17,117,685 - €31,336,053	€655,852 - €921,303	€17,773,537 - €32,257,355
C15 Leather	€93,644,096 - €171,427,174	€0 - €0	€93,644,096 - €171,427,174
C16 Wood	€12,868,427 - €23,557,257	€0 - €0	€12,868,427 - €23,557,257

Sector	PV40 over 40 years, declining discount rate Range of Method 1 – Method 2		
	Asthma M1 – M2	Irritation M1 – M2	Total M1 – M2
C20 Chemicals	€15,188,687 - €27,804,783	€133,585 - €187,653	€15,322,272 - €27,992,435
C22.21 Rigid foam	€4,460,981 - €8,166,381	€0 - €0	€4,460,981 - €8,166,381
C22.29 Flexible foam	€11,263,170 - €20,618,635	€0 - €0	€11,263,170 - €20,618,635
C22 Other	€36,122,353 - €66,126,463	€0 - €0	€36,122,353 - €66,126,463
C26 Computers	€20,893,924 - €38,248,929	€0 - €0	€20,893,924 - €38,248,929
C27 Electrical equipment	€19,377,856 - €35,473,577	€0 - €0	€19,377,856 - €35,473,577
C28 Machinery	€15,298,609 - €28,006,008	€0 - €0	€15,298,609 - €28,006,008
C29 Motor vehicles	€174,762,321 - €319,924,182	€556,841 - €782,218	€175,319,163 - €320,706,400
C30 Transport	€62,954,381 - €115,245,830	€254,881 - €358,041	€63,209,261 - €115,603,871
C31 Furniture	€15,822,375 - €28,964,826	€0 - €0	€15,822,375 - €28,964,826
C33 Machinery repair	€14,034,462 - €25,691,830	€434,795 - €610,774	€14,469,257 - €26,302,604
F41.2 Construction	€1,213,175,081 - €2,220,867,991	€0 - €0	€1,213,175,081 - €2,220,867,991
F42 Civil engineering	€30,903,868 - €56,573,376	€149,559 - €210,091	€31,053,426 - €56,783,467
F43 Specialised construction	€1,697,388,853 - €3,107,281,570	€0 - €0	€1,697,388,853 - €3,107,281,570
F43.29 Other installation	€11,611,873 - €21,256,979	€0 - €0	€11,611,873 - €21,256,979
G45.2 Vehicle repair	€545,302,776 - €998,244,605	€5,071,872 - €7,124,668	€550,374,648 - €1,005,369,273
S95 Repairs	€13,104,423 - €23,989,278	€0 - €0	€13,104,423 - €23,989,278
Total	**€4,034,971,331 - €7,386,517,257**	**€7,628,081 - €10,715,479**	**€4,042,599,412 - €7,397,232,736**

Source: Study team
Notes: Declining discount rate: 4% per year for the first 20 years, 3% per year thereafter
Range: For a description of methods 1 and 2, see section 3.5 of the methodological note.

4.17.4 Cost per case after REACH Restriction

The costs per case over 40 years are shown in Table 4-73. The figures for diisocyanates of approximately €36,000 to €67,000 for asthma are broadly similar to the cost per case for chronic kidney disease and elevate blood pressure in the analysis of lead. These are conditions that people can live with for many years, but which involve repeated doctors' visits, occasional hospital visits and long-term medication. The annual costs may be relatively low but mount up over a lifetime.

Table 4-73 Baseline future burden of disease (PV40) including the impact of the REACH Restriction, 5% turnover of workforce a year, static discount rate

	Asthma	Irritation
M1 cost	€3,913,048,725	€7,399,916
M2 cost	€7,157,611,512	€10,398,324
Cases	106,910	10,099
M1 cost/case	€36,601	€733
M2 cost/case	€66,950	€1,030

Source: Study team

4.18 Summary of the baseline scenario

Table 4-74 provides a summary of the baseline scenario (including the impact of the REACH Restriction) for this impact assessment.

Table 4-74 Diisocyanates – summary of the baseline scenario

Item	Detail
Carcinogen	Diisocyanates
Classification	Carc 2 Resp. Sens. 1
Key sectors used	C13 Textiles C14 Apparel C15 Leather C16 Wood C20 Chemicals C22.21 Rigid foam C22.29 Flexible foam C22 Other C26 Computers C27 Electrical equipment C28 Machinery C29 Motor vehicles C30 Transport

Item	Detail
	C31 Furniture C33 Machinery repair F41.2 Construction F42 Civil engineering F43 Specialised construction F43.29 Other installation G45 Vehicle repair S95 Repairs
Types of ill health caused	Asthma, irritation
No. of exp. workers	4,226,583
Change exp. level	Differs by sector, see section 4.5, Source*: Study team* Table 4-15
Change no. of exp. workers	Modelled: 0% (past, future)
Period for estimation	40 years
Current disease burden (CDB) - cancer cases	Incidence of cancer: none
Future disease burden (FDB) - cancer cases	40-year period: none
CDB ill health effects	Asthma: 5,125 cases per year Irritation: 1,315 cases per year
FDB ill health effects (after REACH Restriction)	Asthma: 106,910 over 40 years Irritation: 10,099 over 40 years
Exp. no. of deaths FDB cancer (after REACH Restriction)	No deaths over 40 years
Exp. no. of deaths FDB other adverse health effects (after REACH Restriction)	Asthma: 0 deaths over 40 years Irritation: 0 deaths over 40 years
Monetary value FDB cancer (after REACH Restriction)	None over 40 years
Monetary value FDB other adverse health effects (after REACH Restriction)	Asthma: €3.9 billion – €7.2 billion PV over 40 years Irritation: €7.4 million – €10.4 million PV over 40 years

4.18.1 Other issues

The assessment for asthma does not capture the full burden of disease (current and future) from historic exposures to diisocyanates for the following reasons:

- Not all past uses of diisocyanates are covered in the assessment; only current uses are considered;
- The estimates assume that the number of workers in the past was the same as today; and
- The assessment of the current burden of disease does not factor in the existence or not of OELs over the past 40 years and it does not consider changes in national OELs over time.

5. Benefits assessment

The benefits assessment consists of the following sub-sections:

- Section 5.1 Summary of the key features of the model
- Section 5.2 Direct benefits – health - avoided cases of ill health
- Section 5.3 Direct benefits – workers & families
- Section 5.4 Direct benefits – public sector
- Section 5.5 Direct benefits – companies
- Section 5.6 Direct benefits – environmental
- Section 5.7 Direct benefits – market efficiency
- Section 5.8 Indirect benefits
- Section 5.9 Aggregated benefits
- Section 5.10 Discussion

5.1 Summary of the key features of the model

The benefits of the potential measures to reduce worker exposure equal the costs of avoided cases of ill health. The model developed to estimate these costs considers the cost categories set out in Table 5-1 below.

Table 5-1 The benefits framework

Category	Cost	Notes
Direct	Healthcare	Cost of medical treatment, including hospitalisation, surgery, consultations, radiation therapy, chemotherapy/immunotherapy, etc.
	Informal care[6]	Opportunity cost of unpaid care (i.e. the monetary value of the working and/or leisure time that relatives or friends provide to those with cancer)
	Cost for employers (e.g. liability insurance)	Cost to employers due to insurance payments and absence from work
Indirect	Mortality – productivity loss	The economic loss to society due to premature death
	Morbidity – lost working days	Loss of earnings and output due to absence from work due to illness or treatment

[6] 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	Cost	Notes
Intangible	Approach 1 WTP[7]: Mortality	A monetary value of the impact on quality of life of affected workers
	Approach 1 WTP: Morbidity	
	Approach 2 DALY[8]: Mortality	
	Approach 2 DALY: Morbidity	

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

- Method 1 (intangible costs estimated based on WTP to avoid a case): *Ctotal= Ch+Ci+Cp+Cvsl+Cvsm*
- Method 2 (intangible costs estimated based on monetised DALYs): *Ctotal= Ch+Ci+Cp+Cl+Cdaly*

The abbreviations are explained in Table 5-2 below.

Table 5-2 Overview of cost categories

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

The benefit model provides the following two outputs:

- The number of new cases for each health endpoint assigned to a specific year in the 40-year assessment period; and
- The Present Value (PV) of the direct, indirect, and intangible costs of each case.

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

8 Disability Adjusted Life Year. One DALY equals one year of health is lost. It is used to calculate the gap between current health status and the ideal health situation (WHO, Metrics: Disability-Adjusted Life Year (DALY)).

The model assumes an annual staff turnover of 5%. Even though this rate is lower than the turnover ratios in the published literature and Eurostat, which are typically derived at the level of individual companies rather than sectors, it is thought that a ratio of 5% is suitable for this study because some workers may continue to work in the same sector and continue to be exposed. Hence, the whole workforce is replaced every 20 years, and within the time period of 40 years, two cohorts of workers are exposed to diisocyanates. The turnover caused by treatment or early retirement due to the conditions considered in this report is not modelled.

A detailed overview of the key features of the model for the estimation of the benefits and the assumptions underpinning it are set out in the methodology report.

5.1.1 Relevant health endpoints for diisocyanates

The substance assessment for diisocyanates entails two endpoints, all are non-carcinogenic:

- Asthma
- Irritation

One of the endpoints, Asthma, is set as an endpoint with a chronic character, where the years lived with disability of the disease is set to 30 years in the model.

5.1.2 Method 1 vs Method 2

Two estimates of the cost savings from ill health avoided under the different OEL/STEL/BLV options (Methods 1 and 2) are presented in this report. These estimates rely on two different monetisation approaches. Both monetise the same number of avoided cases and use identical methods for the monetisation of direct (healthcare, informal care, disruption for employers) and indirect (productivity/lost earnings[9]) impacts. However, they use different approaches to assign monetary values to intangible effects (reduced quality of life, pain and suffering, etc.). The results of both approaches should be considered together and treated as indicative of the general order of magnitude of the cost savings. A detailed explanation of these approaches is provided in the Methodological note.

The values given below are for the present value (PV) discounted over 40 years.

5.1.3 Summary of the key assumptions for diisocyanates

5.1.3.1 Onset of the disease

The time required for the endpoints to develop over an average working takes into account the minimum and maximum time required to develop the condition (MinEx and MaxEx) and the distribution of new cases between these two points in time, combined with the latency period with which the effects are diagnosed.

The MinEx and MaxEx for the two endpoints is summarised in Table 5-3 below.

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[9] This is not the case where lost earnings are already taken into account in the Willingness to Pay estimate in published literature.

Table 5-3 Minimum & maximum exposure duration to develop a condition (MinEx & MaxEx) and latency in years

Endpoint	MinEx (years)	MaxEx (years)	Latency
Asthma	0	40	0
Irritation	0	0	0

5.1.3.1 Effects of disease

The key assumptions on the effects of the disease entering the model are summarised below:

- Treatment period,
- Years lived with disability of the disease (YLD),
- Fatality rate,
- Additional life expectancy at death, and
- Disability weights during treatment and after treatment.

The table below presents the treatment period, YLD, fatality rate, and additional life expectancy at death for the eight endpoints. Neither of the endpoints have a potentially fatal outcome.

Table 5-4 Treatment period, YLD, fatality rate, and additional life expectancy at death in years

Endpoint	Treatment period	YLD	Fatality rate	Additional life expectancy at death
Asthma	1	30	0%	-
Irritation	1	30	0%	-

The table below summarises the disability weights during and after treatment.

Table 5-5 Assigned disability weights during and after treatment

Endpoint	During treatment	After treatment
Asthma	0.045	0.020
Irritation	0.006	0.000

5.2 Direct benefits – health - avoided cases of ill health

The table below presents the cases of ill health associated with all endpoints and OEL options over the study period of 40 years. The number of cases is further plotted in a continuous form in the figure below.

Table 5-6 Cases by endpoint for each OEL option

Endpoint	Asthma	Irritation
0.025 µg NCO/m³	13,297	-
0.1 µg NCO/m³	36,691	-
0.5 µg NCO/m³	98,333	-
1 µg NCO/m³	104,585	-
3 µg NCO/m³	106,860	9,840
6 µg NCO/m³	106,910	10,099
10 µg NCO/m³	106,910	10,099
17.5 µg NCO/m³	106,910	10,099

Source: Study team

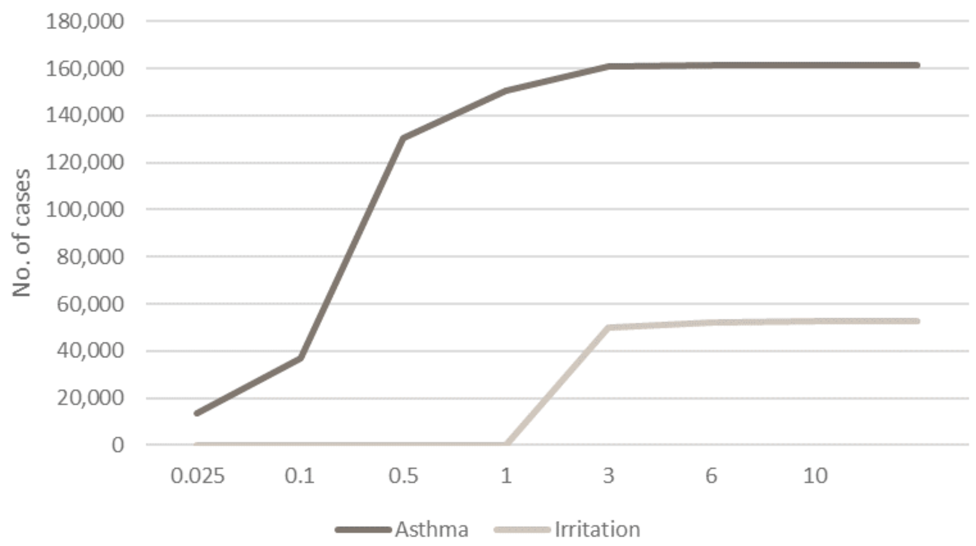


Figure 5-1 Cases of asthma and irritation for each OEL option
Source: Study team

5.3 Direct benefits – workers & families

The avoided costs of ill health relative to the baseline for workers and their families are calculated with the benefit approaches described in the table below. The benefits of the avoided cost of ill health are defined as cost of ill health in the baseline scenario, less the cost of ill health following the introduction of an OEL and STEL.

Table 5-7 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

In the following tables, the results are presented for respectively Methods 1 and 2. The table and figure below present the benefits according to Method 1. In line with the number of cases above, the effect of irritation is limited.

Table 5-8 METHOD 1: Benefits - WORKERS & FAMILIES (relative to baseline), € million

Endpoint	Asthma	Irritation	Total
0.025 µg NCO/m^3	1,425.3	2.4	1,427.7
0.1 µg NCO/m^3	1,069.1	2.4	1,071.5
0.5 µg NCO/m^3	130.6	2.4	133.0
1 µg NCO/m^3	35.4	2.4	37.8
3 µg NCO/m^3	0.8	0.1	0.8
6 µg NCO/m^3	-	-	-
10 µg NCO/m^3	-	-	-
17.5 µg NCO/m^3	-	-	-

Source: Study team

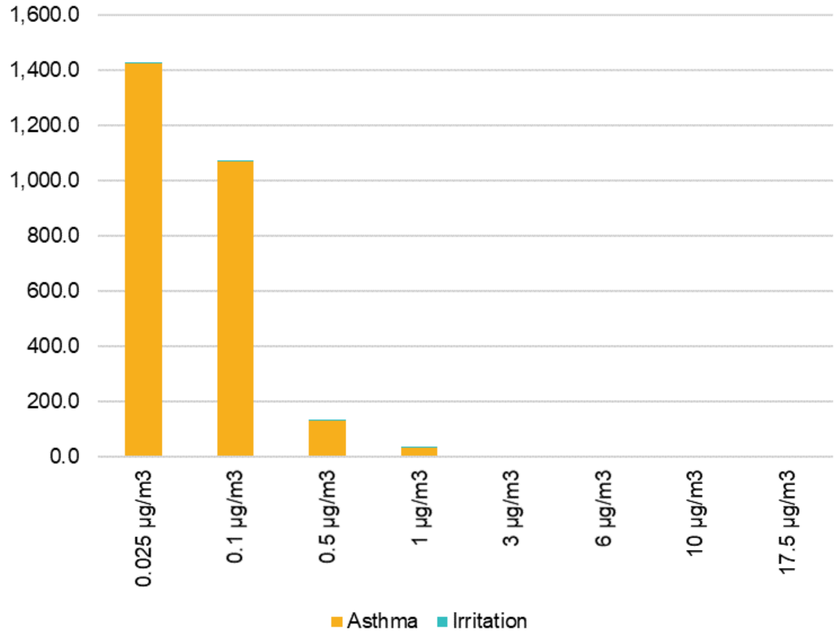


Figure 5-2 METHOD 1: Benefits - WORKERS & FAMILIES (relative to baseline), € million
Source: Study team

The following table and figure present the benefits according to Method 2.

Table 5-9 METHOD 2: Benefits - WORKERS & FAMILIES (relative to baseline), € million

Endpoint	Asthma	Irritation	Total
0.025 µg NCO/m³	3,989.2	4.9	3,994.1
0.1 µg NCO/m³	2,992.3	4.9	2,997.2
0.5 µg NCO/m³	365.5	4.9	370.4
1 µg NCO/m³	99.1	4.9	104.0
3 µg NCO/m³	2.1	0.1	2.2
6 µg NCO/m³	-	-	-
10 µg NCO/m³	-	-	-
17.5 µg NCO/m³	-	-	-

Source: Study team

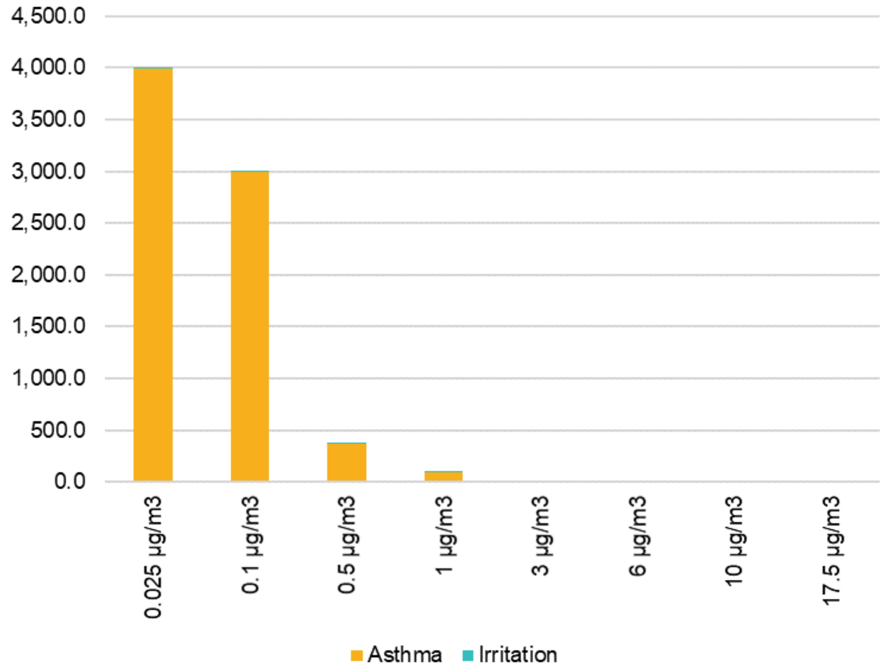


Figure 5-3 METHOD 2: Benefits - WORKERS & FAMILIES (relative to baseline), € million
Source: Study team

5.4 Direct benefits – public sector

The benefits of the avoided costs of ill health relative to the baseline to the public sector are compose 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. These costs do not include informal care costs, which are costs for workers and families covered in section 5.3.

Table 5-10 Benefits to the PUBLIC SECTOR (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: 20% tax rate assumed

Table 5-11 Benefits to PUBLIC SECTOR (relative to the baseline), € million

Endpoint	Asthma	Irritation	Total
0.025 µg NCO/m³	1,666.7	3.0	1,669.7
0.1 µg NCO/m³	1,250.2	3.0	1,253.2
0.5 µg NCO/m³	152.7	3.0	155.7
1 µg NCO/m³	41.4	3.0	44.4
3 µg NCO/m³	0.9	0.1	1.0
6 µg NCO/m³	-	-	-
10 µg NCO/m³	-	-	-
17.5 µg NCO/m³	-	-	-

Source: Study team

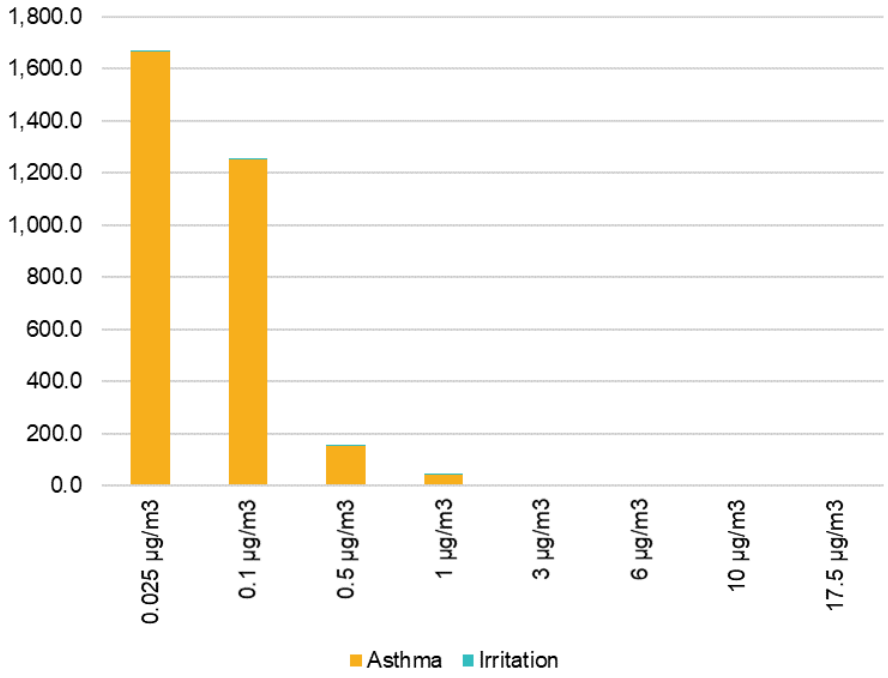


Figure 5-4 Benefits to PUBLIC SECTOR (relative to the baseline), € million
Source: Study team

5.5 Direct benefits – companies

The benefits of employers are composed of the cost savings for employers (of avoided sick leave, reduced labour productivity, and reduced administrative and legal costs like replacing employees) as well as the loss in labour productivity for a fatality. The table below summarises these benefits.

Table 5-12 Benefits to employers

Stakeholder group	Costs	Method of summation
Employers	Ce, Cp	CtotalEmployer=Ce+0.8*Cp[10]

The resulting benefits for employers are presented in following table and figure.

Table 5-13 Benefits to EMPLOYERS (relative to the baseline), € million

Endpoint	Asthma	Irritation	Total
0.025 µg NCO/m^3	611.4	2.5	613.9
0.1 µg NCO/m^3	458.6	2.5	461.1
0.5 µg NCO/m^3	56.0	2.5	58.5
1 µg NCO/m^3	15.2	2.5	17.7
3 µg NCO/m^3	0.3	0.1	0.4
6 µg NCO/m^3	€-	€-	€ 0
10 µg NCO/m^3	€-	€-	€ 0
17.5 µg NCO/m^3	€-	€-	€ 0

Source: Study team

[10] Ce for cancer is taken from published literature rather than estimated as an output of the benefits model.

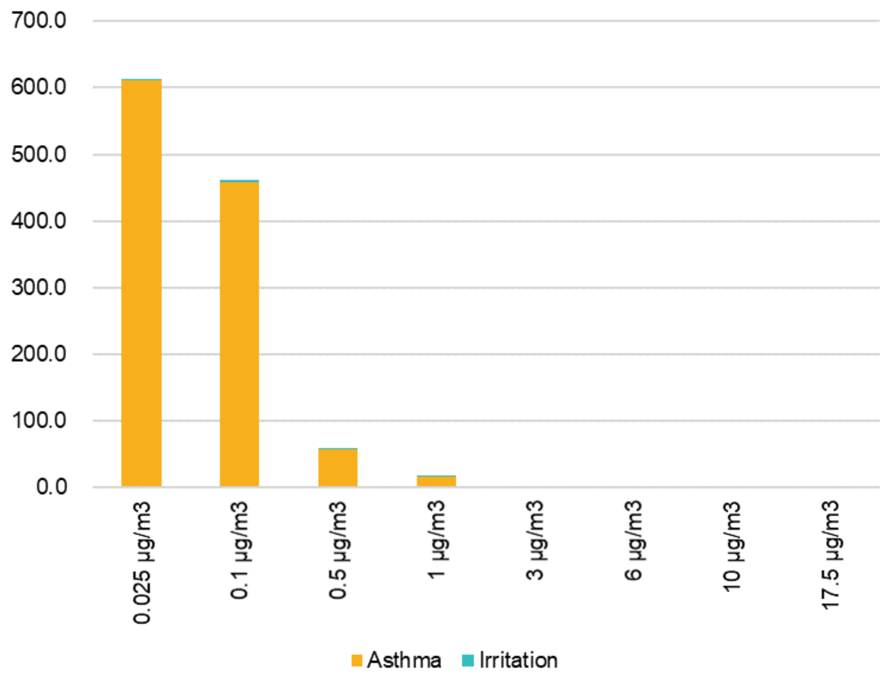


Figure 5-5 Benefits to EMPLOYERS (relative to the baseline), € million
Source: Study team

5.6 Direct benefits – environmental

Section 9 on the environmental impacts provides a detailed assessment of the environmental impacts.

5.7 Direct benefits – market efficiency

The setting of an EU-wide OEL and STEL will lead to an increased harmonisation of limit values across Europe. The increased harmonisation and lead to a nearly level playing field for enterprises across the internal market. This achieved by introducing of a limit in some Member States and closing the gap between the lowest and highest OEL and STEL in the EU. Presently more EU Member States have an OEL than a STEL.

As section 4.2.6 shows, for OELs, only a value of 3 µg NCO/m^3 will introduce a completely level playing field (i.e. all Member States having the same limit value). An OEL of 17.5 µg NCO/m^3 would provide the greatest marginal gains in terms of the number of Member States with the same limit value and would introduce a nearly completely level playing field, in which only Poland, Ireland, Croatia, Hungry and Sweden have lower OELs for a few diisocyanates.

For STELs, the picture is more complicated, but a limit value of approximately 35 µg NCO/m^3 would provide the greatest marginal gains in terms of the number of Member States with the same limit value and would introduce a nearly completely level playing field, in which only Hungary, Germany, Poland, Ireland, Slovenia and Sweden have lower STELs for a few diisocyanates. As an added complexity the German STELs has two levels, the higher tolerated level, which is the same as the baseline and the lower accepted level, which is the same as the OEL (baseline).

Medium and large companies with facilities across the EU can further benefit from a simplification of the applicable limit values, potentially providing savings for research- and design cost, as common solutions can be adopted across facilities, as opposed to designing site-specific solutions to meet different OEL and STEL requirements in each Member State.

5.8 Indirect benefits

5.8.1 Indirect benefits – companies

The harmonisation of OELs and STELs make it easier for companies working in more than one EU Member State as only one set of limit value has to be followed, as also elaborated in the paragraph above. Next to savings in research and design cost, an administrative simplification can be expected for companies. If a company has to work in (say) ten different Member States with ten different limit values, it has to understand each set of limit values, which can each in themselves be complicated if the Member State has different OELs and STELs for each diisocyanates. This takes more staff time than handling a single set of limit values and it is often easier if the staff are based in the relevant Member State. If there is a single OEL and STEL across the EU, the company can have a centralised group of people dealing with the OEL and STEL. This is usually more efficient. The sectors which are mostly composed of large and medium sized enterprises are those most likely to benefit most from these administrative simplifications, for example C20 Chemicals, C29 Motor vehicles and C30 Transport. Further detail about the benefits of a level playing field for the internal market are in section 7.2.2.

The introduction of RMMs in response to a revised OEL and STEL options tends to provide synergies in terms of exposure reduction for other chemical substances used in production sectors. 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.

The benefits of healthier staff could have indirect effects on the reputation of the sectors and associated companies, as work with diisocyanates may be less perceived as a risky line of work associated with health issues. As a result of such an improvement in the public image, companies may have it easier to recruit and retain staff, reducing the cost of recruitment and increasing the productivity of workers.

In section 6.4.2, it will be seen that there are potential situations (negative overall costs) where companies save money over the long term in some circumstances. If this investment is available, there is a long-term benefit to the company in moving to more cost effective RMMs and no longer having to rely on RPE. There is also a benefit for workers if they do not have to wear RPE.

5.8.2 Indirect benefits – public sector

An indirect benefit for Member State authorities is that if they have no OEL or STEL there are cost involved in assessing the impact of an OEL and STEL value and introducing it.

Of the 27 EU Member States, research carried out for this study has confirmed that seventeen have an OEL(s) and sixteen have a STEL(s) for a mixture of diisocyanates, see Table 4-1 and Table 4-2. There is no information about an OEL for diisocyanates for the following Member States and this study assumes that they do not have OELs: Cyprus, Czech Republic, Finland, Greece, Luxembourg, Malta, Netherlands, Portugal and Slovakia. There is no information about a STEL for diisocyanates for the following Member States and this study assumes that they do not have STEL: Bulgaria, Cyprus, Czech Republic, Greece, Italy, Latvia, Luxembourg, Malta, Netherlands, Portugal and Slovakia.

The study takes €100,000 per Member State as an approximation of the general order of magnitude of the applicable costs of introducing an OEL and STEL for Member States where there is currently no OEL or STEL for any diisocyanates and €50,000 per Member State where there is an existing OEL or STEL for at least one diisocyanate.

Table 5-14 Avoided costs of implementing OELs and STELs for Member State authorities

Member State situation	Number of Member States	Avoided cost per Member State	Total cost across the EU
Member States with no OEL or STEL	8	€100,000	€800,000
Member States with mixture of OELs and STELs	19	€50,000	€950,000
Total cost			**€1,750,000**

Source: Study team

5.9 Aggregated benefits

The composition of the aggregated benefits is summarised in the table below. As for the benefits for workers & families, two benefit methods are applied.

Table 5-15 Aggregated benefits

Costs	Method of summation
Aggregated	Method 1: Ctotal= Ch+Ci+Cp+Cvsl+Cvsm Method 2: Ctotal= Ch+Ci+Cp+Cl+Cdaly

In the following, the aggregated benefits are presented for respectively Method 1 and 2. The table and figure below present the benefits according to Method 1.

Table 5-16 METHOD 1: Benefits from avoided ill health (relative to the baseline), € million

Endpoint	Asthma	Irritation	Total
0.025 µg NCO/m³	3,426.4	7.4	3,433.8
0.1 µg NCO/m³	2,570.1	7.4	2,577.5
0.5 µg NCO/m³	313.9	7.4	321.3
1 µg NCO/m³	85.1	7.4	92.5
3 µg NCO/m³	1.8	0.2	2.0
6 µg NCO/m³	-	-	-
10 µg NCO/m³	-	-	-
17.5 µg NCO/m³	-	-	-

Source: Study team
Note: figures presented in this table show minor variation than the sum of Table 5-17 due to rounding.

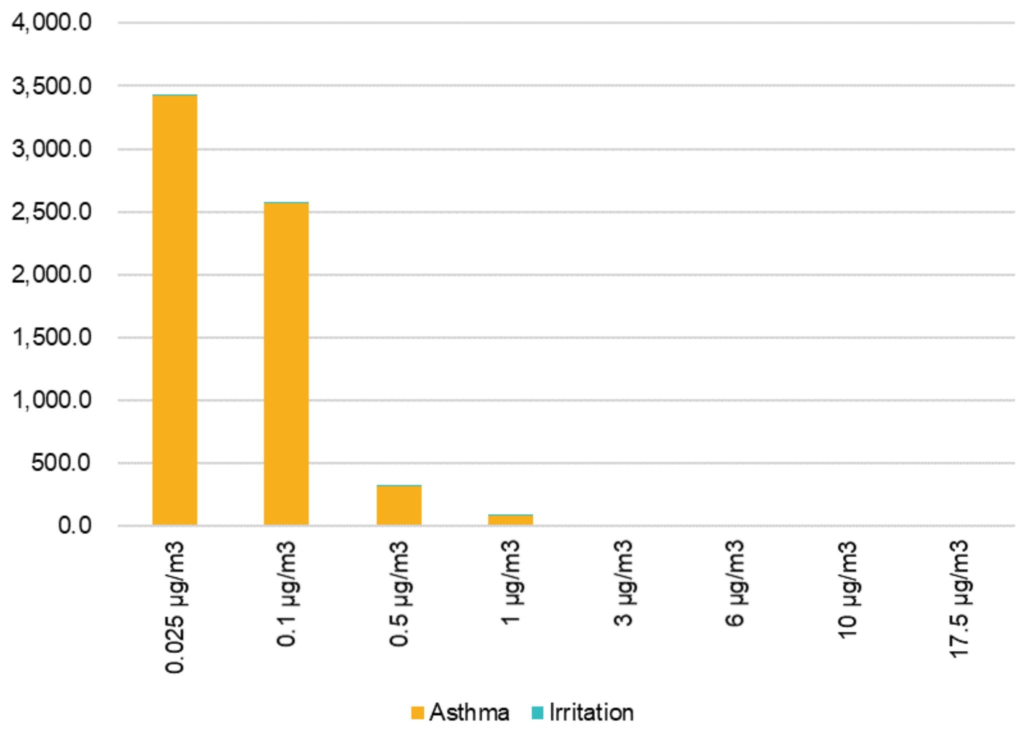


Figure 5-6 METHOD 1: Benefits from avoided ill health (relative to the baseline), € million
Source: Study team

To provide more sector details, the aggregated benefits under Method 1 are once more presented for each sector and OEL option in the table below.

Table 5-17 METHOD 1: Benefits avoided ill health by sector and OEL options (NCO), € million

Sector	0.025 µg/m³	0.1 µg/m³	0.5 µg/m³	1 µg/m³	3 µg/m³	6 µg/m³	10 µg/m³	17.5 µg/m³
C13 Textiles	€ 9	€ 9	€ 7	€ 5	€ 1	€-	€-	€-
C14 Apparel	€ 17	€ 16	€ 12	€ 9	€ 1	€-	€-	€-
C15 Leather	€ 71	€ 14	€-	€-	€-	€-	€-	€-
C16 Wood	€ 11	€ 9	€-	€-	€-	€-	€-	€-
C20 Chemicals	€ 14	€ 12	€ 4	€-	€-	€-	€-	€-
C22.21 Rigid foam	€ 4	€ 2	€-	€-	€-	€-	€-	€-
C22.29 Flexible foam	€ 10	€ 9	€ 4	€-	€-	€-	€-	€-
C22 Other	€ 32	€ 26	€-	€-	€-	€-	€-	€-
C26 Computers	€ 15	€ 3	€-	€-	€-	€-	€-	€-
C27 Electrical equipment	€ 17	€ 13	€-	€-	€-	€-	€-	€-
C28 Machinery	€ 12	€ 4	€-	€-	€-	€-	€-	€-
C29 Motor vehicles	€ 152	€ 124	€ 1	€ 1	€-	€-	€-	€-
C30 Transport	€ 56	€ 48	€ 12	€-	€-	€-	€-	€-
C31 Furniture	€ 13	€ 8	€-	€-	€-	€-	€-	€-
C33 Machinery repair	€ 13	€ 12	€ 6	€-	€-	€-	€-	€-
F41.2 Construction	€ 1,012	€ 739	€-	€-	€-	€-	€-	€-
F42 Civil engineering	€ 27	€ 22	€-	€-	€-	€-	€-	€-
F43 Specialised construction	€ 1,426	€ 1,051	€-	€-	€-	€-	€-	€-
F43.29 Other installation	€ 8	€ 2	€-	€-	€-	€-	€-	€-
G45 Vehicle repair	€ 505	€ 454	€ 275	€ 77	€-	€-	€-	€-
S95 Repairs	€ 10	€ 2	€-	€-	€-	€-	€-	€-
Total	**€ 3,434**	**€ 2,578**	**€ 321**	**€ 93**	**€ 2**	**€-**	**€-**	**€-**

Source: Study team

In the following, the results are presented according to Method 2. The table and figure below show the aggregated benefits per endpoint and OEL option.

Table 5-18 METHOD 2: Benefits from avoided ill health (relative to the baseline), € million

Endpoint	Asthma	Irritation	Total
0.025 µg NCO/m³	6,267.3	10.4	6,277.7
0.1 µg NCO/m³	4,701.1	10.4	4,711.5
0.5 µg NCO/m³	574.2	10.4	584.6
1 µg NCO/m³	155.7	10.4	166.1
3 µg NCO/m³	3.3	0.3	3.6
6 µg NCO/m³	-	-	-
10 µg NCO/m³	-	-	-
17.5 µg NCO/m³	-	-	-

Source: Study team

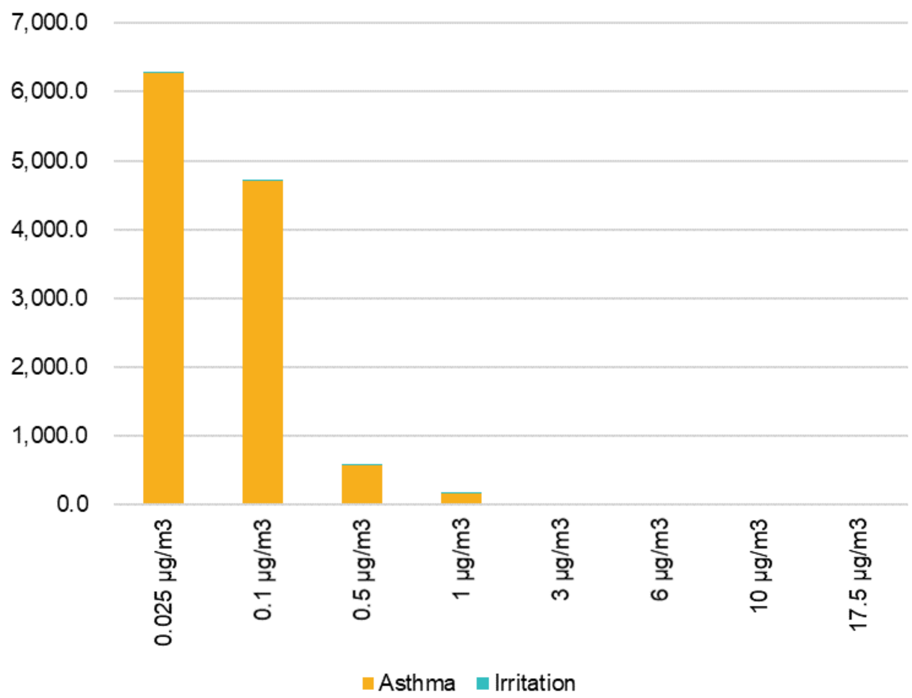


Figure 5-7 METHOD 2: Benefits from avoided ill health (relative to the baseline), € million
Source: Study team

To provide more sector details, the aggregated benefits under Method 2 are presented for each sector and OEL option in the table below.

Table 5-19 METHOD 2: Benefits avoided ill health by sector and OEL options (NCO), € million

Sector	0.025 µg/m³	0.1 µg/m³	0.5 µg/m³	1 µg/m³	3 µg/m³	6 µg/m³	10 µg/m³	17.5 µg/m³
C13 Textiles	€ 17	€ 16	€ 13	€ 9	€ 1	€ -	€ -	€ -
C14 Apparel	€ 30	€ 29	€ 22	€ 16	€ 2	€ -	€ -	€ -
C15 Leather	€ 129	€ 25	€ -	€ -	€ -	€ -	€ -	€ -
C16 Wood	€ 20	€ 16	€ -	€ -	€ -	€ -	€ -	€ -
C20 Chemicals	€ 25	€ 22	€ 8	€ 0.2	€ -	€ -	€ -	€ -
C22.21 Rigid foam	€ 7	€ 4	€ -	€ -	€ -	€ -	€ -	€ -
C22.29 Flexible foam	€ 19	€ 16	€ 7	€ -	€ -	€ -	€ -	€ -
C22 Other	€ 58	€ 47	€ -	€ -	€ -	€ -	€ -	€ -
C26 Computers	€ 28	€ 6	€ -	€ -	€ -	€ -	€ -	€ -
C27 Electrical equipment	€ 31	€ 24	€ -	€ -	€ -	€ -	€ -	€ -
C28 Machinery	€ 21	€ 8	€ -	€ -	€ -	€ -	€ -	€ -
C29 Motor vehicles	€ 277	€ 226	€ 1	€ 1	€ -	€ -	€ -	€ -
C30 Transport	€ 103	€ 88	€ 22	€ 0.3	€ -	€ -	€ -	€ -
C31 Furniture	€ 24	€ 15	€ -	€ -	€ -	€ -	€ -	€ -
C33 Machinery repair	€ 24	€ 21	€ 10	€ 1	€ -	€ -	€ -	€ -
F41.2 Construction	€ 1,852	€ 1,352	€ -	€ -	€ -	€ -	€ -	€ -
F42 Civil engineering	€ 49	€ 40	€ 0.2	€ 0.2	€ -	€ -	€ -	€ -
F43 Specialised construction	€ 2,609	€ 1,923	€ -	€ -	€ -	€ -	€ -	€ -
F43.29 Other installation	€ 15	€ 3	€ -	€ -	€ -	€ -	€ -	€ -
G45 Vehicle repair	€ 922	€ 828	€ 502	€ 138	€ -	€ -	€ -	€ -
S95 Repairs	€ 18	€ 3	€ -	€ -	€ -	€ -	€ -	€ -
Total	**€ 6,278**	**€ 4,712**	**€ 585**	**€ 166**	**€ 4**	**€ -**	**€ -**	**€ -**

Source: Study team

5.10 Discussion

The study team is concerned that some of the outputs of the benefits model do not appear to match reality.

- The model indicates that the benefits of a lower OEL begin 3 µg NCO/m³. At 3 µg NCO/m³ the benefit is also quite low (€ 2 to 3.57 million), there is only a reduction of 50 asthma case numbers beyond this point and therefore little benefit above this level.
- The model also indicates that the number of asthma cases is high at the lowest levels. It is particularly high in the construction sectors, where exposure is believed to be low.

There are few asthma cases above 3 µg NCO/m³ (only 50 additional cases between 3 and 6 µg NCO/m³ are shown on Table 5-6) because the exposure levels (8 hour TWA) are low because the average exposure for the top four percentiles are nearly all under 6 µg NCO/m³. This is because the OELs are being modelled and not the STEL. Unfortunately, it is not possible to derive a DRR for the short-term exposures, and therefore not possible to model the impact of a STEL, see section 2.3.5. Even if a DRR could be derived, the short-term data only exists for two sectors: C20 Chemicals and C22 Plastics. Furthermore, the short-term data is poor: the exposure levels available are lower than the equivalent 8-hour TWA, which makes no sense. If it were possible to model the STEL, the study team believes that this would lead to cases at higher exposure concentrations.

The reason for the high number of cases at the lowest exposure levels is probably due to a combination of reasons:

- The majority of exposure concentrations available indicate that the measurement was below the limit of quantification. This is unknown but is reasonably assumed to be 0.5 µg NCO/m³. The steering group decided that all measurements that were below the limit of quantification should be set at half this level or 0.25 µg NCO/m³. However, no-one knows the value of the actual measurements, and many may be much lower than this. Given that exposure distributions are usually a log-normal distribution and the long tail of concentrations below the median are usually much lower than the 95th percentile, it seems likely that many of the concentrations are indeed much lower than 0.25 µg NCO/m³. This is modelled in the sensitivity analysis in section 10.2.3.
- The DRR does appear to give relatively high excess risk values at the lowest exposure levels: 0.1% excess risk at 0.025 µg NCO/m³. This could be because the RAC opinion and the derivation of the DRRs for asthma are based upon two reports, one of which is based entirely on TDI (Collins et al., 2017) and another report, which is based entirely on HDI and spray painting (Pronk et al., 2009). As described in section 4.5.4, TDI has a greater saturated vapour concentration (SVC), it is more volatile and the vapour is more likely to be breathed in by employees, making it more hazardous. Spray painting is a particularly hazardous use of diisocyanates. Therefore, it is possible that the excess risk for sectors and uses that do not tend to use TDI and/or spray painting is lower than the DRR suggests and because these represent the large number of exposed workers, the number of cases and thus potential benefits is overestimated.

  However, the study team has no evidence that the data in these two reports is not representative of all diisocyanates and sought to consider all possible reasons for the apparent discrepancy between the expected and modelled number of cases occurring at low exposure levels.

- With 4,226,582 exposed workers, the number of cases is multiplied into high numbers quickly, amplifying any possible errors.

In the consultation survey, of the 239 responses, eight respondents report knowledge of cases of asthma and eleven report cases of sensitisation over the last 20 years. However, it is often difficult from the text to work out whether they are describing asthma or sensitisation. Several cases date back more than 20 years. Several cases are described as being related to incidents such as a spillage and/or an employee not wearing the correct protective clothing. Most of these cases related to companies using TDI, which are predominately in the C22.29 flexible foam sector, but sectors also include C20 chemicals and F43 specialised construction.

In C22.29 flexible foam, the sector that consumes the largest volume of TDI (which is described as being the most hazardous diisocyanate in section 4.5.3) and second largest volume of MDI, EUROPUR and EURO-MOULDERS have conducted annual occupational asthma surveys of their members for several years, see 4.6.4.1. EUROPUR and EURO-MOULDERS have calculated that the incidence rate of occupational asthma in their sector is typically below 0.1% or 2 to 5 cases per year. Where it was indicated that exposure was the cause of an occupational asthma cases, the cause is usually attributed to the employee approaching a leak or spill without wearing RPE or, the absence of, or incorrectly fitting RPE.

6. Costs assessment

6.1 Introduction

6.2 Impact of costs on different stakeholders

The costs assessed in this section, together with an indication of which stakeholders are likely to be affected, are presented Table 6-1 below.

Table 6-1 Impact of costs on different stakeholders

Type of cost		Consumers	Workers	Enterprises	Public authorities
Direct	Compliance costs Monitoring costs Administrative burden			✓	✓
Indirect	Product choice/price	✓	✓	✓	✓
Enforcement	Transposition, enforcement, monitoring and adjudication				✓
Employment	Lost wages		✓		

These costs are assessed below qualitatively and, whenever possible, quantitatively.

6.3 The cost framework

6.3.1 Introduction

Compliance costs are defined as the additional costs of complying with a limit value such as the costs incurred by companies in bringing down their exposure to levels below the limit value. This depends on the number of companies above the limit value and the cost for each company of reducing the exposure concentration to a level below the limit value. The costs for each company depend on the size of the relevant activities such as the number of machines and number of workers, and the gap between the actual exposure and the limit value, as well as the type of risk management measures required to bridge the gap.

A cost model developed for the previous OELs studies was developed to estimate the compliance costs of complying with the different limit value options. In summary, the characteristics of the relevant sectors, the RMMs in place, the sizes of the companies, and the required reduction in exposure, are used to propose suitable RMMs for each company. The model subsequently selects the cheapest of the suitable options. The results are summed up across all companies and sectors. A detailed description of the model is provided in the methodology report.

6.3.2 Summary of the key features of the cost model

The cost model is described in the methodology report accompanying this report. The cost model takes several inputs and calculates the predicted costs incurred for a range of OEL options. There are eleven types of inputs:

- Limit value options, see Table 3-1;
- Number of small, medium and large enterprises at each of the current exposure concentrations for each sector, see section 6.3.3;
- Estimated breakdown of primary risk management measures (RMM) used by enterprises for each sector, see section 6.3.4;
- Characteristics of diisocyanates and type of work, see section 6.3.8;
- Effectiveness of RMMs, see the methodological note;
- Cost of RMMs, see the methodological note;
- Discount rates, see the methodological note;
- Level of compliance with the OEL option, see the methodological note;
- Discontinuation cots per sector, see section 6.3.7;
- Estimated average number of exposed workers per company, see section 6.3.5; and
- Estimated average number of workstations using diisocyanates in small, medium and large enterprises, see section 6.3.6.

The output is the cost of implementing the OEL split by:

- Sector;
- Company size: small, medium and large; and
- Capital expenditure (one-off) and operating expenditure (recurrent).

6.3.3 Number of enterprises at current exposure levels

The key input parameters for both the cost and benefit estimation models developed for this study are the distribution of the actual exposure levels across enterprises or workers respectively. Whilst the distribution function for the benefit model focuses on the distribution of the workforce over different exposure concentrations, the key parameter for the cost function is the distribution of companies across different exposure levels. Although the ideal parameter would be the number of same exposure groups (SEGs), factory lines or facilities/sites operated by the different companies, such data are not available for diisocyanates and the number of companies together with their distribution across the different size bands is taken as a proxy in the cost model.

As explained in section 4.2.5, the companies in Member States that have already implemented OELs at different levels are not excluded, which means that the costs are overestimated by approximately 10%.

The exposure data for diisocyanates were collected through questionnaires, CSRs, literature review and communication with industry for each key sector and this is discussed in section 4.5. The exposure data was analysed to provide estimated percentile values (50th or median, 75th, 90th, 95th and 100th).

The cost model is based on three sizes of enterprise named small, medium and large. Small companies are those with less than 50 employees.

To obtain a cost estimate for each sector, the numbers of small, medium and large companies affected by diisocyanates at different exposure levels are entered into the model for each OEL option. These numbers are based upon the analysis described in section 4.5.8, and particularly the exposure levels in Table 4-15, adjusted according to Table 4-16, and then reduced by 50% to take account of REACH Restriction forming the revised baseline, see sections 4.17.1 and 4.17.3. Table 6-2 contains the numbers of companies allocated to each exposure levels. For example, in C13 Textiles, there are 2,982 companies of which 2,880 are small. Half of these, or 1,440 companies, are below the 50th percentile or median, and an exposure level of 0.3090 µg NCO/m³ is applied to this group of companies. A further 25%, or 720 companies, are taken to be between the 50th and 75th percentile and an exposure level of 0.5975 µg NCO/m³ is applied to this group of companies.

Table 6-2 Number of enterprises with workers exposed to diisocyanates at current exposure levels by size of enterprise by sector

Sector & exposure levels µg NCO/m³	Small	Medium	Large	Total
C13 Textiles	**2,880**	**87**	**15**	**2,982**
0.3090	1,440	44	7	1,491
0.5975	720	22	4	746
1.2255	432	13	2	447
2.5003	144	4	1	149
9.4055	144	4	1	149
C14 Apparel	**7,348**	**152**	**38**	**7,538**
0.3090	3,675	75	19	3,769
0.5975	1,837	38	9	1,884
1.2255	1,102	23	6	1,131
2.5003	367	8	2	377
9.4055	367	8	2	377
C15 Leather	**17,985**	**640**	**88**	**18,713**
0.1250	8,993	320	5	9,358
0.1250	4,496	160	22	4,678
0.1250	2,698	96	13	2,807
0.1250	899	32	4	935
0.2264	899	32	4	935
C16 Wood	**3,007**	**46**	**32**	**3,085**
0.1250	1,504	23	15	1,542

Sector & exposure levels µg NCO/m³	Small	Medium	Large	Total
0.1250	752	12	8	772
0.1250	451	7	5	463
0.2525	150	2	2	154
0.8026	150	2	2	154
C20 Chemicals	**1,295**	**133**	**44**	**1,472**
0.1250	647	66	22	735
0.1250	324	33	11	368
0.1850	194	20	7	221
0.5225	65	7	2	74
3.1106	65	7	2	74
C22.21 Rigid foam	**76**	**52**	**80**	**208**
0.1250	38	25	9	72
0.1250	19	13	36	68
0.1313	11	8	21	40
0.1938	4	3	7	14
0.9110	4	3	7	14
C22.29 Flexible foam	**124**	**81**	**27**	**232**
0.1380	62	41	14	117
0.1463	31	20	7	58
0.3018	19	12	4	35
0.6973	6	4	1	11
2.0889	6	4	1	11
C22 Other	**6,076**	**627**	**280**	**6,983**
0.1250	3,038	314	140	3,492
0.1250	1,519	157	70	1,746
0.1465	911	94	42	1,047
0.3210	304	31	14	349
0.9029	304	31	14	349
C26 Computers	**8,376**	**546**	**182**	**9,104**
0.1250	4,188	273	91	4,552
0.1250	2,094	137	46	2,277
0.1250	1,256	82	27	1,365
0.1250	419	27	9	455

Sector & exposure levels µg NCO/m³	Small	Medium	Large	Total
1.0329	419	27	9	455
C27 Electrical equipment	**8,120**	**944**	**378**	**9,442**
0.1250	4,060	472	189	4,721
0.1250	2,030	236	94	2,360
0.1250	1,218	142	57	1,417
0.2700	406	47	19	472
1.7583	406	47	19	472
C28 Machinery	**6,296**	**406**	**67**	**6,769**
0.1250	3,148	203	34	3,385
0.1250	1,574	102	17	1,693
0.1250	944	61	10	1,015
0.1388	315	20	3	338
1.6644	315	20	3	338
C29 Motor vehicles	**11,862**	**1,428**	**1,000**	**14,290**
0.1250	5,931	715	500	7,146
0.1250	2,966	357	250	3,573
0.1625	1,779	214	150	2,143
0.3328	593	71	50	714
2.5787	593	71	50	714
C30 Transport	**11,166**	**727**	**242**	**12,135**
0.1250	5,583	364	121	6,068
0.1250	2,792	182	61	3,035
0.1975	1,675	109	36	1,820
0.4750	558	36	12	606
2.6657	558	36	12	606
C31 Furniture	**17,120**	**316**	**58**	**17,494**
0.1250	8,560	158	29	8,747
0.1250	4,280	79	14	4,373
0.1250	2,568	47	9	2,624
0.1833	856	16	3	875
1.4470	856	16	3	875
C33 Machinery repair	**5,147**	**79**	**14**	**5,240**
0.1250	2,574	39	7	2,620

Sector & exposure levels µg NCO/m³	Small	Medium	Large	Total
0.1250	1,287	20	3	1,310
0.3125	772	12	2	786
0.7500	257	4	1	262
5.6218	257	4	1	262
F41.2 Construction	**604,907**	**4,434**	**360**	**609,701**
0.1250	302,454	2,217	180	304,851
0.1250	151,227	1,108	90	152,425
0.1358	90,736	665	54	91,455
0.2193	30,245	222	18	30,485
1.2167	30,245	222	18	30,485
F42 Civil engineering	**4,086**	**173**	**43**	**4,302**
0.1250	2,043	86	22	2,151
0.1250	1,022	43	11	1,076
0.1250	613	26	6	645
0.2823	204	9	2	215
2.7153	204	9	2	215
F43 Specialised construction	**1,278,848**	**5,139**	**514**	**1,284,501**
0.1250	639,425	2,569	257	642,251
0.1250	319,712	1,285	128	321,125
0.1250	191,827	771	77	192,675
0.2133	63,942	257	26	64,225
1.0236	63,942	257	26	64,225
F43.29 Other installation	**4,968**	**27**	**2**	**4,997**
0.1250	2,485	14	1	2,500
0.1250	1,242	7	1	1,250
0.1250	745	4	0	749
0.1250	248	1	0	249
1.5433	248	1	0	249
G45.2 Vehicle repair	**429,576**	**733**	**128**	**430,437**
0.1250	214,788	366	65	215,219
0.1250	107,394	183	32	107,609
0.2413	64,436	110	19	64,565
0.7988	21,479	37	6	21,522

Sector & exposure levels µg NCO/m³	Small	Medium	Large	Total
3.1965	21,479	37	6	21,522
S95 Repairs	**15,941**	**8**	**1**	**15,950**
0.1250	7,971	5	1	7,977
0.1250	3,985	2	0	3,987
0.1250	2,391	1	0	2,392
0.1250	797	0	0	797
0.2264	797	0	0	797
Total	**2,445,204**	**16,778**	**3,593**	**2,465,575**

Source: Study team
Note: Totals may not be the sum of all sectors due to rounding

6.3.4 Estimated breakdown of RMMs used by enterprises

The model requires a profile of the primary risk management measure used by enterprises in each sector. This is based upon the information in Table 4-30 and the data in section 4.7.3, together with detailed examination of the survey data and information from interviews with trade associations and site visits. This is difficult to define as most companies use several RMMs, but generally the primary is taken to be the highest level of RMM upon which the company depends.

Table 6-3 Percentage breakdown of primary RMMs currently used by enterprises by sector

Sector/	Full en-closure	Partial enclo-sure	Open hood	Pressur-ised or sealed cabin	Simple enclosed cabin	Breath-ing ap-paratus	HEPA fil-ter	Simple mask	Organi-sational measures	General dilution ventila-tion	No venti-lation	Total
C13 Textiles	10%	30%	30%	0%	0%	0%	10%	10%	0%	10%	0%	100%
C14 Apparel	10%	30%	30%	0%	0%	0%	10%	10%	0%	10%	0%	100%
C15 Leather	10%	30%	40%	0%	0%	0%	0%	10%	0%	10%	0%	100%
C16 Wood	10%	20%	30%	0%	0%	0%	30%	0%	0%	10%	0%	100%
C20 Chemicals	10%	20%	30%	0%	0%	0%	30%	0%	0%	10%	0%	100%
C22.21 Rigid foam	5%	45%	25%	0%	0%	0%	15%	0%	0%	10%	0%	100%
C22.29 Flexible foam	5%	45%	20%	0%	0%	10%	10%	0%	0%	10%	0%	100%
C22 Other	10%	35%	35%	0%	0%	5%	5%	0%	0%	10%	0%	100%
C26 Computers	0%	20%	30%	0%	0%	0%	50%	0%	0%	0%	0%	100%
C27 Electrical equipment	0%	40%	20%	0%	0%	0%	30%	0%	0%	10%	0%	100%
C28 Machinery	5%	25%	20%	0%	0%	25%	15%	0%	0%	10%	0%	100%
C29 Motor vehicles	5%	5%	20%	0%	0%	40%	20%	0%	0%	10%	0%	100%
C30 Transport	5%	5%	20%	0%	0%	40%	20%	0%	0%	10%	0%	100%

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	Total
C31 Furniture	10%	20%	20%	0%	0%	15%	15%	0%	0%	20%	0%	100%
C33 Machinery repair	5%	5%	20%	0%	0%	40%	20%	0%	0%	10%	0%	100%
F41.2 Construction	0%	0%	0%	0%	0%	0%	10%	30%	0%	0%	60%	100%
F42 Civil engineering	0%	0%	30%	0%	0%	0%	50%	0%	0%	0%	20%	100%
F43 Specialised construction	0%	0%	0%	0%	0%	0%	10%	30%	0%	0%	60%	100%
F43.29 Other installation	0%	0%	0%	0%	0%	0%	10%	30%	0%	0%	60%	100%
G45.2 Vehicle repair	0%	10%	10%	0%	0%	0%	30%	10%	0%	10%	30%	100%
S95 Repairs	0%	0%	10%	0%	0%	0%	0%	20%	0%	20%	50%	100%

Source: Study team

6.3.5 Estimated average number of exposed workers

The model requires an estimate of the average number of exposed workers per enterprise by size of enterprise in each sector. These estimates made by the study team are based upon the information in Table 4-27,and data in Table 4-56 split by size of enterprise according to Eurostat data about employees and the size of enterprise for which they work.

Table 6-4 Estimated average number of exposed workers per enterprise by size of enterprise by sector

Sector name	Number of exposed workers per company		
	Small	Medium	Large
C13 Textiles	1	16	82
C14 Apparel	1	15	45
C15 Leather	3	64	248
C16 Wood	3	68	122
C20 Chemicals	1	21	216
C22.21 Rigid foam	17	37	110
C22.29 Flexible foam	20	44	132
C22 Other	1	20	65
C26 Computers	1	9	79
C27 Electrical equipment	0.5	4	38
C28 Machinery	1	11	126
C29 Motor vehicles	1	11	142
C30 Transport	0.5	12	181
C31 Furniture	0.5	14	98
C33 Machinery repair	1	30	234
F41.2 Construction	2	56	448
F42 Civil engineering	2	40	356
F43 Specialised construction	1	38	281
F43.29 Other installation	2	64	718
G45.2 Vehicle repair	1	36	125
S95 Repairs	1	46	452

Source: Study team

6.3.6 Estimated average number of workstations

The model requires an estimate of the average number of workstations per enterprise by size of enterprise in each sector. These estimates made by the study team are based upon the information in Table 6-4 and the assumption that there will be five exposed employees per workstation; the numbers are rounded to the nearest integer and all values of 0.5 or lower are set to 0.5.

Table 6-5 Estimated average number of workstations per enterprise by size of enterprise by sector

Sector	Number of workstations per enterprises		
	Small	Medium	Large
C13 Textiles	0.5	3.0	16.0
C14 Apparel	0.5	3.0	9.0
C15 Leather	1.0	13.0	50.0
C16 Wood	0.5	14.0	24.0
C20 Chemicals	0.5	4.0	43.0
C22.21 Rigid foam	3.0	7.0	22.0
C22.29 Flexible foam	4.0	9.0	26.0
C22 Other	0.5	4.0	13.0
C26 Computers	0.5	2.0	16.0
C27 Electrical equipment	0.5	1.0	8.0
C28 Machinery	0.5	2.0	25.0
C29 Motor vehicles	0.5	2.0	28.0
C30 Transport	0.5	2.0	36.0
C31 Furniture	0.5	3.0	20.0
C33 Machinery repair	0.5	6.0	47.0
F41.2 Construction	0.5	11.0	89.0
F42 Civil engineering	0.5	8.0	71.0
F43 Specialised construction	0.5	8.0	56.0
F43.29 Other installation	0.5	13.0	144.0
G45.2 Vehicle repair	0.5	7.0	25.0
S95 Repairs	0.5	9.0	90.0

Source: Study team

6.3.7 Discontinuation costs by sector

A significant part of the cost of compliance is the cost of a company discontinuing if either the model can find no risk management measures that can comply with the OEL option or the costs of the risk management measures is higher than the cost of discontinuing. The discontinuation cost is taken as the loss of profit taken over 20 years and the average profit is assumed to be 10% of turnover of an average company in sector[11]. The average turnover of small, medium and large companies in the key sectors is shown in Table 6-6.

It is assumed that if the company has to discontinue activities using diisocyanates that this would mean the closure of a small or medium sized company, and the closure of a division representing 10% of a large company. The lost profit is therefore assumed to be 10% of annual turnover for 20 years for small and medium sized companies, discounted. For large companies, it is assumed to be 1% of annual turnover for 20 years, discounted.

Companies enter and exit the market continually and ideally discontinuations would be compared with the general level of companies leaving. The study team has not been able to identify any data on the typical number of firms leaving the market under normal circumstances. Whilst it would be possible to identify the number of firms in specific sectors and identify trends over time, these can be influenced by a multitude of different factors and represent net figures (they also include firms entering the market).

Further detail about discontinuation costs and the normal rate of insolvencies is in the methodological note. Further detail about the impact of discontinuation is provided in section 7.2.1.2.

Table 6-6 Average turnover by size of enterprise by sector

Sector	Average turnover in € millions		
	Small	Medium	Large
C13 Textiles	€400,000	€16,000,000	€79,000,000
C14 Apparel	€200,000	€7,000,000	€76,000,000
C15 Leather	€500,000	€11,000,000	€125,000,000
C16 Wood	€300,000	€17,000,000	€160,000,000
C20 Chemicals	€1,900,000	€48,000,000	€523,000,000
C22.21 Rigid foam	€1,100,000	€19,000,000	€103,000,000
C22.29 Flexible foam	€1,100,000	€19,000,000	€103,000,000
C22 Other	€1,100,000	€19,000,000	€163,000,000
C26 Computers	€900,000	€22,000,000	€333,000,000

[11] In RAC/SEAC 2017, on page 30, SEAC states that the “welfare impacts should be measured in terms of the expected profit losses as those correspond to the loss in producer surplus.” The study team makes the assumptions of profits being an average of 10% of turnover and that the losses are taken over 20 years.

Sector	Average turnover in € millions		
	Small	Medium	Large
C27 Electrical equipment	€800,000	€19,000,000	€267,000,000
C28 Machinery	€1,400,000	€21,000,000	€255,000,000
C29 Motor vehicles	€1,200,000	€24,000,000	€870,000,000
C30 Transport	€800,000	€21,000,000	€661,000,000
C31 Furniture	€300,000	€13,000,000	€89,000,000
C33 Machinery repair	€400,000	€15,000,000	€151,000,000
F41.2 Construction	€300,000	€18,000,000	€270,000,000
F42 Civil engineering	€700,000	€15,000,000	€204,000,000
F43 Specialised construction	€200,000	€13,000,000	€144,000,000
F43.29 Other installation	€200,000	€13,000,000	€144,000,000
G45.2 Vehicle repair	€200,000	€15,000,000	€201,000,000
S95 Repairs	€100,000	€14,000,000	€96,000,000

Source: Eurostat (2018)

6.3.8 Characteristics of diisocyanates and type of work

The use of diisocyanates in each sector identified in section 4.4 has certain characteristics and certain types of work during which exposure occurs. This information helps to determine the type of risk management measures that are suitable. These characteristics split into three groups:

- Duration of exposure over one day;
- Form of diisocyanates to which workers are exposed; and
- Extent to which diisocyanates disperse or spread when emitted.

The amount of exposure is split into work where the worker is exposed to diisocyanates for less than an hour a day and for more than an hour a day. This also equates to exposure for more or less than 2.5 days/month. Many production activities only occasionally use diisocyanates. Where the exposure is less than an hour a day, it is acceptable, and often more cost effective, to use respiratory protective equipment (RPE) such as masks with filters or breathing apparatus.

The form of substance to which workers are exposed varies considerably from dust and fibres to vapour, fumes, gas, mist, and aerosol. Again, the form of substance has a direct bearing on the types of RMM that are suitable. For example, general dilution ventilation is not recommended for removing dust as it tends to stir it up and spread it around. For this analysis, the substance form is split into two types: dust which also includes fibres; and gas which includes all the other types.

The extent of the spread is the final characteristic that affects the choice of RMM and this is split into three types: local, diffuse and peripheral. Local means the dust or gas is created around a specific machine and often means that highly targeted ventilation can effectively remove the chemical. Other processes spread the substance over a wider area and this is known as diffuse. In this case, dilution ventilation, workers enclosures or full enclosures are more suitable, the choice depending upon the decrease in exposure required. Peripheral means that the substance spreads more widely and cause exposure to workers beyond the area where the diisocyanates are being used. This means that administrators, managers and sales staff may be exposed.

In Table 6-7 below, the percentage split for each characteristic used in the analysis is given for each sector. These values were built into the cost model.

Table 6-7 Diisocyanates: amount of exposure, form of diisocyanates and extent of spread by sector

Sector	Amount		Form		Spread		
	<1h	>1h	Dust	Gas	Local	Diffuse	Peripheral
C13 Textiles	50%	50%	0%	100%	80%	20%	0%
C14 Apparel	50%	50%	0%	100%	80%	20%	0%
C15 Leather	50%	50%	0%	100%	80%	20%	0%
C16 Wood	50%	50%	0%	100%	80%	20%	0%
C20 Chemicals	50%	50%	0%	100%	80%	20%	0%
C22.21 Rigid foam	50%	50%	0%	100%	80%	20%	0%
C22.29 Flexible foam	20%	80%	0%	100%	80%	20%	0%
C22 Other	20%	80%	0%	100%	80%	20%	0%
C26 Computers	50%	50%	0%	100%	80%	20%	0%
C27 Electrical equipment	50%	50%	0%	100%	80%	20%	0%
C28 Machinery	50%	50%	0%	100%	80%	20%	0%
C29 Motor vehicles	20%	80%	0%	100%	80%	20%	0%
C30 Transport	20%	80%	0%	100%	80%	20%	0%
C31 Furniture	50%	50%	0%	100%	80%	20%	0%
C33 Machinery repair	20%	80%	0%	100%	80%	20%	0%
F41.2 Construction	80%	20%	0%	100%	80%	20%	0%

Sector	Amount		Form		Spread		
	<1h	>1h	Dust	Gas	Local	Diffuse	Peripheral
F42 Civil engineering	80%	20%	0%	100%	80%	20%	0%
F43 Specialised construction	20%	80%	0%	100%	80%	20%	0%
F43.29 Other installation	20%	80%	0%	100%	80%	20%	0%
G45.2 Vehicle repair	20%	80%	0%	100%	80%	20%	0%

Source: Study team
Note: Dust = dust and fibres, Gas = vapour, fumes, gas, mist and aerosol

6.4 Direct costs – compliance - for companies

The direct cost of compliance for companies is split into two parts:

- Cost of compliance with the required OEL: risk management measures
- Cost of monitoring to prove compliance

6.4.1 Survey and stakeholder consultation data on compliance costs

6.4.1.1 Survey - RMMs needed to achieve compliance

Table 6-8 outlines the percentage of companies currently using each RMM, and the RMM to which they would change if each of the STEL/OEL options were implemented. In addition to this, respondents that indicated they would not use a particular RMM under any of the STEL/OEL options are identified in the table under the 'never' category. This category implies respondents would use alternative RMMs to meet the STEL/OEL option. Each percentage in Table 6-8 is a percentage of the respondents in the sector. For example, in C16 Wood, currently no respondents use closed systems and 55% use partially closed systems. For the option of for a STEL of 12 µg NCO/m³ and an OEL of 6 µg NCO/m³, 64% of respondents say they would use closed systems. 45% of respondents state they would use partially closed systems: this may be because 36% say that they will substitute at this level. However, at a STEL of 2 µg NCO/m³ and an 1 µg NCO/m³, no respondents would use either closed or partially closed systems implying that respondents will not be able to reach this level, and this is reflected in the 82% that say they will discontinue.

The typical trend for these results is that the lower the STEL and OEL, the more intensive/expensive the RMMs required to reduce the exposure level. For example, a shift from open hoods to a partially closed system at a lower OEL. The table below shows some variation of this trend in that percentages at the lowest level may be lower than the previous RMM, suggesting companies may not move to the most effective RMM at the lowest level. However, where this occurs respondents usually indicate that they would expect to discontinue the line/business.

Table 6-9 provides the percentage of respondents that would not implement alternative RMMs as they are already complying with the proposed options. As shown in this table, 42% of respondents would not need to take any action to achieve a STEL of 12 µg NCO/m³ and OEL of 6 µg NCO/m^3 level. Only the C16 Wood, C20 Chemicals, C22.21 rigid foam and C22.29 flexible foam sectors have significant numbers of responses.

Table 6-10 outlines responses to the consultation question regarding other RMMs currently used in the workplace. Types of RMM typically involve the assessment and documentation of changes to risks in relation to diisocyanate exposure. However, as the table shows respondents did not indicate any additional RMMs that were not already included in this study.

Table 6-8 Companies' estimated change of RMMs for individual processes to meet each STEL/OEL option by sector

RMMs required / Sector STEL & OEL µg NCO/m³	Partial substitution	Discontinuation	Reduce amount	Reduce number	Worker rotation	Redesign	Closed systems	Partially closed sys	Open hoods	General ventilation	Sealed control cabs	Simple control cabs	Breathing apparatus	Powered respirators	Half & full facemasks	Disposable respirators	Face screens	Gloves	Gloves with a cuff	Safety boots	Rubber boots	Overalls	Coveralls	Training	REACH Restriction	Cleaning	Clothing storage	RPE cleaning	Continuous monitoring	Other
C15 Leather (1)																														
Current	0	0	0	100	100	0	0	0	100	0	0	0	0	0	0	0	0	100	0	100	0	0	0	0	0	0	0	0	0	0
12 & 6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6 & 3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2 & 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0.05 & 0.025	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Never	100	100	100	0	0	100	100	100	0	100	100	100	100	100	100	100	100	0	100	0	100	100	100	100	100	100	100	100	100	100
C16 Wood (11)																														
Current	9	0	36	64	64	0	0	55	64	100	27	9	0	9	82	36	9	91	18	100	36	64	9	100	82	82	91	91	27	0
12 & 6	36	0	36	55	55	9	64	45	55	55	0	9	27	27	82	73	73	91	27	91	27	36	27	91	91	91	91	91	27	0
6 & 3	36	27	36	45	45	9	45	45	55	55	0	9	36	0	64	55	55	64	0	64	9	9	0	64	64	64	64	64	0	0
2 & 1	0	82	0	0	0	0	0	0	9	9	0	9	18	0	18	9	9	18	0	18	9	9	0	64	27	18	18	18	0	0

RMMs required / Sector STEL & OEL µg NCO/m^3	Partial substitution	Discontinuation	Reduce amount	Reduce number	Worker rotation	Redesign	Closed systems	Partially closed sys	Open hoods	General ventilation	Sealed control cabs	Simple control cabs	Breathing apparatus	Powered respirators	Half & full facemasks	Disposable respirators	Face screens	Gloves	Gloves with a cuff	Safety boots	Rubber boots	Overalls	Coveralls	Training	REACH Restriction	Cleaning	Clothing storage	RPE cleaning	Continuous monitoring	Other
0.05 & 0.025	0	82	0	0	0	9	0	9	9	0	9	0	0	9	18	9	9	18	0	18	9	9	0	18	18	18	18	18	0	0
Never	55	18	64	36	36	82	27	36	0	0	64	91	18	64	0	18	27	9	73	0	55	36	73	0	9	9	0	9	45	100
C20 Chemicals (108)																														
Current	13	0	12	44	34	26	23	41	62	62	5	6	11	9	35	10	23	82	33	91	9	55	23	95	44	81	88	47	42	23
12 & 6	1	0	1	6	6	9	4	10	13	17	1	5	6	2	8	3	4	7	6	7	0	6	3	22	33	24	9	7	16	0
6 & 3	1	8	1	11	13	19	11	19	26	19	7	9	10	5	18	5	5	6	8	8	4	9	3	30	41	30	10	11	30	16
2 & 1	2	17	2	12	13	40	21	23	31	20	15	14	17	22	19	4	4	6	8	10	3	11	8	30	39	31	13	11	21	6
0.05 & 0.025	3	42	5	14	14	30	29	16	19	12	10	2	19	11	9	6	5	7	6	9	3	10	6	23	30	25	14	15	12	7
Never	83	58	85	50	53	38	45	41	19	30	70	74	63	70	52	83	73	18	63	8	88	43	69	4	32	16	11	45	38	71
C22.21 Rigid foam (19)																														
Current	0	0	5	47	16	32	5	63	37	58	0	5	0	11	21	21	5	74	47	100	5	26	21	95	68	79	47	5	53	11
12 & 6	0	5	0	16	16	5	5	21	16	11	5	11	5	5	11	16	5	16	5	16	5	11	11	26	21	21	16	0	5	0

RMMs required Sector STEL & OEL µg NCO/m^3	Partial substitution	Discontinuation	Reduce amount	Reduce number	Worker rotation	Redesign	Closed systems	Partially closed sys	Open hoods	General ventilation	Sealed control cabs	Simple control cabs	Breathing apparatus	Powered respirators	Half & full facemasks	Disposable respirators	Face screens	Gloves	Gloves with a cuff	Safety boots	Rubber boots	Overalls	Coveralls	Training	REACH Restriction	Cleaning	Clothing storage	RPE cleaning	Continuous monitoring	Other
6 & 3	5	0	5	16	11	26	21	0	5	11	16	0	11	11	16	11	5	5	5	5	0	5	11	16	11	11	5	0	16	0
2 & 1	5	21	0	5	11	21	26	5	11	5	16	5	16	16	16	11	11	16	21	16	11	11	11	16	11	11	11	11	11	0
0.05 & 0.025	5	26	5	5	16	26	26	0	11	5	16	0	16	21	11	11	5	16	21	16	5	5	11	32	21	16	11	5	11	0
Never	89	63	84	42	63	32	58	21	32	32	63	79	68	68	53	58	79	16	37	0	84	68	58	0	16	5	37	84	37	89
C22.29 Flexible foam (65)																														
Current	2	2	6	51	52	31	11	65	78	78	3	20	15	22	52	9	15	86	35	97	14	43	25	100	74	97	75	66	46	25
12 & 6	0	5	5	12	14	28	5	42	32	34	5	18	5	8	23	2	3	17	11	29	3	5	9	35	37	35	28	26	35	8
6 & 3	3	6	5	18	37	32	23	43	32	45	17	25	9	29	17	0	2	22	14	29	3	15	15	38	37	38	29	28	43	12
2 & 1	6	25	6	42	35	51	38	42	45	51	17	22	28	28	14	2	5	25	28	40	3	18	22	38	49	48	43	31	31	12
0.05 & 0.025	2	55	6	18	22	31	38	25	37	35	23	12	28	15	20	3	5	22	18	37	5	28	22	40	42	38	40	37	34	12
Never	89	45	83	34	22	31	34	15	11	8	66	51	46	58	38	88	83	12	40	3	82	37	52	0	12	3	6	17	17	58
C22 Other (6)																														
Current	0	0	0	17	33	17	33	50	50	50	0	0	0	0	17	33	0	83	0	83	0	17	0	83	50	67	67	0	33	17

RMMs required / Sector STEL & OEL µg NCO/m³	Partial substitution	Discontinuation	Reduce amount	Reduce number	Worker rotation	Redesign	Closed systems	Partially closed sys	Open hoods	General ventilation	Sealed control cabs	Simple control cabs	Breathing apparatus	Powered respirators	Half & full facemasks	Disposable respirators	Face screens	Gloves	Gloves with a cuff	Safety boots	Rubber boots	Overalls	Coveralls	Training	REACH Restriction	Cleaning	Clothing storage	RPE cleaning	Continuous monitoring	Other
12 & 6	17	17	0	33	50	17	33	50	67	50	0	0	17	0	17	33	17	67	17	67	0	0	17	67	67	33	17	17	17	0
6 & 3	0	17	0	0	0	0	17	17	33	17	0	0	0	0	17	0	0	33	0	33	0	0	0	17	33	17	0	0	0	0
2 & 1	17	17	0	17	17	0	17	33	33	0	0	0	0	0	33	17	17	33	0	33	0	17	0	17	33	33	33	0	0	0
0.05 & 0.025	0	33	0	17	17	33	50	33	17	0	0	0	17	17	50	0	17	33	17	33	0	0	17	17	33	17	17	17	17	0
Never	67	67	100	50	33	50	33	33	17	33	100	100	67	83	33	50	67	17	67	17	100	67	67	17	17	17	0	67	50	83
C26 Computers (1)																														
Current	0	0	0	100	0	100	0	0	0	100	0	0	0	0	100	0	0	100	0	100	0	100	0	100	100	0	100	0	100	0
12 & 6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	100	0	0	100	0	100	0	100	0	100	100	0	100	0	100	0
6 & 3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	100	0	0	100	0	100	0	100	0	100	100	0	100	0	100	0
2 & 1	0	0	0	100	100	100	100	0	0	0	0	100	0	100	0	0	0	100	100	100	0	100	100	100	100	0	0	100	100	100
0.05 & 0.025	0	0	0	100	100	100	100	0	0	0	0	100	0	100	0	0	0	100	100	100	0	100	100	100	100	0	0	100	100	100
Never	100	100	100	0	0	0	0	100	100	0	100	0	100	0	0	100	100	0	0	0	100	0	0	0	0	100	0	0	0	0

RMMs required / Sector STEL & OEL µg NCO/m³	Partial substitution	Discontinuation	Reduce amount	Reduce number	Worker rotation	Redesign	Closed systems	Partially closed sys	Open hoods	General ventilation	Sealed control cabs	Simple control cabs	Breathing apparatus	Powered respirators	Half & full facemasks	Disposable respirators	Face screens	Gloves	Gloves with a cuff	Safety boots	Rubber boots	Overalls	Coveralls	Training	REACH Restriction	Cleaning	Clothing storage	RPE cleaning	Continuous monitoring	Other
C27 Electrical equipment (1)																														
Current	0	0	0	100	100	100	0	100	100	100	0	100	0	0	100	0	0	100	0	100	0	0	0	100	100	100	100	100	0	0
12 & 6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6 & 3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2 & 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0.05 & 0.025	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Never	100	100	100	0	0	0	100	0	0	0	100	0	100	100	0	100	100	0	100	0	100	100	100	0	0	0	0	0	100	100
C29 Motor vehicles (5)																														
Current	20	0	20	40	20	20	20	20	60	40	20	0	40	0	40	40	0	80	80	100	20	40	40	100	80	100	20	40	40	0
12 & 6	0	0	0	0	0	0	0	0	0	0	0	0	20	20	20	20	20	20	20	20	20	20	20	40	20	40	20	20	20	20
6 & 3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	20	20	20	0	0	0	0
2 & 1	20	0	20	20	40	20	40	20	0	20	0	0	0	20	40	0	0	0	0	0	0	0	20	20	20	20	40	0	40	0

RMMs required / Sector STEL & OEL µg NCO/m³	Partial substitution	Discontinuation	Reduce amount	Reduce number	Worker rotation	Redesign	Closed systems	Partially closed sys	Open hoods	General ventilation	Sealed control cabs	Simple control cabs	Breathing apparatus	Powered respirators	Half & full facemasks	Disposable respirators	Face screens	Gloves	Gloves with a cuff	Safety boots	Rubber boots	Overalls	Coveralls	Training	REACH Restriction	Cleaning	Clothing storage	RPE cleaning	Continuous monitoring	Other
0.05 & 0.025	20	20	0	20	20	0	40	20	0	20	0	0	0	20	40	0	0	0	0	0	0	0	20	20	0	20	20	0	40	0
Never	60	80	80	40	40	60	40	60	40	40	80	100	60	60	0	60	80	20	20	0	60	40	20	0	20	0	40	40	40	80
F42 Civil engineering (1)																														
Current	0	0	0	0	0	0	0	0	100	0	0	0	0	0	100	0	0	100	0	100	0	100	0	0	0	0	0	0	0	0
12 & 6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6 & 3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2 & 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0.05 & 0.025	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Never	100	100	100	100	100	100	100	100	0	100	100	100	100	100	0	100	100	0	100	0	100	0	100	100	100	100	100	100	100	100
F43 Specialised construction (3)																														
Current	0	0	0	0	0	0	0	0	33	33	0	0	0	0	33	0	0	67	0	0	0	33	0	33	33	33	67	33	33	0

RMMs required / Sector STEL & OEL µg NCO/m^3	Partial substitution	Discontinuation	Reduce amount	Reduce number	Worker rotation	Redesign	Closed systems	Partially closed sys	Open hoods	General ventilation	Sealed control cabs	Simple control cabs	Breathing apparatus	Powered respirators	Half & full facemasks	Disposable respirators	Face screens	Gloves	Gloves with a cuff	Safety boots	Rubber boots	Overalls	Coveralls	Training	REACH Restriction	Cleaning	Clothing storage	RPE cleaning	Continuous monitoring	Other
12 & 6	0	33	0	0	0	0	33	0	33	33	0	0	33	33	33	0	0	67	0	67	33	33	67	67	33	67	67	33	0	0
6 & 3	0	67	0	0	0	33	33	0	0	0	0	0	0	33	0	0	0	33	0	33	33	33	33	33	33	33	33	0	0	0
2 & 1	0	67	0	0	0	33	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	33	0	0	0	0	0	0
0.05 & 0.025	0	67	0	0	0	33	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Never	100	33	100	100	100	67	67	100	67	67	100	100	67	67	67	100	100	33	100	33	67	33	33	33	67	33	33	67	67	100

Source: Consultation survey
Notes: Numbers against each sector indicate the number of responses

Table 6-9 Percentage of companies indicating no RMM action required at four STEL/OEL options by sector

STEL & OEL µg NCO/m³ Sector	12 & 6	6 & 3	2 & 1	0.05 & 0.025	Number of responses
C15 Leather	0%	0%	0%	0%	1
C16 Wood	27%	9%	9%	0%	11
C20 Chemicals	40%	24%	10%	4%	114
C22.21 Rigid foam	53%	37%	47%	5%	19
C22.29 Flexible foam	48%	31%	6%	0%	67
C22 Other	33%	17%	0%	0%	6
C26 Computers	100%	100%	0%	0%	1
C27Electrical equipment	0%	0%	0%	0%	1
C29 Motor vehicles	50%	17%	0%	0%	6
C30 Transport	0%	0%	0%	0%	1
F42 Civil engineering	0%	0%	0%	0%	1
F43 Specialised construction	33%	0%	0%	0%	3
Total	42%	25%	11%	3%	234

Source: Consultation survey

Table 6-10 Responses to consultation question: Other RMMs used in workplaces (n= 35)

Response	Frequency
Management of change in written form (one company) (A)	34% (12)
Preventative maintenance (one company) (B)	31% (11)
Medical surveillance (three companies) (C)	20% (7)
Workplace risk assessments (one company) (D)	6% (2)
Standard Operation Procedures (SOPs) (one company) (E)	6% (2)
Sampling devices in closed system (one company) (F)	6% (2)
Other unclassified responses	23% (8)

Source: Consultation survey
Notes: letters indicate that these responses include several from one organisation, A: 12 from one organisation, B: 11 from one, C: 7 from three, D: 2 from one, E: 2 from one, and F: 2 from one

6.4.1.2 Survey - Estimated cost of compliance

In the consultation survey, respondents were asked to estimate the magnitude of both one-off investment and annual recurrent costs required to achieve the STEL/OEL options. The results are displayed in Table 6-11 and Table 6-12. In general, the estimated value of investment costs increases by one order of magnitude with each step down in STEL/OEL options. Values in Table 6-11 represent percentages split by enterprise size, followed by the number of respondents in the last three columns to the right. For example, in C20 Chemicals, for a STEL of 12 µg NCO/m³ and an OEL of 6 µg NCO/m³, one-off costs are between zero and €10 million; for the STEL of 6 µg NCO/m³ and OEL of 3 µg NCO/m³, one-off costs range up to €100 million; for the STEL of 2 µg NCO/m³ and OEL of 1 µg NCO/m³, one-off costs range up to €1 billion; and for the STEL of 0.05 µg NCO/m³ and OEL of 0.025 µg NCO/m³, one-off costs range up to over €1 billion.

The results for the recurrent costs in Table 6-12 show as similar rise in costs with each step down in STEL/OEL options. Looking at the totals for each set of options, for a STEL of 12 µg NCO/m³ and an OEL of 6 µg NCO/m³, recurrent annual costs are between zero and €10 million; for 6 and 3 µg NCO/m³, recurrent annual costs are higher, and one company estimates an annual cost up to €100 million; and at the two lowest options, one company estimates costs of over €1 billion.

Table 6-11 Companies anticipated cost range for RMM initial investment costs required to achieve STEL/OEL options, by company size (values = %)

Sector	< €10,000			€10,000 - €100,000			€100,000 - €1 million			€1 million - €10 million			€10 million - €100 million			€100 million - €1 billion			Over € 1 billion			Number of responses per sector		
	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L
STEL of 12 µg NCO/m³ and OEL of 6 µg NCO/m³																								
C16	0	0	0	0	0	0	0	100	50	0	0	0	0	0	50	0	0	0	0	0	0	0	2	6
C20	100	38	53	0	25	12	0	28	18	0	9	18	0	0	0	0	0	0	0	0	0	3	32	17
C22.21	50	67	0	50	0	0	0	33	0	0	0	100	0	0	0	0	0	0	0	0	0	2	3	1
C22.29	0	26	73	20	6	0	40	55	18	40	13	9	0	0	0	0	0	0	0	0	0	5	31	11
C22	0	0	33	100	0	33	0	0	0	0	0	0	0	0	33	0	0	0	0	0	0	1	0	3
C26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F43	0	100	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
Total	**36**	**33**	**46**	**27**	**14**	**10**	**18**	**42**	**21**	**18**	**10**	**13**	**0**	**0**	**10**	**0**	**0**	**0**	**0**	**0**	**0**	**11**	**69**	**39**
STEL OF 6 µg NCO/m³ and OEL of 3 µg NCO/m³																								
C16	0	0	0	0	0	0	0	0	0	0	100	100	0	0	0	0	0	0	0	0	0	0	2	3
C20	0	24	6	100	18	0	0	34	39	0	18	39	0	5	17	0	0	0	0	0	0	3	38	18
C22.21	50	50	0	0	0	0	50	50	0	0	0	100	0	0	0	0	0	0	0	0	0	2	2	1

Sector	< €10,000			€10,000 - €100,000			€100,000 - €1 million			€1 million - €10 million			€10 million - €100 million			€100 million - €1 billion			Over € 1 billion			Number of responses per sector		
	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L
C22.29	0	19	50	0	6	20	40	23	20	20	48	10	40	3	0	0	0	0	0	0	0	5	31	10
C22	0	0	33	100	0	0	0	0	33	0	0	0	0	0	0	0	0	33	0	0	0	1	0	3
C26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F43	0	0	0	0	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Total	**9**	**22**	**19**	**36**	**12**	**6**	**27**	**29**	**31**	**9**	**33**	**33**	**18**	**4**	**8**	**0**	**0**	**3**	**0**	**0**	**0**	**11**	**73**	**36**
STEL of 2 µg NCO/m³ and OEL of 1 µg NCO/m³																								
C16	0	0	0	0	0	0	0	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	1
C20	0	5	6	44	11	0	56	16	0	0	43	24	0	22	65	0	3	6	0	0	0	9	37	17
C22.21	0	0	0	0	100	0	50	0	0	50	0	0	0	0	0	0	0	0	0	0	0	2	3	0
C22.29	0	5	0	0	33	50	0	14	20	100	43	20	0	5	10	0	0	0	0	0	0	5	21	10
C22	0	0	0	100	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
C26	0	0	0	0	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
F43	0	0	0	0	0	0	0	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	1
Total	**0**	**5**	**3**	**29**	**23**	**19**	**35**	**15**	**10**	**35**	**41**	**26**	**0**	**15**	**39**	**0**	**2**	**3**	**0**	**0**	**0**	**17**	**61**	**31**

Sector	< €10,000			€10,000 - €100,000			€100,000 - €1 million			€1 million - €10 million			€10 million - €100 million			€100 million - €1 billion			Over € 1 billion			Number of responses per sector		
	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L
STEL of 0.05 µg NCO/m³ and OEL of 0.025 µg NCO/m³																								
C16	0	0	0	0	0	0	0	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	1
C20	0	3	0	0	10	0	56	10	6	22	32	6	22	19	47	0	23	24	0	3	18	9	31	17
C22.21	33	0	0	0	0	100	0	0	0	67	0	0	0	0	0	0	0	0	0	0	0	3	0	1
C22.29	0	0	0	0	0	0	0	36	50	67	27	50	33	36	0	0	0	0	0	0	0	3	11	8
C22	0	0	0	100	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	2	0	1
C26	0	0	0	0	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
F43	0	0	0	0	0	0	0	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	1
Total	**6**	**2**	**0**	**12**	**7**	**3**	**29**	**17**	**23**	**35**	**31**	**23**	**18**	**24**	**27**	**0**	**17**	**13**	**0**	**2**	**10**	**17**	**42**	**30**

Source: Consultation survey

Table 6-12 Companies anticipated recurrent annual cost range for RMMs required to achieve STEL/OEL options, by company size (values = %)

Sector	< €10,000			€10,000 - €100,000			€100,000 - €1 million			€1 million - €10 million			€10 million - €100 million			€100 million - €1 billion			Over € 1 billion			Number of responses per sector		
	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L
STEL of 12 µg NCO/m³ and OEL of 6 µg NCO/m³																								
C16	0	0	0	0	0	0	0	100	40	0	0	60	0	0	0	0	0	0	0	0	0	0	2	5
C20	60	45	63	40	33	19	0	21	19	0	0	0	0	0	0	0	0	0	0	0	0	5	33	16
C22.21	33	100	0	67	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	3	3	1
C22.29	0	28	73	60	50	9	40	22	9	0	0	9	0	0	0	0	0	0	0	0	0	5	32	11
C22	100	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
C26	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
F43	0	100	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
Total	**36**	**39**	**56**	**50**	**38**	**14**	**14**	**23**	**19**	**0**	**0**	**11**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**14**	**71**	**36**
STEL OF 6 µg NCO/m³ and OEL of 3 µg NCO/m³																								
C16	0	0	0	0	0	0	0	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	2
C20	40	36	6	60	31	47	0	33	29	0	0	18	0	0	0	0	0	0	0	0	0	5	39	17
C22.21	100	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1

Sector	< €10,000			€10,000 - €100,000			€100,000 - €1 million			€1 million - €10 million			€10 million - €100 million			€100 million - €1 billion			Over € 1 billion			Number of responses per sector		
	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L
C22.29	33	50	0	33	50	0	33	0	100	0	0	0	0	0	0	0	0	0	0	0	0	3	2	1
C22	0	25	55	20	25	9	80	50	27	0	0	0	0	0	9	0	0	0	0	0	0	5	32	11
C26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F43	0	0	0	0	100	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
Total	**29**	**31**	**24**	**36**	**30**	**27**	**36**	**39**	**30**	**0**	**0**	**15**	**0**	**0**	**3**	**0**	**0**	**0**	**0**	**0**	**0**	**14**	**74**	**33**
STEL of 2 µg NCO/m³ and OEL of 1 µg NCO/m³																								
C16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
C20	33	10	6	56	33	11	11	35	44	0	20	33	0	0	6	0	0	0	0	3	0	9	40	18
C22.21	100	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
C22.29	0	0	0	67	100	0	33	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	2	0
C22	0	10	0	40	48	70	60	38	0	0	5	30	0	0	0	0	0	0	0	0	0	5	21	10
C26	0	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
F43	0	0	0	0	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Total	**22**	**10**	**3**	**50**	**40**	**35**	**28**	**35**	**29**	**0**	**14**	**29**	**0**	**0**	**3**	**0**	**0**	**0**	**0**	**2**	**0**	**18**	**63**	**31**

Sector	< €10,000			€10,000 - €100,000			€100,000 - €1 million			€1 million - €10 million			€10 million - €100 million			€100 million - €1 billion			Over € 1 billion			Number of responses per sector		
	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L
STEL of 0.05 µg NCO/m^3 and OEL of 0.025 µg NCO/m^3																								
C16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
C20	11	12	6	78	15	6	0	44	35	11	18	29	0	9	24	0	0	0	0	3	0	9	34	17
C22.21	50	0	0	50	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	1
C22.29	33	100	100	0	0	0	67	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	1	1
C22	0	9	0	67	0	13	33	64	50	0	27	25	0	0	13	0	0	0	0	0	0	3	11	8
C26	0	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
F43	0	0	0	0	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Total	**18**	**13**	**7**	**59**	**11**	**14**	**18**	**48**	**38**	**6**	**20**	**24**	**0**	**7**	**17**	**0**	**0**	**0**	**0**	**2**	**0**	**17**	**46**	**29**

Source: Consultation survey

6.4.1.3 Survey - Lowest technically possible and economically feasible options

As part of survey, respondents were asked for their view of the lowest technically possible, and economically feasible OEL/STEL options for their organisation using diisocyanates. The following four tables provide an overview of the responses.

The survey indicates that for the majority of companies, the STEL option of 10 µg NCO/m³ is the lowest technically possible and feasible limit value without significant numbers of companies' discontinuing operations using diisocyanates. A t a STEL of 6 µg/m³, only 50% respondents from C20 and C22.29 indicate they could reach this level.

Similar feedback is provided regarding lowest technically possible and feasible STEL and OEL options. At a STEL of 6 µg/m³, the percentage of companies technically able to meet the option value begins to drop substantially. Although respondents indicate they could technically reach lower OELs, the economic cost of doing so would render the change unfeasible for many. For example, in C20 Chemicals only 31% believe that a STEL of 6 µg/m³ or lower is technically possible, and only 25% think it is economically feasible. Looking at the OELs, for C20 Chemicals, only 40% believe that an OEL of 3 µg/m³ or lower is technically possible, and only 35% think it is economically feasible.

Table 6-13 Lowest technically possible 15-minute STEL (µg/m³ NCO) Values = %

Sector (n)	Lowest technically possible STEL %						
	<0.05	0.05 - 2	2 - 6	6 - 12	12 - 20	20 - 35	>35
	(µg NCO/m³)						
C16 (1)	0%	0%	0%	0%	0%	0%	100%
C20 (40)	3%	15%	13%	20%	23%	20%	8%
C22.21 (6)	0%	83%	0%	17%	0%	0%	0%
C22.29 (48)	0%	8%	35%	33%	21%	2%	0%
C22 (2)	0%	50%	0%	50%	0%	0%	0%
C26 (1)	0%	100%	0%	0%	0%	0%	0%
C29 (1)	0%	0%	100%	0%	0%	0%	0%
F43 (2)	0%	50%	50%	0%	0%	0%	0%
Total (101)	**1%**	**18%**	**24%**	**26%**	**19%**	**9%**	**4%**

Source: Consultation survey
Notes: n = number of responses

Table 6-14 Lowest economically feasible 15-minute STEL (µg/m³ NCO) Values = %

Sector (n)	Lowest economically feasible STEL %						
	<0.05	0.05 - 2	2 - 6	6 - 12	12 - 20	20 - 35	>35
	(µg NCO/m³)						
C16 (0)	0%	0%	0%	0%	0%	0%	0%
C20 (39)	0%	15%	10%	15%	31%	21%	8%
C22.21 (6)	17%	67%	0%	0%	17%	0%	0%
C22.29 (48)	0%	4%	33%	33%	15%	10%	4%
C22 (2)	0%	0%	50%	0%	0%	50%	0%
C26 (1)	0%	100%	0%	0%	0%	0%	0%
F43 (1)	0%	100%	0%	0%	0%	0%	0%
Total (97)	**1%**	**14%**	**22%**	**23%**	**21%**	**14%**	**5%**

Source: Consultation survey
Notes: n = number of responses

Table 6-15 Lowest technically possible 15-minute OEL (µg/m³ NCO) Values = %

Sector (n)	Lowest technically possible OEL %						
	<0.025	0.025 - 1	1 - 3	3 - 6	6 - 10	10 - 17.5	>17.5
	(µg NCO/m³)						
C16 (2)	0%	0%	50%	0%	0%	50%	0%
C20 (49)	4%	24%	12%	22%	8%	18%	10%
C22.21 (11)	0%	73%	9%	0%	0%	9%	9%
C22.29 (59)	0%	22%	27%	39%	2%	8%	2%
C22 (2)	0%	0%	50%	0%	50%	0%	0%
C26 (1)	0%	100%	0%	0%	0%	0%	0%
F43 (2)	0%	0%	50%	50%	0%	0%	0%
Total (129)	2%	26%	21%	27%	5%	12%	5%

Source: Consultation survey
Notes: n = number of responses

Table 6-16 Lowest economically feasible 15-minute OEL (µg/m³ NCO) Values = %

Sector (n)	Lowest economically feasible OEL %						
	<0.025	0.025 - 1	1 - 3	3 - 6	6 - 10	10 - 17.5	>17.5
	(µg NCO/m³)						
C16 (2)	0%	0%	50%	0%	0%	50%	0%
C20 (46)	0%	24%	9%	20%	13%	26%	9%
C22.21 (10)	0%	50%	0%	10%	0%	30%	10%
C22.29 (60)	0%	15%	27%	20%	22%	10%	7%
C22 (3)	0%	0%	67%	0%	0%	33%	0%
C26 (1)	0%	100%	0%	0%	0%	0%	0%
C27 (1)	100%	0%	0%	0%	0%	0%	0%
F43 (1)	0%	0%	100%	0%	0%	0%	0%
Total (125)	**1%**	**21%**	**19%**	**18%**	**15%**	**18%**	**8%**

Source: Consultation survey
Notes: n = number of responses

6.4.1.4 Survey - EU Member State Authorities

A total of 18 questionnaire responses were received from Member State Authorities (MSA). Ten MSAs answered the question *“what would be the impact of the following STELs and OELs for diisocyanates”* and the results are shown in Table 6-17 and Table 6-18 for STELs and OELs.

The MSAs think that there would be little impact at the highest STEL option, with increasing positive impact as the STEL options decrease, with 67% giving a significant positive impact at a STEL of 0.05 µg NCO/m³. The MSAs think there is a greater positive impact for the associated OELs, with 69% giving a moderate positive impact at a OEL of 6 µg NCO/m³ and the same percentage giving a significant positive impact at a OEL of 0.025 µg NCO/m³.

Table 6-17 Impact of the STEL options for di-isocyanates? Values = % (n) (N = 10)

Impact	STEL (µg NCO/m³)	Significant negative impact	Moderate negative impact	No impact	Moderate positive impact	Significant positive impact
Costs for companies	12	30%	40%	30%	-	-
	6	80%	20%	-	-	-
	2	90%	10%	-	-	-
	0.05	100%	-	-	-	-

Impact	STEL (µg NCO/m³)	Significant negative impact	Moderate negative impact	No impact	Moderate positive impact	Significant positive impact
Costs for public authorities	12	20%	30%	40%	-	10%
	6	40%	20%	30%	-	10%
	2	40%	30%	10%	-	10%
	0.05	63%	25%	-	-	12%
Competitive-ness	12	20%	30%	50%	-	-
	6	40%	30%	30%	-	-
	2	40%	30%	30%	-	-
	0.05	50%	20%	20%	10%	-
SMEs	12	30%	40%	30%	-	-
	6	70%	30%	-	-	-
	2	100%	-	-	-	-
	0.05	100%	-	-	-	-
Occupational health	12	17%	75%	-	-	8%
	6	34%	-	8%	58%	0%
	2	-	-	17%	33%	50%
	0.05	-	-	17%	17%	67%
Environment	12	-	-	56%	33%	11%
	6	-	-	44%	33%	22%
	2	-	-	44%	11%	44%
	0.05	-	-	44%	11%	44%

Source: Consultation survey

Table 6-18 Impact of the OEL options for di-isocyanates? Values = % (n) (N = 10)

Impact	OEL (µg/m³)	Significant negative impact	Moderate negative impact	No impact	Moderate positive impact	Significant positive impact
Costs for companies	6	36%	46%	18%	-	-
	3	64%	27%	-	-	-
	1	83%	17%	-	-	-
	0.025	92%	8%	-	-	-
Costs for public authorities	6	18%	27%	36%	-	9%
	3	36%	27%	27%	-	9%
	1	50%	17%	25%	-	8%
	0.025	55%	9%	27%	-	9%
Competitive-ness	6	40%	20%	30%	10%	-
	3	40%	30%	20%	10%	-
	1	-	70%	20%	-	10%
	0.025	70%	10%	20%	-	-
SMEs	6	46%	46%	8%	-	-
	3	64%	36%	-	-	-
	1	92%	8%	-	-	-
	0.025	100%	-	-	-	-
Occupational health	6	-	-	8%	69%	23%
	3	-	-	8%	62%	31%
	1	-	-	8%	39%	54%
	0.025	-	-	8%	23%	69%
Environment	6	-	-	44%	22%	33%
	3	-	-	44%	22%	33%
	1	-	-	44%	11%	44%
	0.025	-	-	44%	11%	44%

Source: Consultation survey

6.4.1.5 Industry report on cost estimates for OEL compliance on C22.21 Rigid Foam and C22.29 Flexible Foam production

For the foam sector, Triskelion was commissioned by ISOPA and ALIPA to conduct a study on the feasibility of diisocyanate OEL options. The data gathering involved companies answering a questionnaire similar to that developed by the study team.

The Triskelion study considered the use of RPE during activities where exposure data gathered included the use of RPE. Three different RPE considerations were developed:

- Half face mask with A2P2 filter (cf. EN 136/143) with an assigned protection factor of 10
- Full face mask with A2P3 filter (cf. EN 136/143) with an assigned protection factor of 20
- Powered full face mask (TM3) or powered hood or helmet (TH3) with (cf. EN 12942 or EN 12941) with an assigned protection factor of 40.

The study team assumed a 50% reduction factor where RPE was worn, this assumption may underestimate the protection offered by RPE when it is worn properly, however, in some cases it might have applied a factor where it was not being worn and therefore, overestimate the protection.

A total of 139 completed questionnaires were returned. The flexible foam sector (C22.29) formed the majority, with 91 completed questionnaires. Sectors for rigid foam (C22.21) and CASE (C20) were represented by 20 and 24 completed questionnaires respectively. Four responses were submitted by companies recycling fluid prepolymers, and a system house (companies creating complete bespoke systems) with different systems. Responses were provided from 18 EU Member States and the UK (the second highest number of responses came from the UK). There were responses by companies of different sizes, although most were from medium sized enterprises.

The use of diisocyanates by sectors matches the study team's expectations. All responders in the flexible slabstock foam C22.29 sector use TDI and the 78% that produce C22.21flexible foam also use MDI/pMDI. All responses from the rigid foam sector use MDI/pMDI only. The CASE C20 sector involved the most varied use of diisocyanates with most using MDI, TDI, IPDI, HDI and H12MDI.

The exposure data provided did not allowed for a clear calculation of exposure. However, from the average values provided, a weighted average (with a weight related to the number of datapoints) was calculated. The geometric mean of all single values (126 in total) was 0.27 ppb, with a GSD of 5.89. While these averages are below 1 ppb, this does not imply industry would easily comply with 1 ppb in general. See also Table 2-4 for conversion factors; 1 ppb of TDI equates to 3.42 µg NCO/m^3 and 1 ppb of MDI equates to 3.44 µg NCO/m^3,

The current technical controls in the flexible foam and rigid foam sectors are outlined in Figure 6-1. Comparing this with Table 6-3, whilst bearing in mind that the two tables present the data differently, there is broad similarity with both showing heavy reliance on enclosure or partially closed systems and fixed ventilation or open hoods. The Triskelion study indicates greater reliance on automation or closed systems that that shown in Table 6-3. If the percentages for closed systems had been higher in Table 6-3, this would have increased costs for these sectors.

	All	Flexible Foam	Rigid Foam
Enclosure	53.9	65.3	66.7
Local exhaust ventilation (flexible)	36.8	26.5	42.9
Local exhaust ventilation (fixed)	83.2	87.2	85.7
Room ventilation	63.0	61.1	83.3
Automation	50.7	51.0	75.0
Other technical controls	41.7	33.3	20.0

Figure 6-1 Reported current technical controls (in %) in the flexible foam and rigid foam sector by respondents
Source: (TRISKELION, 2021)

To achieve a lower OEL option, most respondents indicated that the process would need to become enclosed, also important was improving extraction ventilation and general ventilation. At the lowest levels in the survey, (fourteen respondents at 0.05 ppb (around 0.17 µg NCO/m^3) and eight respondents at 0.2 ppb (around 0.68 µg NCO/m^3)) some respondents indicated that it was not feasible to comply with the levels.

Operational controls required to meet the different levels were also considered. The most important one indicated by respondents was monitoring (personal monitoring and stationary concentration monitoring programmes) followed by training, see Figure 6-2. However, a number of responders also indicated that continuous exposure monitoring is not able to measure diisocyanate levels below 1 ppb.

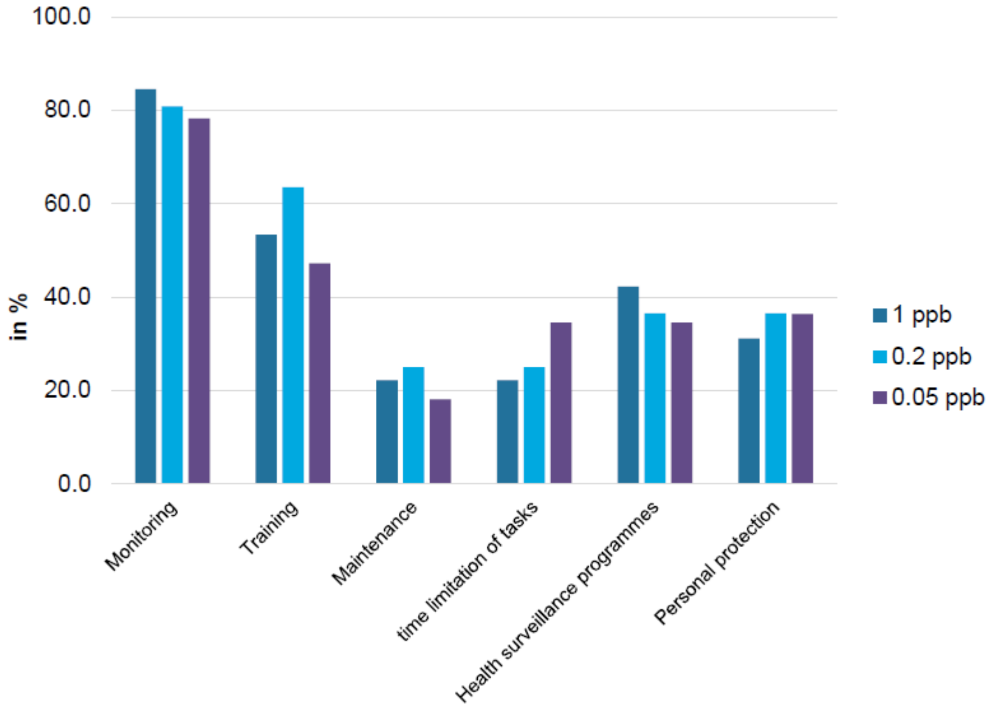


Figure 6-2 Percentage of questionnaires with investment needs indicating operational control measures to comply with questionnaire values (1 ppb n=45; 0.2 ppb n=52; 0.05 ppb n= 55).
Source: (TRISKELION, 2021)

The use of different types of RPE (Half-face mask (A2P2), Full-face mask (A2P3) and Powered mask (TM3/TH3)) was predicted to significantly increase the level of protection offered to exposed employees, however, to comply with some of the options values investigated, some operational areas would require the continuous use of RPE.

Triskelion also investigated the one-off investment and recurrent costs. Not all questionnaire responses provided information on costs, of those responding, investments were required at 54% of sites at an option value of 1 ppb, this increased to 72% of sites at an option value of 0.2 ppb. At 0.2 ppb, two sites indicate that it is not feasible to comply with this option value and seven sites indicate that further assessment of the exposure values on site would be necessary. At the option value of 0.05 ppb, 68% of sites indicated the need for investment, three sites indicated this level would not be feasible for them to comply with and three sites would need further assessment of the exposure values on site.

Although two sites indicated investments would not be needed at 0.05 ppb, one of these sites has a small-scale production of limited quantities of PU Elastomer with low exposure values. The second site is a testing laboratory for final product testing. Neither site is considered representative of the general PU industry.

The average investment costs per option value were calculated based on the sites that indicated an investment would be needed. Two slabstock (C22.29) production sites suggested that investment costs for a new factory would range between €10,000,000 and €51,000,000. The average, minimum, maximum and total costs indicated in the completed surveys are indicated in Figure 6-3 and the average costs in the flexible foam sector, where costs are highest, are indicated in Figure 6-4. The maximum cost per site for 0.05 ppb appears to be an error and is believed to be 9,000 or €9,000,000.

(number of sites)	1 ppb *(44)*	0.2 ppb *(59)*	0.05 ppb *(56)*
Average*	223	591	1334
Min	4	4	14
Max	1500	7500	900
Total reported costs	10017	37246	80067

* Excluding sites which indicated that new factories need to be built to comply with lower reference values.

Figure 6-3 Investment costs per site per option value (in thousands of euros) for sites indicating investment costs, but not needing to build a new factory to achieve these values

Source: (TRISKELION, 2021)

	1 ppb	0.2 ppb	0.05 ppb
All	223	591	1334
- Flexible Foam	234	738	1796
- Rigid Foam	150	257	412
- CASE	203	250	411
- Other:	0	0	0

Figure 6-4 Average investment costs per site indicating the need of investment costs, but excluding those that need completely new factories (in thousands of euros) per option value for the different sectors

Source: (TRISKELION, 2021)

From the responses about investment costs, there was no apparent relationship between company size and average investment costs. The average investment costs were estimated as increase from €223,000 per site at 1 ppb to €1,334,000 per site at 0.05 ppb, but Triskelion noted the large variation. The investment costs for companies with 50-100 employees were identified as being much higher in comparison with other company sizes, these average investment costs were €2,441,000 per site. However, there was a greater response from enterprises of this size than from enterprises with more than 500 employees.

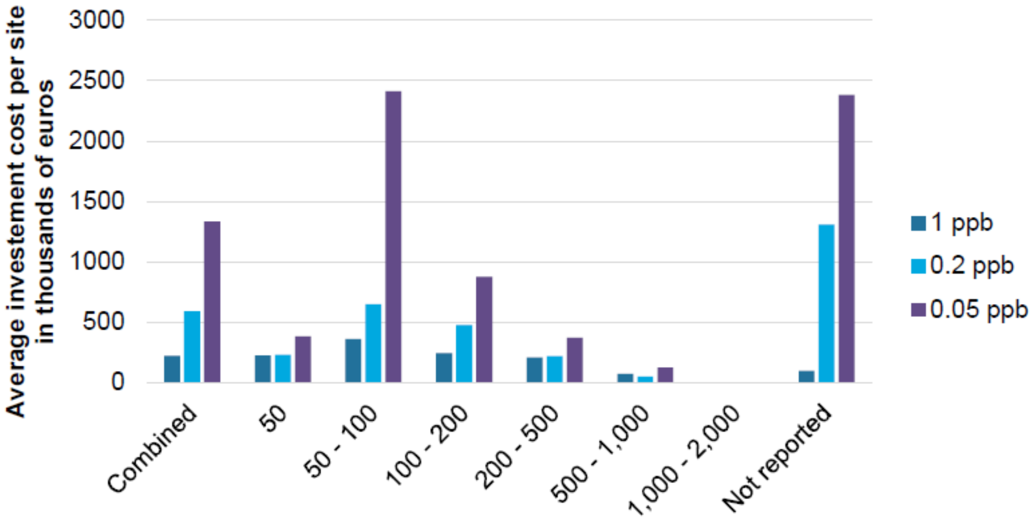


Figure 6-5 Average investment costs in thousands of Euros per site indicating a need for investment costs, but excluding sites that indicated a need to build a complete new factory (number of respondents are listed in the table below).

Source: (TRISKELION, 2021)

Average recurring costs were calculated based on the available data for flexible and rigid foam. For flexible slabstock (C22.29), the cost increased from €42,000 /year at 1 ppb to €54,000/year at 0.2 ppb.

For rigid foam (C22.21), the few responses also showed an increase in recurring costs with an average of around €38,000/year at 1 ppb and €84,000/year at 0.05 ppb.

Several additional comments were provided by responders which are consistent with the study team's findings, including the fact that you cannot presently conduct continuous monitoring at the lower option values as the measurement devices currently available have a limit of detection at about 1 ppb.

TRISKELIN concluded that for sites to comply with a STEL of 1.75 ppb level, without further technical control measures, it would be necessary for employees to use a powered full-face mask or hood/helmet (TM3/TH3), with an assigned protection factor of 40. However, for most sites to comply with a STEL of 5 ppb, the use of a full face mask with A2P3 filter with an assigned protection factor of 20 would be sufficient.

Assuming that the total investment costs provided in the survey are representative of the total industry, Triskelion extrapolated costs for the flexible slabstock (C22.29) and flexible moulded (C22.21) sectors, including UK based factors and excluding sites needing a new factory to be built. For flexible slabstock (C22.29), the total one-off investment costs are indicated as increasing from around €8-25 million for 1 ppb to €69-766 million for 0.05 ppb. For the moulded sub-sector and the rigid foam (C22.21), there are also clear increases in expected investment costs, but they are at a lower level, reaching around €13-35 million at 0.05 ppb for both. When new factories are included, the total one-off investment costs rise to around €900 million for the flexible slabstock (C22.29) enterprises.

For all flexible slabstock, flexible moulded and rigid foam, recurrent costs were estimated at between an order of € 1 to 10 million per year at an OEL of 1 ppb. Although recurring costs were estimated to increase at lower OEL levels, the increase was not clear.

Triskelion suggested that whilst an OEL of 1 ppb may be feasible, with a STEL of 2 ppb, the investment and recurring costs would be high. The flexible slabstock (C22.29) sector would have the greatest difficulty complying with lower values, because of the exposures in the sector and the costs to achieve the lower option values. Triskelion suggested that it is likely that a substantial number of diisocyanate using companies would become unprofitable, but their study did not quantify the financial viability of companies or their ability to cope with much higher costs.

6.4.2 Cost of risk management measures to achieve compliance

The cost model considers companies using each type of RMM and works out which new RMM is required to achieve the OEL option. The model calculates the one-off and recurrent costs of the new RMM. It also calculates the recurrent cost of the old RMM and the one-off costs of the old RMM that would have been expected at 20 and 40 years: these are deducted from the costs for the new RMMs as the company was already expecting to pay for these.

The estimated compliance costs over 40 years (one-off and recurrent) that are incremental to the baseline, together with the combined present value over 40 years for the key sectors are summarised in Table 6-19, Table 6-20 and Table 6-21 below.

The estimated combined compliance costs over 40 years split by company size are shown in Table 6-22 and these compliance costs per company are shown in Table 6-23. As explained in section 4.5.5, some costs are over-estimated by approximately 10% as the companies in Member States that already have OELs are not excluded.

In Table 6-20, the recurrent compliance costs are given and there are several negative values. There are good reasons for negative values in some circumstances such as when the industry predominantly uses RPE and moves to local exhaust ventilation (LEV). RPE tends to have a small one-off cost, but a high recurrent cost, whereas LEV has high one-off costs and lower recurrent costs. However, negative values also arise when a company using closed systems has to discontinue. In these circumstances, the one-off and recurrent costs are also deducted and because discontinuation has no recurrent costs, this immediately appears as a negative cost. It is debatable whether or not these costs should be deducted; if they were not, the overall present value of these costs would increase further. This is explained in detail in the methodological note.

In Table 6-21, there is a negative total compliance cost for a few sectors, which occurs when companies primarily use RPE, and which the costs model estimates move to LEV probably closed systems or partially closed systems. As explained above, RPE tends to have a small one-off cost, but a high recurrent cost, whereas LEV has high one-off costs and lower recurrent costs. This negative value shows that in this instance, over 40 years, the cost of operating RPE is higher than installing and running LEV. This sounds irrational, but companies may prefer to pay more over 40 years, rather than face a substantial one-off sum: in particular, small companies may find it difficult to borrow the funds for the investment.

If this investment is available, there is a long-term benefit to the company in moving to more cost effective RMMs and no longer having to rely on RPE. There is also a benefit for workers if they do not have to wear RPE.

Initial and recurrent investment costs estimated by respondents in the consultation survey, see section 6.4.1.2, Table 6-11 and Table 6-12, generally corroborate the modelled compliance costs (RMM compliance) in most OEL options for C20 Chemicals and C22 Plastics. However, for some OEL options, the modelled costs for C20 Chemicals and C22.29 underestimate the values according to those provided by industry representatives in the consultation survey.

Consultation feedback in Table 6-11 and Table 6-12 suggests potentially much higher levels, with one-off investment costs between under €10,000 and up to €100 million for medium sized companies. Specifically, in Table 6-11, for an OEL option of 1 µg NCO/m³, 5% of medium sized companies indicate initial investment of under €10,000, 23% between €10,000 and €100,000, 15% between €100,000 and €1 million, 41% between €1 million and €10 million, 4% between €10 million and €100 million, and 2% between €100 million and €1 billion. This approximates to an initial investment of over €1 million. These costs cannot be directly compared with those in Source: *Study team*

Table 6-23 as the study's cost model assumes two rounds of one-off investment at year 1 and year 21, and the costs are discounted over 40 years. In Table 6-12, 10% of medium sized companies indicate annual running costs of under €10,000, 40% between €10,000 and €100,000, 35% between €100,000 and €1 million, and 14% between €1 million and €10 million. This approximates to a recurrent cost of hundreds of thousands of euro. Again, these are not at all comparable costs as study's cost model adds these to the one-off costs, and these costs would be taken for all 40 years and discounted. The companies in the consultation survey were predominantly from C20 chemicals and the C22 sectors.

Examining the C20 compliance (RMMs only) costs for a medium sized company in Table 6-21, they are € 85,427,338, which divided by the number of medium sized C20 Chemicals companies (132) gives a cost per company of € 647,177 for both initial investment and recurrent costs. This indicates that the study's cost model may be underestimating the cost of compliance (RMMs only).

In Table 6-18 of section 6.4.1.4, are the Member State authorities' views of the potential impact of the different OEL options. For an OEL of 3 µg NCO/m³, 64% expect a significant negative impact and 27% expect a moderate negative impact.

In section 6.4.1.5, the Triskelion study estimates that for flexible slabstock (C22.29), the total one-off investment costs are indicated as increasing from around €9 million - €25 million for 1 ppb, which is approximately 3.4 µg NCO/m³. These numbers also indicate that the study's cost model may be underestimating the cost of compliance (RMMs only).

Table 6-19 One-off compliance costs (present value) over 40 years for the OEL options by sector (excluding the costs of monitoring and associated administrative burden)

Sector	OEL options (µg NCO /m3)							
	0.025	0.1	0.5	1	3	6	10	17.5
C13	€1,106,545,828	€639,377,357	€145,865,700	€62,975,659	€24,224,950	€4,503,097	€0	€0
C14	€1,272,573,070	€799,693,236	€214,896,680	€96,256,256	€31,977,224	€10,321,333	€0	€0
C15	€3,789,789,967	€1,176,913,087	€0	€0	€0	€0	€0	€0
C16	€473,123,989	€128,675,034	€4,813,672	€0	€0	€0	€0	€0
C20	€2,509,559,871	€459,673,819	€86,100,256	€81,853,531	€3,359,182	€0	€0	€0
C22.21	€290,300,208	€103,868,363	€6,410,371	€0	€0	€0	€0	€0
C22.29	€589,190,051	€170,231,101	€26,186,559	€23,281,682	€0	€0	€0	€0
C22	€5,765,137,849	€1,084,030,035	€29,572,519	€0	€0	€0	€0	€0
C26	€1,796,987,413	€440,038,829	€25,564,456	€21,532,811	€0	€0	€0	€0
C27	€2,404,609,974	€565,064,878	€37,345,331	€27,977,156	€0	€0	€0	€0
C28	€8,818,044,457	€722,302,282	€414,479,398	€16,368,907	€0	€0	€0	€0
C29	€90,742,577,700	€12,112,057,503	€4,324,481,507	€4,307,279,997	€0	€0	€0	€0
C30	€27,606,290,611	€7,598,526,131	€1,329,995,309	€1,284,577,279	€0	€0	€0	€0

Sector	OEL options (μg NCO /m3)							
	0.025	0.1	0.5	1	3	6	10	17.5
C31	€4,063,411,659	€674,535,071	€188,881,071	€24,889,328	€0	€0	€0	€0
C33	€2,407,136,419	€782,635,615	€124,904,189	€112,719,745	€10,892,552	€0	€0	€0
F41.2	€20,595,314,309	€7,909,774,148	€534,754,048	€330,177,035	€0	€0	€0	€0
F42	€419,440,163	€202,581,312	€3,702,919	€1,137,435	€0	€0	€0	€0
F43	€43,070,035,482	€18,032,133,994	€895,413,224	€770,102,165	€0	€0	€0	€0
F43.29	€160,775,635	€53,096,821	€2,976,266	€2,095,088	€0	€0	€0	€0
G45.2	€19,677,877,219	€11,591,633,836	€1,106,889,659	€507,660,733	€439,194,879	€0	€0	€0
S95	€501,722,916	€156,740,748	€0	€0	€0	€0	€0	€0
Total	**€238,060,444,786**	**€65,403,583,200**	**€9,503,233,132**	**€7,670,884,807**	**€509,648,786**	**€14,824,430**	**€0**	**€0**

Source: Study team

Table 6-20 Recurrent compliance costs (present value) over 40 years for the OEL options by sector (excluding the costs of monitoring and associated administrative burden)

Sector	OEL options (µg NCO /m3)							
	0.025	0.1	0.5	1	3	6	10	17.5
C13	€113,029,790	€51,843,055	€7,400,980	€4,126,723	€164,754	-€1,227,625	€0	€0
C14	€284,542,737	€126,793,201	€17,360,046	€9,840,260	€173,103	-€3,135,864	€0	€0
C15	€674,770,854	-€141,382,853	€0	€0	€0	€0	€0	€0
C16	€124,296,961	€24,256,224	€771,735	€0	€0	€0	€0	€0
C20	€118,211,399	€31,949,719	€7,760,341	€3,573,807	€1,164,260	€0	€0	€0
C22.21	€136,666,673	€32,267,729	€1,601,334	€0	€0	€0	€0	€0
C22.29	-€45,105,832	-€71,252,691	-€5,920,673	-€3,028,255	€0	€0	€0	€0
C22	€299,628,399	-€209,708,205	-€12,113,713	€0	€0	€0	€0	€0
C26	€1,127,263,772	€328,604,522	€44,975,459	€13,493,255	€0	€0	€0	€0
C27	€1,159,044,729	€110,126,175	€33,877,424	€1,118,123	€0	€0	€0	€0
C28	-€218,277,753	-€223,176,326	-€19,520,650	-€11,134,786	€0	€0	€0	€0
C29	-€5,753,436,748	-€4,549,256,229	-€284,555,209	-€306,786,777	€0	€0	€0	€0
C30	-€1,863,034,356	-€1,450,230,259	-€155,190,343	-€100,856,375	€0	€0	€0	€0

Sector	OEL options (µg NCO /m3)							
	0.025	0.1	0.5	1	3	6	10	17.5
C31	-€174,541,969	-€217,502,231	-€18,127,692	-€10,369,909	€0	€0	€0	€0
C33	-€304,510,111	-€202,960,757	-€20,411,906	-€14,997,771	-€7,729,162	€0	€0	€0
F41.2	€18,067,274,478	€3,286,205,590	€455,579,579	€94,313,500	€0	€0	€0	€0
F42	€295,242,563	€71,089,214	€15,308,012	€13,008,996	€0	€0	€0	€0
F43	€45,423,373,911	€16,608,264,361	€1,189,720,074	€628,615,509	€0	€0	€0	€0
F43.29	€177,183,036	€60,439,188	€4,501,562	€2,262,769	€0	€0	€0	€0
G45.2	€18,404,666,487	€8,837,001,576	€1,202,756,521	€670,560,682	€322,785,331	€0	€0	€0
S95	€116,673,134	-€97,831,189	€0	€0	€0	€0	€0	€0
Total	**€78,162,962,154**	**€22,405,539,814**	**€2,465,772,881**	**€993,739,752**	**€316,558,285**	**-€4,363,489**	**€0**	**€0**

Source: Study team

Table 6-21 Total compliance costs, (one-off and recurring, present value) over 40 years for the OEL options by sector (excluding the costs of monitoring and associated administrative burden)

Sector	OEL options (µg NCO /m3)							
	0.025	0.1	0.5	1	3	6	10	17.5
C13	€1,219,575,617	€691,220,412	€153,266,680	€67,102,382	€24,389,704	€3,275,472	€0	€0
C14	€1,557,115,807	€926,486,437	€232,256,725	€106,096,516	€32,150,327	€7,185,469	€0	€0
C15	€4,464,560,821	€1,035,530,234	€0	€0	€0	€0	€0	€0
C16	€597,420,950	€152,931,257	€5,585,408	€0	€0	€0	€0	€0
C20	€2,627,771,270	€491,623,538	€93,860,597	€85,427,338	€4,523,442	€0	€0	€0
C22.21	€426,966,881	€136,136,092	€8,011,705	€0	€0	€0	€0	€0
C22.29	€544,084,219	€98,978,409	€20,265,886	€20,253,426	€0	€0	€0	€0
C22	€6,064,766,248	€874,321,830	€17,458,806	€0	€0	€0	€0	€0
C26	€2,924,251,185	€768,643,351	€70,539,914	€35,026,066	€0	€0	€0	€0
C27	€3,563,654,702	€675,191,052	€71,222,755	€29,095,279	€0	€0	€0	€0
C28	€8,599,766,704	€499,125,956	€394,958,748	€5,234,121	€0	€0	€0	€0
C29	€84,989,140,951	€7,562,801,274	€4,039,926,298	€4,000,493,219	€0	€0	€0	€0
C30	€25,743,256,255	€6,148,295,872	€1,174,804,966	€1,183,720,903	€0	€0	€0	€0

Sector	OEL options (µg NCO /m3)							
	0.025	0.1	0.5	1	3	6	10	17.5
C31	€3,888,869,691	€457,032,840	€170,753,379	€14,519,420	€0	€0	€0	€0
C33	€2,102,626,308	€579,674,858	€104,492,284	€97,721,974	€3,163,389	€0	€0	€0
F41.2	€38,662,588,786	€11,195,979,738	€990,333,627	€424,490,536	€0	€0	€0	€0
F42	€714,682,726	€273,670,526	€19,010,931	€14,146,431	€0	€0	€0	€0
F43	€88,493,409,392	€34,640,398,355	€2,085,133,299	€1,398,717,674	€0	€0	€0	€0
F43.29	€337,958,670	€113,536,009	€7,477,828	€4,357,857	€0	€0	€0	€0
G45.2	€38,082,543,706	€20,428,635,412	€2,309,646,180	€1,178,221,415	€761,980,209	€0	€0	€0
S95	€618,396,050	€58,909,559	€0	€0	€0	€0	€0	€0
Total	**€316,223,406,940**	**€87,809,123,013**	**€11,969,006,014**	**€8,664,624,559**	**€826,207,072**	**€10,460,941**	**€0**	**€0**

Source: Study team

Table 6-22 PV compliance costs over 40 years for the OEL options by company size (excluding the costs of monitoring and associated administrative burden)

Size	OEL options (µg NCO /m3)							
	0.025	0.1	0.5	1	3	6	10	17.5
Small	€188,389,707,224	€71,213,522,263	€6,650,575,826	€3,894,386,273	€792,311,986	€6,582,562	€0	€0
Medium	€57,271,927,794	€10,798,107,834	€2,251,159,003	€1,819,567,592	€27,316,222	€2,158,097	€0	€0
Large	€70,561,771,922	€5,797,492,916	€3,067,271,185	€2,950,670,694	€6,578,864	€1,720,281	€0	€0
Total	€316,223,406,940	€87,809,123,013	€11,969,006,014	€8,664,624,559	€826,207,072	€10,460,941	**€0**	**€0**

Source: Study team

Table 6-23 PV compliance costs per company over 40 years per company for the OEL options by company size (excluding the costs of monitoring and associated administrative burden)

Size	OEL options (µg NCO /m3)							
	0.025	0.1	0.5	1	3	6	10	17.5
Small	€77,044	€29,124	€2,720	€1,593	€324	€3	€0	€0
Medium	€3,413,449	€643,575	€134,171	€108,448	€1,628	€129	€0	€0
Large	€19,972,577	€1,640,986	€868,194	€835,190	€1,862	€487	€0	€0
Total	€128,258	€35,615	€4,855	€3,514	€335	€4	**€0**	**€0**

Source: Study team

6.4.3 Monitoring costs

In section 4.2.5, approximately 65% of enterprises are assumed to be operating in Member States that have existing OELs and STELs for at least MDI or TDI diisocyanates. Although all enterprises in Member States with an existing OEL and STEL are required to comply with these limits, only a proportion are believed to already be measuring the 8-hour TWA and short-term exposure levels regularly. In most Member States, if a company has low exposure levels, well below the OEL/STEL, it is usually not expected to measure it. The study team assumes that 50% of companies are currently monitoring compliance with the OEL and STEL if their Member State has OEL is the baseline of 17.5 NCO µg/m^3 or higher. From this, it follows that if an OEL is introduced in the Member States covering the remaining 35% of enterprises, 50% of these would start to monitor.

As the OEL/STEL options decrease, the study team assumes that the proportion of companies that have to monitor will increase as fewer and fewer companies operate well below the OEL and STEL. The estimated proportions of companies for the OEL options have been grouped into three bands as shown in Table 6-24. Figure 6-6 shows the proportions of enterprises that are currently monitoring and would have to start monitoring as EU-wide OELs and STELs were introduced at the different OEL options.

Table 6-24 Proportion of enterprises assumed to be currently monitoring and estimated to start monitoring at different OEL options

OEL option (µg NCO /m^3)	Proportion of companies monitoring
10, 17.5	50%
3, 6	75%
1, 0.5, 0.1, 0.025	100%

Source: Study team estimates

The cost of monitoring the OEL and STEL for small, medium and large companies is based upon several further assumptions. The first is that OEL and STEL monitoring are done at same time, which means that the costs of administration, planning, execution and reporting are shared and only cost of sample/filter and analysis is specific to OEL or STEL. The sample and analysis costs are shown in Table 6-25: the sample filter costs for LOQ below 1 NCO µg/m^3 are believed to be available and are estimated. The base cost is the one-off cost of analysis in addition to the cost of analysis of each sample.

However, it is possible that OEL options of 0.1 and 0.025 cannot be sampled at all due to the limit of quantification as discussed in section 4.12.3:

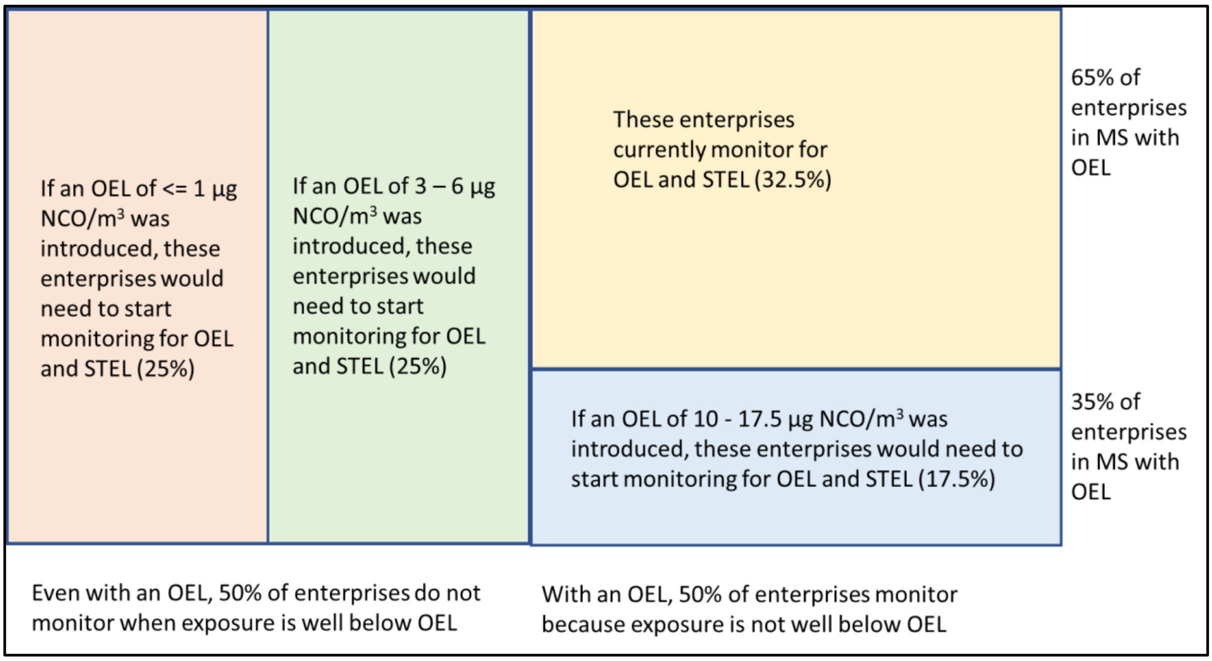


Figure 6-6 Proportion of enterprises currently monitoring and estimated to start monitoring at different OEL options

Source: Study team estimates

Table 6-25 Proportion of enterprises currently monitoring and estimated to start monitoring at different OEL options

Sample or analysis	Cost €
Sample/filter – 8 hour TWA LOQ >= 1 NCO µg/m³ ISO 16702:2007 / LC-MS. 25 or 47 mm glass fiber filtre coated with 1-(2-methoxyphenyl)piperazin (2-MP)	55
Sample/filter – 8 hour TWA LOQ < 1 NCO µg/m³	110 Estimated
Sample/filter – Short term LOQ >= 1 NCO µg/m³ ISO 16702:2001, ISO 17734-1:2006, ISO 17734-2:2006. Impingers containing Dibutyl amine reagent in Toluene	110
Sample/filter – Short term LOQ < 1 NCO µg/m³	220 Estimated
Analysis – 8 hour TWA	184
Analysis – Short term	166
Analysis – base cost	278

Source: Eurofins

Furthermore, three samples per workstation for OEL and STEL each are assumed, and, from these assumptions, the cost of sampling and analysis is estimated. The planning, execution and reporting is assumed to be done by a middle manager or external OSH consultant and an average daily rate of €500/day is assumed. Based upon the numbers of workstations calculated in Table 6-5, the number of days required according to the size of company is approximately shown in Table 6-26.

Table 6-26 Approximate number of days to complete monitoring by company size

	No. workstations	Days required
Small	1	2.5
Medium	6	4
Large	40	20

Source: Study team estimates

The study team is aware that Member State authorities enforcing OELs are amenable to ways of reducing the number and frequency of measurements required if they believe that the exposure levels are low and/or unlikely to change. Methods include (with many variations):

- Measuring every three to five years or whenever the process changed.
- Measuring exposure levels, together with the extraction rates of the ventilation system. No further measurements are required other than a regular check on the ventilation extraction rates unless the process is changed.

The monitoring and their associated administrative burden, see section 6.5, can be reduced, according to CAD, as there is no need for monitoring if you can demonstrate by other means adequate protection. If there were OSH guidelines on good practice for each sector and company size, this could help companies to recognise when they could use alternative means to demonstrate adequate protection and could reduce the monitoring and administrative burden costs.

To arrive at a cost, the study team assumes that monitoring will take place every five years and therefore the average costs for all sizes of company are discounted over 40 years, taking the cost every fifth year. These costs for LOQ above and below 1 NCO µg/m^3 are shown in Table 6-27.

Table 6-27 Cost of monitoring and average cost discounted over 40 years, measuring every fifth year, by size of enterprise, by LOQ above and below 1 NCO µg/m^3

Company size	Cost per company of monitoring (taking place every five years)	Cost per company of monitoring discounted over 40 years, measuring every fifth year
LOQ >= 1 NCO µg/m^3		
Small	€2,328	€10,351
Medium	€7,405	€32,922
Large	€40,945	€182,041
LOQ < 1 NCO µg/m^3		
Small	€2,490	€11,071
Medium	€8,377	€37,244
Large	€47,425	€210,851

Source: Study team

ISOPA/ALIPA, a trade association, estimated that the cost of samples/filters and analysis for 10 samples using a conventional HPLC-UV method (LOQ approximately 1 NCO µg/m^3) using a treated filter sampler is approximately €50 per sample. This equates to approximately €500 for a 10-sample monitoring campaign excluding shipment costs.

ISOPA/ALIPA's estimate of the cost of a similar campaign using monitoring methods with LOQs down to 0.0025 NCO µg/m^3 is of costs of approximately €300 per sample and therefore a 10-sample campaign would cost approximately €3,000. This would use methods such as:

- ISO 17734-1:2013 Workplace air quality for isocyanates: Impinger/filter or tube/filter containing, impregnated, or coated with DBA and HPLC/MS analytics
- ISO 17734-2:2013 Workplace air quality for isocyanates: Impinger/filter or tube/filter containing, impregnated, or coated with DBA and ECF using HPLC/MS analytics

These costs do not include the planning, execution, and reporting of the campaign.

Based upon these costs and the numbers of companies in each sector by size, the total cost of additional monitoring by company size and sector discounted over 40 years is shown in Table 6-28.

Table 6-28 PV cost of monitoring discounted over 40 years, based upon measuring every fifth year by size of enterprise by sector, by groups of OEL options

Sector	PV cost of monitoring over 40 years, based upon measuring every fifth year by group of OEL options			
	Small	Medium	Large	Total
OEL options of 10 and 17.5 µg NCO/m³				
C13 Textiles	€5,216,552	€508,606	€456,051	€6,181,209
C14 Apparel	€13,313,247	€868,587	€1,200,703	€15,382,536
C15 Leather	€32,578,687	€3,687,569	€2,861,788	€39,128,044
C16 Wood	€5,448,257	€266,593	€982,741	€6,697,591
C20 Chemicals	€2,345,650	€763,004	€1,406,332	€4,514,987
C22.21 Rigid foam	€137,288	€288,356	€546,668	€972,311
C22.29 Flexible foam	€224,653	€471,855	€894,548	€1,591,055
C22. Other	€11,004,787	€3,620,835	€8,898,329	€23,523,951
C26 Computers	€15,172,333	€3,147,166	€5,800,702	€24,120,201
C27 Electrical equipment	€14,707,898	€5,439,463	€12,030,902	€32,178,263
C28 Machinery	€11,404,071	€2,340,087	€2,156,567	€15,900,725
C29 Motor vehicles	€21,488,227	€8,234,293	€31,871,798	€61,594,318
C30 Transport	€20,227,111	€4,195,668	€7,733,250	€32,156,029
C31 Furniture	€31,012,398	€1,816,150	€1,842,215	€34,670,762
C33 Machinery repair	€9,326,115	€452,859	€417,344	€10,196,319
F41.2 Construction	€1,095,746,511	€25,541,259	€11,456,435	€1,132,744,205
F42 Civil engineering	€7,401,908	€991,252	€1,370,270	€9,763,430
F43 Specialised construction	€2,316,539,675	€29,601,839	€16,368,199	€2,362,509,712
F43.29 Other installation	€9,001,936	€159,322	€89,624	€9,250,882
G45.2 Vehicle repair	€778,145,657	€4,215,830	€4,113,748	€786,475,235
S95 Repairs	€28,877,611	€55,147	€50,822	€28,983,580
Total	**€4,429,320,572**	**€96,665,739**	**€112,549,035**	**€4,638,535,346**
OEL options of 3 and 6 µg NCO /m³				
C13 Textiles	€12,668,768	€1,235,187	€1,107,553	€15,011,508

Sector	PV cost of monitoring over 40 years, based upon measuring every fifth year by group of OEL options			
	Small	Medium	Large	Total
C14 Apparel	€32,332,171	€2,109,425	€2,915,992	€37,357,588
C15 Leather	€79,119,668	€8,955,524	€6,950,057	€95,025,249
C16 Wood	€13,231,482	€647,439	€2,386,657	€16,265,578
C20 Chemicals	€5,696,580	€1,853,010	€3,415,378	€10,964,968
C22.21 Rigid foam	€333,413	€700,292	€1,327,622	€2,361,328
C22.29 Flexible foam	€545,586	€1,145,932	€2,172,473	€3,863,991
C22. Other	€26,725,912	€8,793,457	€21,610,226	€57,129,595
C26 Computers	€36,847,094	€7,643,117	€14,087,420	€58,577,631
C27 Electrical equipment	€35,719,181	€13,210,124	€29,217,905	€78,147,209
C28 Machinery	€27,695,600	€5,683,069	€5,237,377	€38,616,047
C29 Motor vehicles	€52,185,693	€19,997,569	€77,402,938	€149,586,200
C30 Transport	€49,122,983	€10,189,479	€18,780,751	€78,093,213
C31 Furniture	€75,315,823	€4,410,650	€4,473,950	€84,200,423
C33 Machinery repair	€22,649,137	€1,099,801	€1,013,550	€24,762,488
F41.2 Construction	€2,661,098,670	€62,028,772	€27,822,771	€2,750,950,213
F42 Civil engineering	€17,976,063	€2,407,325	€3,327,798	€23,711,187
F43 Specialised construction	€5,625,882,067	€71,890,180	€39,751,340	€5,737,523,587
F43.29 Other installation	€ 21,861,846	€386,925	€217,657	€22,466,428
G45.2 Vehicle repair	€1,889,782,310	€10,238,445	€9,990,530	€1,910,011,286
S95 Repairs	€70,131,342	€133,928	€123,425	€70,388,695
Total	**€10,756,921,389**	**€234,759,652**	**€273,333,371**	**€11,265,014,412**
OEL options of 1 µg NCO /m³				
C13 Textiles	€20,120,985	€1,961,767	€1,759,054	€23,841,806
C14 Apparel	€51,351,095	€3,350,263	€4,631,281	€59,332,640
C15 Leather	€125,660,650	€14,223,480	€11,038,325	€150,922,455
C16 Wood	€21,014,707	€1,028,286	€3,790,572	€25,833,565
C20 Chemicals	€9,047,509	€2,943,017	€5,424,424	€17,414,950

Sector	PV cost of monitoring over 40 years, based upon measuring every fifth year by group of OEL options			
	Small	Medium	Large	Total
C22.21 Rigid foam	€529,539	€1,112,228	€2,108,577	€3,750,344
C22.29 Flexible foam	€866,518	€1,820,010	€3,450,398	€6,136,927
C22. Other	€42,447,037	€13,966,078	€34,322,124	€90,735,239
C26 Computers	€58,521,855	€12,139,068	€22,374,137	€93,035,060
C27 Electrical equipment	€56,730,463	€20,980,784	€46,404,908	€124,116,156
C28 Machinery	€43,987,130	€9,026,051	€8,318,188	€61,331,368
C29 Motor vehicles	€82,883,159	€31,760,845	€122,934,079	€237,578,083
C30 Transport	€78,018,855	€16,183,291	€29,828,251	€124,030,397
C31 Furniture	€119,619,249	€7,005,150	€7,105,685	€133,730,083
C33 Machinery repair	€35,972,159	€1,746,743	€1,609,756	€39,328,658
F41.2 Construction	€4,226,450,829	€98,516,285	€44,189,106	€4,369,156,221
F42 Civil engineering	€28,550,217	€3,823,399	€5,285,327	€37,658,944
F43 Specialised construction	€8,935,224,459	€114,178,521	€63,134,481	€9,112,537,462
F43.29 Other installation	€34,721,755	€614,528	€345,691	€35,681,974
G45.2 Vehicle repair	€3,001,418,963	€16,261,060	€15,867,313	€3,033,547,336
S95 Repairs	€111,385,073	€212,709	€196,028	€111,793,809
Total	**€17,084,522,206**	**€372,853,565**	**€434,117,706**	**€17,891,493,477**
OEL options of 0.025, 0.1, 0.5 µg NCO /m³				
C13 Textiles	€21,521,379	€2,219,279	€2,037,445	€25,778,103
C14 Apparel	€54,925,065	€3,790,036	€5,364,235	€64,079,336
C15 Leather	€134,406,468	€16,090,525	€12,785,268	€163,282,261
C16 Wood	€22,477,303	€1,163,264	€4,390,474	€28,031,041
C20 Chemicals	€9,677,204	€3,329,332	€6,282,902	€19,289,438
C22.21 Rigid foam	€566,394	€1,258,225	€2,442,283	€4,266,903
C22.29 Flexible foam	€926,827	€2,058,914	€3,996,464	€6,982,205
C22. Other	€45,401,295	€15,799,336	€39,753,998	€100,954,629
C26 Computers	€62,594,900	€13,732,503	€25,915,103	€102,242,507

Sector	PV cost of monitoring over 40 years, based upon measuring every fifth year by group of OEL options			
	Small	Medium	Large	Total
C27 Electrical equipment	€60,678,830	€23,734,827	€53,749,022	€138,162,679
C28 Machinery	€47,048,577	€10,210,855	€9,634,637	€66,894,069
C29 Motor vehicles	€88,651,720	€35,929,932	€142,389,820	€266,971,472
C30 Transport	€83,448,867	€18,307,591	€34,548,917	€136,305,374
C31 Furniture	€127,944,593	€7,924,681	€8,230,242	€144,099,516
C33 Machinery repair	€38,475,775	€1,976,029	€1,864,518	€42,316,322
F41.2 Construction	€4,520,606,337	€111,448,026	€51,182,544	€4,683,236,907
F42 Civil engineering	€30,537,276	€4,325,278	€6,121,791	€40,984,345
F43 Specialised construction	€9,557,104,518	€129,166,165	€73,126,244	€9,759,396,927
F43.29 Other installation	€37,138,344	€695,194	€400,401	€38,233,939
G45.2 Vehicle repair	€3,210,313,839	€18,395,568	€18,378,499	€3,247,087,905
S95 Repairs	€119,137,330	€240,630	€227,051	€119,605,011
Total	**€18,273,582,842**	**€421,796,189**	**€502,821,859**	**€19,198,200,891**

Source: Study team

6.5 Direct costs – administrative burdens and charges

The administrative burden is the administrative costs for companies and Member State authorities (MSAs).

MSAs incur admin costs if, for example, more reporting back to the EU is required, for example, or there are other additional administrative burdens. No significant additional reporting is anticipated and any other administrative burdens for MSAs cannot be identified or quantified.

For enterprises, the cost of planning, executing and reporting the sampling and analysis of monitoring is part of compliance costs and is usually done by a specialist company. However, someone in the enterprise has to work out what is required and the management of monitoring by the third party and this administrative task is as company administrative burden. The number of days required each year to manage a monitoring event, the cost of a monitoring event, and the cost of monitoring every five years discounted over 40 years is shown in Table 6-29.

Table 6-29 Annual cost of companies' administrative burden and administrative burden discounted over 40 years, measuring every fifth year, by size of enterprise

Company size	Days to manage monitoring	Cost per company to manage monitoring	Cost per company to manage monitoring discounted over 40 years, measuring every fifth year
Small	1	€500	€2,223
Medium	5	€2,500	€11,115
Large	10	€5,000	€22,230

Based upon these costs and the numbers of companies in each sector by size, see Table 4-57, and the proportions of companies monitoring, see Table 6-24 and Figure 6-6, the total cost of the enterprises administrative burden of managing monitoring by company size and sector, discounted over 40 years, based upon monitoring every five years, is shown in Table 6-30.

All enterprises must comply with OELs and STELs. However, in the construction sectors (F41.2, F42, F43 and F43.29) and the vehicle repair sector (G45.2), there are numerous micro companies, many of which employ one person. It is possible that many will not be required to monitor their compliance. As a result, the costs of monitoring and administrative burden could be overestimated. The option of removing micro companies from the calculations of monitoring and administrative burden is explored in the sensitivity analysis in section 10.2.5.

As explained in section 6.4.3 on monitoring costs, monitoring and the administrative burden of monitoring can be reduced, according to CAD, as there is no need for monitoring if you can demonstrate by other means adequate protection. If there were OSH guidelines on good practice for each sector and company size, this could help companies to recognise when they could use alternative means to demonstrate adequate protection and could reduce the monitoring and administrative burden costs.

Table 6-30 PV cost of administrative burden of managing monitoring discounted over 40 years, based upon monitoring every fifth year by size of enterprise by sector, by groups of OEL options

Sector	PV administrative burden of managing monitoring over 40 years, based upon monitoring every fifth year by group of OEL options			
	Small	Medium	Large	Total
OEL options of 10 and 17.5 µg NCO /m³				
C13 Textiles	€1,120,316	€171,714	€55,691	€1,347,721
C14 Apparel	€2,859,178	€293,249	€146,624	€3,299,051
C15 Leather	€6,996,659	€1,244,983	€349,469	€8,591,111
C16 Wood	€1,170,078	€90,006	€120,008	€1,380,092
C20 Chemicals	€503,756	€257,603	€171,735	€933,094

Sector	PV administrative burden of managing monitoring over 40 years, based upon monitoring every fifth year by group of OEL options			
	Small	Medium	Large	Total
C22.21 Rigid foam	€29,484	€97,354	€66,757	€193,594
C22.29 Flexible foam	€48,247	€159,306	€109,238	€316,791
C22. Other	€2,363,409	€1,222,453	€1,086,625	€4,672,486
C26 Computers	€3,258,438	€1,062,534	€708,356	€5,029,329
C27 Electrical equipment	€3,158,695	€1,836,451	€1,469,161	€6,464,307
C28 Machinery	€2,449,159	€790,051	€263,350	€3,502,561
C29 Motor vehicles	€4,614,851	€2,780,031	€3,892,043	€11,286,926
C30 Transport	€4,344,012	€1,416,526	€944,350	€6,704,888
C31 Furniture	€6,660,280	€613,162	€224,963	€7,498,405
C33 Machinery repair	€2,002,894	€152,893	€50,964	€2,206,751
F41.2 Construction	€235,324,557	€8,623,144	€1,399,009	€245,346,710
F42 Civil engineering	€1,589,648	€334,663	€167,331	€2,091,642
F43 Specialised construction	€497,504,366	€9,994,061	€1,998,812	€509,497,240
F43.29 Other installation	€1,933,273	€53,790	€10,944	€1,998,007
G45.2 Vehicle repair	€167,116,008	€1,423,333	€502,353	€169,041,693
S95 Repairs	€6,201,810	€18,618	€6,206	€6,226,634
Total	**€951,249,119**	**€32,635,922**	**€13,743,992**	**€997,629,033**
OEL options of 3 and 6 µg NCO /m^3				
C13 Textiles	€2,720,768	€417,019	€135,249	€3,273,037
C14 Apparel	€6,943,717	€712,176	€356,088	€8,011,981
C15 Leather	€16,991,887	€3,023,530	€848,710	€20,864,128
C16 Wood	€2,841,618	€218,586	€291,448	€3,351,652
C20 Chemicals	€1,223,408	€625,606	€417,071	€2,266,085
C22.21 Rigid foam	€71,604	€236,430	€162,123	€470,158
C22.29 Flexible foam	€117,171	€386,885	€265,293	€769,349
C22. Other	€5,739,707	€2,968,814	€2,638,946	€11,347,466

Sector	PV administrative burden of managing monitoring over 40 years, based upon monitoring every fifth year by group of OEL options			
	Small	Medium	Large	Total
C26 Computers	€7,913,350	€2,580,440	€1,720,294	€12,214,084
C27 Electrical equipment	€7,671,118	€4,459,952	€3,567,962	€15,699,031
C28 Machinery	€5,947,959	€1,918,696	€639,565	€8,506,220
C29 Motor vehicles	€11,207,496	€6,751,504	€9,452,105	€27,411,106
C30 Transport	€10,549,743	€3,440,134	€2,293,422	€16,283,299
C31 Furniture	€16,174,966	€1,489,107	€546,339	€18,210,412
C33 Machinery repair	€4,864,171	€371,311	€123,770	€5,359,252
F41.2 Construction	€571,502,497	€20,941,920	€3,397,594	€595,842,011
F42 Civil engineering	€3,860,573	€812,752	€406,376	€5,079,701
F43 Specialised construction	€1,208,224,890	€24,271,291	€4,854,258	€1,237,350,440
F43.29 Other installation	€4,695,091	€130,632	€26,579	€4,852,302
G45.2 Vehicle repair	€405,853,162	€3,456,665	€1,219,999	€410,529,826
S95 Repairs	€15,061,537	€45,216	€15,072	€15,121,826
Total	**€2,310,176,432**	**€79,258,668**	**€33,378,266**	**€2,422,813,366**
OEL options of 0.025, 0.1, 0.5, 1 µg NCO /m³				
C13 Textiles	€4,321,220	€662,325	€214,808	€5,198,353
C14 Apparel	€11,028,257	€1,131,103	€565,552	€12,724,912
C15 Leather	€26,987,115	€4,802,078	€1,347,952	€33,137,144
C16 Wood	€4,513,158	€347,166	€462,888	€5,323,211
C20 Chemicals	€1,943,060	€993,610	€662,407	€3,599,077
C22.21 Rigid foam	€113,725	€375,506	€257,490	€746,721
C22.29 Flexible foam	€186,095	€614,465	€421,347	€1,221,908
C22. Other	€9,116,004	€4,715,175	€4,191,266	€18,022,446
C26 Computers	€12,568,262	€4,098,346	€2,732,231	€19,398,840
C27 Electrical equipment	€12,183,540	€7,083,453	€5,666,763	€24,933,756
C28 Machinery	€9,446,758	€3,047,341	€1,015,780	€13,509,879

Sector	PV administrative burden of managing monitoring over 40 years, based upon monitoring every fifth year by group of OEL options			
	Small	Medium	Large	Total
C29 Motor vehicles	€17,800,141	€10,722,977	€15,012,167	€43,535,286
C30 Transport	€16,755,474	€5,463,742	€3,642,494	€25,861,710
C31 Furniture	€25,689,652	€2,365,052	€867,715	€28,922,419
C33 Machinery repair	€7,725,448	€589,729	€196,576	€8,511,753
F41.2 Construction	€907,680,436	€33,260,697	€5,396,179	€946,337,312
F42 Civil engineering	€6,131,498	€1,290,842	€645,421	€8,067,760
F43 Specialised construction	€1,918,945,413	€38,548,522	€7,709,704	€1,965,203,639
F43.29 Other installation	€7,456,909	€207,475	€42,214	€7,706,598
G45.2 Vehicle repair	€644,590,315	€5,489,998	€1,937,646	€652,017,959
S95 Repairs	€23,921,265	€71,814	€23,938	€24,017,017
Total	**€3,669,103,745**	**€125,881,415**	**€53,012,539**	**€3,847,997,699**

Source: Study team

6.6 Direct costs – for public authorities

6.6.1 Transposition

Member States incur costs transposing the relevant changes into national legislation. In practice, the exact costs depend on the specific changes agreed in the final version of the Directive and the regulatory model used in each country to implement the Directive (i.e. the number of departments involved in transposition or implementing the Directive). These costs vary significantly between Member States (for example, some Member States are obliged to carry out an impact assessment on new EU legislation).

Of the 27 EU Member States, research carried out for this study has confirmed that nineteen have an OEL(s) and or STEL(s) for a mixture of diisocyanates, see Table 4-1. There is no information about OELs or STELs for diisocyanates for the following Member States and this study assumes that they have none: Cyprus, Czech Republic, Greece, Luxembourg, Malta, Netherlands, Portugal and Slovakia. It is thus assumed that these eight Member States would incur higher costs for transposing an OEL and STEL introduced under the CAD than those with existing OELs and STELs.

A further complication is that all the Member States with OELs and STELs for diisocyanates vary considerably not only in the level, but also in the specific diisocyanates included, sometimes having several OELs and/or STELs for different diisocyanates. This is described in detail in section 4.2.5. This may make it more difficult for them to amend their legislation to the new OEL and STEL.

Specific data on the costs of transposition of EU legislation by Member States and their relevant departments/ministries are not readily available. As noted in (RPA, 2012), one UK impact assessment states that *"the costs of amending current regulations to implement a Directive are thought to be around £700,000"* (around €900,000 in €2017). Although no details are given on the basis for this calculation, it is expected that these costs relate to a rather substantial legislative change and would include those costs of making (including preparing an impact assessment, drafting a substantial bill and presenting the legislation before parliament), printing and publishing the legislation. This estimate is significantly higher than the cost estimated in (UK Department for Transport, 2011), which notes that *"a combination of legal and technical resources as well as policy advisors are usually required to implement such a change, costing approximately £15,687 per amendment"* (approximately €20,000 in 2017).

Considering that all Member States have transposed the CAD which already contains an OEL for lead, it appears more likely that the cost of transposing an additional OEL and STEL would be closer to the low-end estimate. However, it also appears that there has been a general trend towards increased impact assessment in the Member States (see, for example, (RPA, 2015)), which suggests that the costs would probably be higher than €20,000.

This study thus takes €50,000 per Member State as an approximation of the general order of magnitude of the applicable transposition costs for Member States where there is currently no OEL or STEL and €30,000 per Member State where there is some existing OEL or STEL.

Table 6-31 Transposition costs for Member State authorities

Member State situation	Number of Member States	Transposition cost per Member State	Total cost across the EU
Member States: no OEL or STEL	8	€50,000	€400,000
Member States: mixture of OELs and STELs	19	€30,000	€570,000
Total cost			**€970,000**

Source: Study team

If limit values for more than one substance are introduced at the same time, there may be a reduction in cost, but this impossible to estimate. A Member State may already have a limit value for one substance but not for the other. Furthermore, if the OEL and STEL has a phased introduction, there may be an increase in transposition costs as Member States have to alert companies at each stage.

6.6.2 Enforcement, monitoring and adjudication costs

The enforcement, monitoring and adjudication costs depend on the number of companies that will be covered by the OEL. In principle, national authorities are supposed to inspect companies already as they have the general obligation to protect workers. However, there could be an additional cost due to the need to ensure compliance with the new rules. Such enforcement costs depend on the inspection regime in each Member State, and they are not estimated in this study.

In section 6.4.1.4, the views of member State authorities are considered and in Table 6-17 and Table 6-18 for are their opinions on the likely impact of STELs and OELs. At a STEL of 6 µg NCO /m^3 and an OEL of 3 µg NCO /m^3, approximately half the MSAs think there will be a negative impact and at a STEL of 2 µg NCO /m^3 and an OEL of 1 µg NCO /m^3, approximately 70% MSAs think there will be a negative impact.

6.7 Indirect costs

These are covered in section 7 on market effects and section 8 on distributional effects.

6.8 Aggregated costs and discussion

The aggregated costs of compliance, monitoring and administrative burden for companies by sector are shown in Table 6-32; by sector and size of company in Table 6-33; by size of company in Table 6-34; and as costs per company by size of company in Table 6-35. The total aggregated costs of risk management measures, monitoring, administrative burden for companies and public authorities are shown in Table 6-38.

These costs exclude the social costs from employment changes which are covered in section 7.5. As explained in section 4.2.5, some costs are over-estimated by approximately 10% as the companies in Member States that already have OELs are not excluded.

The risk management costs may be underestimated as explained in section 6.4.2: estimates from other sources tend to be higher. In addition, the cost of compliance with STELs is not modelled and therefore costs associated with achieving STELs particularly at higher OEL/STEL option values is not included and cannot be estimated.

In section 4.8.3, some sectors such as construction and vehicle repair are shown to have a low average number of workers per enterprise (less than 2). Some of these micro companies will be one person enterprises, but some will be inactive, however, the study team has no data to estimate the number of inactive micro companies. Therefore, as the costs are related to the number of enterprises it is possible that the costs are overestimated.

All enterprises must comply with OELs and STELs. However, in the construction sectors (F41.2, F42, F43 and F43.29) and the vehicle repair sector (G45.2), there are numerous micro companies, many of which employ one person. It is possible that many will not be required to monitor their compliance. As a result, the costs of monitoring and administrative burden could be overestimated. The option of removing micro companies from the calculations of monitoring and administrative burden is explored in the sensitivity analysis in section 10.2.5.

Table 6-32 PV compliance, monitoring and administrative burden costs over 40 years for the OEL options by sector

Sector	OEL options (µg NCO/m³)							
	0.025	0.1	0.5	1	3	6	10	17.5
C13 Textiles	€1,250,552,073	€722,196,868	€184,243,136	€96,142,541	€42,674,248	€21,560,017	€7,528,930	€7,528,930
C14 Apparel	€1,633,920,054	€1,003,290,684	€309,060,972	€178,154,067	€77,519,896	€52,555,038	€18,681,587	€18,681,587
C15 Leather	€4,660,980,226	€1,231,949,640	€196,419,405	€184,059,599	€115,889,377	€115,889,377	€47,719,155	€47,719,155
C16 Wood	€630,775,203	€186,285,510	€38,939,661	€31,156,776	€19,617,230	€19,617,230	€8,077,683	€8,077,683
C20 Chemicals	€2,650,659,784	€514,512,053	€116,749,111	€106,441,365	€17,754,496	€13,231,054	€5,448,081	€5,448,081
C22.21 Rigid foam	€431,980,505	€141,149,716	€13,025,329	€4,497,066	€2,831,486	€2,831,486	€1,165,906	€1,165,906
C22.29 Flexible foam	€552,288,331	€107,182,522	€28,469,998	€27,612,261	€4,633,340	€4,633,340	€1,907,846	€1,907,846
C22. Other	€6,183,743,323	€993,298,905	€136,435,880	€108,757,685	€68,477,061	€68,477,061	€28,196,437	€28,196,437
C26 Computers	€3,045,892,532	€890,284,698	€192,181,261	€147,459,966	€70,791,715	€70,791,715	€29,149,530	€29,149,530
C27 Electrical equipment	€3,726,751,137	€838,287,488	€234,319,190	€178,145,191	€93,846,241	€93,846,241	€38,642,570	€38,642,570
C28 Machinery	€8,680,170,653	€579,529,905	€475,362,696	€80,075,369	€47,122,267	€47,122,267	€19,403,286	€19,403,286
C29 Motor vehicles	€85,299,647,709	€7,873,308,032	€4,350,433,056	€4,281,606,588	€176,997,306	€176,997,306	€72,881,244	€72,881,244
C30 Transport	€25,905,423,340	€6,310,462,956	€1,336,972,050	€1,333,613,011	€94,376,512	€94,376,512	€38,860,917	€38,860,917

Sector	OEL options (µg NCO/m³)							
	0.025	0.1	0.5	1	3	6	10	17.5
C31 Furniture	€4,061,891,626	€630,054,775	€343,775,314	€177,171,922	€102,410,835	€102,410,835	€42,169,167	€42,169,167
C33 Machinery repair	€2,153,454,383	€630,502,933	€155,320,359	€145,562,385	€33,285,130	€30,121,740	€12,403,069	€12,403,069
F41.2 Construction	€44,292,163,005	€16,825,553,957	€6,619,907,846	€5,739,984,068	€3,346,792,224	€3,346,792,224	€1,378,090,916	€1,378,090,916
F42 Civil engineering	€763,734,830	€322,722,631	€68,063,036	€59,873,135	€28,790,888	€28,790,888	€11,855,071	€11,855,071
F43 Specialised construction	€100,218,009,959	€46,364,998,921	€13,809,733,865	€12,476,458,776	€6,974,874,027	€6,974,874,027	€2,872,006,952	€2,872,006,952
F43.29 Other installation	€383,899,207	€159,476,546	€53,418,365	€47,746,430	€27,318,731	€27,318,731	€11,248,889	€11,248,889
G45.2 Vehicle repair	€41,981,649,571	€24,327,741,276	€6,208,752,044	€4,863,786,710	€3,082,521,321	€2,320,541,112	€955,516,928	€955,516,928
S95 Repairs	€762,018,078	€202,531,588	€143,622,029	€135,810,827	€85,510,521	€85,510,521	€35,210,214	€35,210,214
Total	**€339,269,605,530**	**€110,855,321,603**	**€35,015,204,603**	**€30,404,115,735**	**€14,514,034,849**	**€13,698,288,719**	**€5,636,164,379**	**€5,636,164,379**

Source: Study team

Table 6-33 Aggregated costs of PV compliance, monitoring and administrative burden discounted over 40 years, by size of enterprise, by sector, by OEL options

Sector	Aggregated costs of PV compliance, monitoring and administrative burden over 40 years, size of enterprise, by sector by OEL options			
	Small	Medium	Large	Total
OELs options of 17.5 µg NCO /m³				
C13 Textiles	€6,336,868	€680,320	€511,742	€7,528,930
C14 Apparel	€16,172,425	€1,161,836	€1,347,327	€18,681,587
C15 Leather	€39,575,346	€4,932,552	€3,211,257	€47,719,155
C16 Wood	€6,618,335	€356,599	€1,102,749	€8,077,683
C20 Chemicals	€2,849,407	€1,020,607	€1,578,067	€5,448,081
C22.21 Rigid foam	€166,772	€385,709	€613,425	€1,165,906
C22.29 Flexible foam	€272,900	€631,160	€1,003,786	€1,907,846
C22. Other	€13,368,196	€4,843,288	€9,984,953	€28,196,437
C26 Computers	€18,430,771	€4,209,700	€6,509,058	€29,149,530
C27 Electrical equipment	€17,866,593	€7,275,914	€13,500,063	€38,642,570
C28 Machinery	€13,853,230	€3,130,139	€2,419,918	€19,403,286
C29 Motor vehicles	€26,103,078	€11,014,324	€35,763,842	€72,881,244
C30 Transport	€24,571,122	€5,612,194	€8,677,601	€38,860,917
C31 Furniture	€37,672,678	€2,429,312	€2,067,178	€42,169,167
C33 Machinery repair	€11,329,009	€605,752	€468,308	€12,403,069
F41.2 Construction	€1,331,071,069	€34,164,403	€12,855,444	€1,378,090,916
F42 Civil engineering	€8,991,556	€1,325,914	€1,537,601	€11,855,071
F43 Specialised construction	€2,814,044,041	€39,595,900	€18,367,011	€2,872,006,952
F43.29 Other installation	€10,935,209	€213,112	€100,568	€11,248,889
G45.2 Vehicle repair	€945,261,665	€5,639,163	€4,616,100	€955,516,928
S95 Repairs	€35,079,421	€73,765	€57,028	€35,210,214
Total	**€5,380,569,691**	**€129,301,661**	**€126,293,027**	**€5,636,164,379**
OELs options of 10 µg NCO /m³				
C13 Textiles	€6,336,868	€680,320	€511,742	€7,528,930
C14 Apparel	€16,172,425	€1,161,836	€1,347,327	€18,681,587
C15 Leather	€39,575,346	€4,932,552	€3,211,257	€47,719,155
C16 Wood	€6,618,335	€356,599	€1,102,749	€8,077,683
C20 Chemicals	€2,849,407	€1,020,607	€1,578,067	€5,448,081
C22.21 Rigid foam	€166,772	€385,709	€613,425	€1,165,906

Sector	Aggregated costs of PV compliance, monitoring and administrative burden over 40 years, size of enterprise, by sector by OEL options			
	Small	Medium	Large	Total
C22.29 Flexible foam	€272,900	€631,160	€1,003,786	€1,907,846
C22. Other	€13,368,196	€4,843,288	€9,984,953	€28,196,437
C26 Computers	€18,430,771	€4,209,700	€6,509,058	€29,149,530
C27 Electrical equipment	€17,866,593	€7,275,914	€13,500,063	€38,642,570
C28 Machinery	€13,853,230	€3,130,139	€2,419,918	€19,403,286
C29 Motor vehicles	€26,103,078	€11,014,324	€35,763,842	€72,881,244
C30 Transport	€24,571,122	€5,612,194	€8,677,601	€38,860,917
C31 Furniture	€37,672,678	€2,429,312	€2,067,178	€42,169,167
C33 Machinery repair	€11,329,009	€605,752	€468,308	€12,403,069
F41.2 Construction	€1,331,071,069	€34,164,403	€12,855,444	€1,378,090,916
F42 Civil engineering	€8,991,556	€1,325,914	€1,537,601	€11,855,071
F43 Specialised construction	€2,814,044,041	€39,595,900	€18,367,011	€2,872,006,952
F43.29 Other installation	€10,935,209	€213,112	€100,568	€11,248,889
G45.2 Vehicle repair	€945,261,665	€5,639,163	€4,616,100	€955,516,928
S95 Repairs	€35,079,421	€73,765	€57,028	€35,210,214
Total	**€5,380,569,691**	**€129,301,661**	**€126,293,027**	**€5,636,164,379**
OELs options of 6 µg NCO /m^3				
C13 Textiles	€17,242,674	€2,458,876	€1,858,466	€21,560,017
C14 Apparel	€44,005,312	€4,173,029	€4,376,697	€52,555,038
C15 Leather	€96,111,555	€11,979,055	€7,798,767	€115,889,377
C16 Wood	€16,073,100	€866,025	€2,678,105	€19,617,230
C20 Chemicals	€6,919,988	€2,478,617	€3,832,449	€13,231,054
C22.21 Rigid foam	€405,018	€936,722	€1,489,746	€2,831,486
C22.29 Flexible foam	€662,757	€1,532,818	€2,437,766	€4,633,340
C22. Other	€32,465,618	€11,762,271	€24,249,172	€68,477,061
C26 Computers	€44,760,444	€10,223,557	€15,807,713	€70,791,715
C27 Electrical equipment	€43,390,298	€17,670,076	€32,785,867	€93,846,241
C28 Machinery	€33,643,559	€7,601,765	€5,876,943	€47,122,267
C29 Motor vehicles	€63,393,189	€26,749,073	€86,855,044	€176,997,306
C30 Transport	€59,672,726	€13,629,613	€21,074,173	€94,376,512
C31 Furniture	€91,490,789	€5,899,757	€5,020,289	€102,410,835

Sector	Aggregated costs of PV compliance, monitoring and administrative burden over 40 years, size of enterprise, by sector by OEL options			
	Small	Medium	Large	Total
C33 Machinery repair	€27,513,308	€1,471,112	€1,137,320	€30,121,740
F41.2 Construction	€3,232,601,167	€82,970,692	€31,220,365	€3,346,792,224
F42 Civil engineering	€21,836,636	€3,220,078	€3,734,175	€28,790,888
F43 Specialised construction	€6,834,106,957	€96,161,471	€44,605,598	€6,974,874,027
F43.29 Other installation	€26,556,936	€517,557	€244,237	€27,318,731
G45.2 Vehicle repair	€2,295,635,472	€13,695,110	€11,210,530	€2,320,541,112
S95 Repairs	€85,192,879	€179,144	€138,497	€85,510,521
Total	**€13,073,680,383**	**€316,176,418**	**€308,431,917**	**€13,698,288,719**
OELs options of 3 µg NCO /m^3				
C13 Textiles	€26,812,667	€12,864,557	€2,997,025	€42,674,248
C14 Apparel	€58,041,161	€12,331,743	€7,146,993	€77,519,896
C15 Leather	€96,111,555	€11,979,055	€7,798,767	€115,889,377
C16 Wood	€16,073,100	€866,025	€2,678,105	€19,617,230
C20 Chemicals	€8,475,942	€4,165,389	€5,113,164	€17,754,496
C22.21 Rigid foam	€405,018	€936,722	€1,489,746	€2,831,486
C22.29 Flexible foam	€662,757	€1,532,818	€2,437,766	€4,633,340
C22. Other	€32,465,618	€11,762,271	€24,249,172	€68,477,061
C26 Computers	€44,760,444	€10,223,557	€15,807,713	€70,791,715
C27 Electrical equipment	€43,390,298	€17,670,076	€32,785,867	€93,846,241
C28 Machinery	€33,643,559	€7,601,765	€5,876,943	€47,122,267
C29 Motor vehicles	€63,393,189	€26,749,073	€86,855,044	€176,997,306
C30 Transport	€59,672,726	€13,629,613	€21,074,173	€94,376,512
C31 Furniture	€91,490,789	€5,899,757	€5,020,289	€102,410,835
C33 Machinery repair	€37,953,205	-€676,212	-€3,991,864	€33,285,130
F41.2 Construction	€3,232,601,167	€82,970,692	€31,220,365	€3,346,792,224
F42 Civil engineering	€21,836,636	€3,220,078	€3,734,175	€28,790,888
F43 Specialised construction	€6,834,106,957	€96,161,471	€44,605,598	€6,974,874,027
F43.29 Other installation	€26,556,936	€517,557	€244,237	€27,318,731
G45.2 Vehicle repair	€3,045,763,203	€20,749,391	€16,008,727	€3,082,521,321
S95 Repairs	€85,192,879	€179,144	€138,497	€85,510,521
Total	**€13,859,409,807**	**€341,334,542**	**€313,290,500**	**€14,514,034,849**

Sector	Aggregated costs of PV compliance, monitoring and administrative burden over 40 years, size of enterprise, by sector by OEL options			
	Small	Medium	Large	Total
OELs options of 1 µg NCO /m³				
C13 Textiles	€58,166,200	€29,422,313	€8,554,028	€96,142,541
C14 Apparel	€127,671,141	€30,950,332	€19,532,594	€178,154,067
C15 Leather	€152,647,764	€19,025,558	€12,386,277	€184,059,599
C16 Wood	€25,527,865	€1,375,452	€4,253,460	€31,156,776
C20 Chemicals	€30,821,107	€51,519,731	€24,100,527	€106,441,365
C22.21 Rigid foam	€643,264	€1,487,735	€2,366,067	€4,497,066
C22.29 Flexible foam	€1,120,826	€18,887,265	€7,604,171	€27,612,261
C22. Other	€51,563,041	€18,681,253	€38,513,391	€108,757,685
C26 Computers	€86,624,273	€24,953,054	€35,882,639	€147,459,966
C27 Electrical equipment	€75,939,396	€34,854,682	€67,351,113	€178,145,191
C28 Machinery	€59,696,005	€15,248,189	€5,131,174	€80,075,369
C29 Motor vehicles	€546,707,319	€1,118,539,983	€2,616,359,286	€4,281,606,588
C30 Transport	€385,161,906	€498,817,563	€449,633,542	€1,333,613,011
C31 Furniture	€157,377,502	€11,763,151	€8,031,269	€177,171,922
C33 Machinery repair	€108,142,536	€35,801,308	€1,618,541	€145,562,385
F41.2 Construction	€5,538,884,181	€164,411,922	€36,687,965	€5,739,984,068
F42 Civil engineering	€48,670,360	€8,747,847	€2,454,929	€59,873,135
F43 Specialised construction	€12,208,503,044	€197,415,497	€70,540,235	€12,476,458,776
F43.29 Other installation	€46,669,615	€981,663	€95,152	€47,746,430
G45.2 Vehicle repair	€4,802,168,543	€35,133,553	€26,484,614	€4,863,786,710
S95 Repairs	€135,306,338	€284,523	€219,966	€135,810,827
Total	**€24,648,012,224**	**€2,318,302,572**	**€3,437,800,940**	**€30,404,115,735**
OELs options of 0.5 µg NCO /m³				
C13 Textiles	€101,535,413	€66,411,097	€16,296,626	€184,243,136
C14 Apparel	€207,190,765	€65,196,077	€36,674,130	€309,060,972
C15 Leather	€161,393,583	€20,892,603	€14,133,220	€196,419,405
C16 Wood	€30,791,436	€1,755,069	€6,393,156	€38,939,661
C20 Chemicals	€33,941,688	€54,771,652	€28,035,771	€116,749,111
C22.21 Rigid foam	€669,956	€2,380,280	€9,975,093	€13,025,329
C22.29 Flexible foam	€38,069	€19,367,452	€9,064,477	€28,469,998

Sector	Aggregated costs of PV compliance, monitoring and administrative burden over 40 years, size of enterprise, by sector by OEL options			
	Small	Medium	Large	Total
C22. Other	€57,864,152	€25,686,043	€52,885,686	€136,435,880
C26 Computers	€104,801,186	€34,865,590	€52,514,485	€192,181,261
C27 Electrical equipment	€88,654,412	€47,848,683	€97,816,095	€234,319,190
C28 Machinery	€242,404,639	€192,987,989	€39,970,069	€475,362,696
C29 Motor vehicles	€556,736,573	€1,130,072,366	€2,663,624,117	€4,350,433,056
C30 Transport	€426,903,928	€513,258,372	€396,809,750	€1,336,972,050
C31 Furniture	€245,434,296	€82,111,419	€16,229,599	€343,775,314
C33 Machinery repair	€124,089,019	€34,252,748	-€3,021,408	€155,320,359
F41.2 Construction	€6,366,122,627	€202,703,151	€51,082,067	€6,619,907,846
F42 Civil engineering	€52,186,883	€10,808,163	€5,067,990	€68,063,036
F43 Specialised construction	€13,477,486,595	€241,205,601	€91,041,669	€13,809,733,865
F43.29 Other installation	€52,007,782	€1,200,899	€209,684	€53,418,365
G45.2 Vehicle repair	€6,119,950,814	€50,748,910	€38,052,321	€6,208,752,044
S95 Repairs	€143,058,595	€312,444	€250,989	€143,622,029
Total	**€28,593,262,413**	**€2,798,836,606**	**€3,623,105,584**	**€35,015,204,603**
OELs options of 0.1 µg NCO /m³				
C13 Textiles	€351,209,397	€319,530,265	€51,457,205	€722,196,868
C14 Apparel	€605,466,458	€276,649,061	€121,175,165	€1,003,290,684
C15 Leather	€755,952,888	€328,462,569	€147,534,182	€1,231,949,640
C16 Wood	€122,959,037	€18,068,206	€45,258,267	€186,285,510
C20 Chemicals	€132,442,122	€265,937,936	€116,131,995	€514,512,053
C22.21 Rigid foam	€1,127,995	€24,350,604	€115,671,117	€141,149,716
C22.29 Flexible foam	-€15,183,815	€94,481,368	€27,884,969	€107,182,522
C22. Other	€269,863,767	€383,886,228	€339,548,909	€993,298,905
C26 Computers	€412,279,250	€208,073,905	€269,931,543	€890,284,698
C27 Electrical equipment	€231,499,431	€183,777,824	€423,010,232	€838,287,488
C28 Machinery	€363,466,805	€253,786,414	-€37,723,314	€579,529,905
C29 Motor vehicles	€1,618,597,199	€3,036,363,840	€3,218,346,992	€7,873,308,032
C30 Transport	€2,167,832,883	€2,756,311,199	€1,386,318,875	€6,310,462,956
C31 Furniture	€482,132,924	€127,830,002	€20,091,850	€630,054,775
C33 Machinery repair	€548,495,338	€155,818,018	-€73,810,423	€630,502,933

Sector	Aggregated costs of PV compliance, monitoring and administrative burden over 40 years, size of enterprise, by sector by OEL options			
	Small	Medium	Large	Total
F41.2 Construction	€15,935,049,752	€1,016,112,325	-€125,608,120	€16,825,553,957
F42 Civil engineering	€239,544,415	€137,677,745	-€54,499,529	€322,722,631
F43 Specialised construction	€44,894,810,252	€1,306,530,041	€163,658,629	€46,364,998,921
F43.29 Other installation	€158,991,309	€5,281,538	-€4,796,301	€159,476,546
G45.2 Vehicle repair	€23,679,829,500	€445,046,383	€202,865,393	€24,327,741,276
S95 Repairs	€199,841,942	€1,809,968	€879,678	€202,531,588
Total	**€93,156,208,851**	**€11,345,785,438**	**€6,353,327,315**	**€110,855,321,603**
OELs options of 0.025 µg NCO /m³				
C13 Textiles	€588,101,165	€582,802,503	€79,648,405	€1,250,552,073
C14 Apparel	€950,344,676	€487,337,140	€196,238,238	€1,633,920,054
C15 Leather	€2,699,014,094	€1,508,800,575	€453,165,558	€4,660,980,226
C16 Wood	€335,908,010	€141,288,867	€153,578,326	€630,775,203
C20 Chemicals	€612,191,452	€1,466,528,160	€571,940,172	€2,650,659,784
C22.21 Rigid foam	€8,040,077	€112,495,444	€311,444,984	€431,980,505
C22.29 Flexible foam	€11,539,174	€430,671,738	€110,077,419	€552,288,331
C22. Other	€1,711,005,941	€2,880,682,605	€1,592,054,777	€6,183,743,323
C26 Computers	€1,117,541,670	€1,016,550,468	€911,800,393	€3,045,892,532
C27 Electrical equipment	€769,252,667	€1,345,415,351	€1,612,083,120	€3,726,751,137
C28 Machinery	€4,092,898,187	€3,907,510,295	€679,762,171	€8,680,170,653
C29 Motor vehicles	€9,543,654,464	€22,780,519,339	€52,975,473,907	€85,299,647,709
C30 Transport	€6,369,111,885	€10,330,667,344	€9,205,644,110	€25,905,423,340
C31 Furniture	€2,253,543,521	€1,606,422,396	€201,925,708	€4,061,891,626
C33 Machinery repair	€1,422,615,263	€724,482,905	€6,356,215	€2,153,454,383
F41.2 Construction	€40,289,298,839	€3,418,205,661	€584,658,505	€44,292,163,005
F42 Civil engineering	€498,779,749	€248,425,069	€16,530,013	€763,734,830
F43 Specialised construction	€95,457,197,240	€3,749,165,040	€1,011,647,678	€100,218,009,959
F43.29 Other installation	€363,291,405	€19,403,319	€1,204,483	€383,899,207
G45.2 Vehicle repair	€40,487,384,595	€1,055,965,665	€438,299,311	€41,981,649,571
S95 Repairs	€751,679,736	€6,265,516	€4,072,826	€762,018,078
Total	**€210,332,393,812**	**€57,819,605,398**	**€71,117,606,321**	**€339,269,605,530**

Source: Study team

Table 6-34 PV compliance, monitoring and administrative burden costs over 40 years for the OEL options by sector by company size

Size	OEL options (µg NCO/m^3)							
	0.025	0.1	0.5	1	3	6	10	17.5
Small	€210,332,393,812	€93,156,208,851	€28,593,262,413	€24,648,012,224	€13,859,409,807	€13,073,680,383	€5,380,569,691	€5,380,569,691
Medium	€57,819,605,398	€11,345,785,438	€2,798,836,606	€2,318,302,572	€341,334,542	€316,176,418	€129,301,661	€129,301,661
Large	€71,117,606,321	€6,353,327,315	€3,623,105,584	€3,437,800,940	€313,290,500	€308,431,917	€126,293,027	€126,293,027
Total	€339,269,605,530	€110,855,321,603	€35,015,204,603	€30,404,115,735	€14,514,034,849	€13,698,288,719	€5,636,164,379	€5,636,164,379

Source: Study team

Table 6-35 PV compliance, monitoring and administrative burden costs per company over 40 years for the OEL options by sector by company size

Size	OEL options (µg NCO/m3)							
	0.025	0.1	0.5	1	3	6	10	17.5
Small	€86,018	€38,097	€11,694	€10,080	€5,668	€5,347	€2,200	€2,200
Medium	€3,446,091	€676,217	€166,813	€138,173	€20,344	€18,844	€7,706	€7,706
Large	€20,129,907	€1,798,315	€1,025,524	€973,073	€88,677	€87,302	€35,747	€35,747
Total	€137,605	€44,962	€14,202	€12,332	€5,887	€5,556	€2,286	€2,286

Source: Study team

Table 6-36 Annual compliance, monitoring and administrative burden costs for the OEL options by sector by company size

Size	OEL options (µg NCO/m^3)							
	0.025	0.1	0.5	1	3	6	10	17.5
Small	€5,258,309,845	€2,328,905,221	€714,831,560	€616,200,306	€346,485,245	€326,842,010	€134,514,242	€134,514,242
Medium	€1,445,490,135	€283,644,636	€69,970,915	€57,957,564	€8,533,364	€7,904,410	€3,232,542	€3,232,542
Large	€1,777,940,158	€158,833,183	€90,577,640	€85,945,024	€7,832,263	€7,710,798	€3,157,326	€3,157,326
Total	€8,481,740,138	€2,771,383,040	€875,380,115	€760,102,893	€362,850,871	€342,457,218	€140,904,109	€140,904,109

Source: Study team
Note: The PV40 values in this study are converted into annual values by dividing the PV40 values by 40, for more detail about annualised costs, see the methodological note.

Table 6-37 Annual compliance, monitoring and administrative burden costs per company for the OEL options by sector by company size

Size	OEL options (µg NCO/m3)							
	0.025	0.1	0.5	1	3	6	10	17.5
Small	€2,150	€952	€292	€252	€142	€134	€55	€55
Medium	€86,152	€16,905	€4,170	€3,454	€509	€471	€193	€193
Large	€503,248	€44,958	€25,638	€24,327	€2,217	€2,183	€894	€894
Total	€3,440	€1,124	€355	€308	€147	€139	€57	€57

Source: Study team
Note: The PV40 values in this study are converted into annual values by dividing the PV40 values by 40, for more detail about annualised costs, see the methodological note.

Table 6-38 Aggregated total costs over 40 years for the OEL options (compliance, measurement, administrative burden and public authorities)

Cost	OEL options (µg NCO/m³)							
	0.025	0.1	0.5	1	3	6	10	17.5
Companies - risk management measure costs–€ million	€316,223	€87,809	€11,969	€8,665	€826	€10	€0	€0
Companies - monitoring costs € million	€19,198	€19,198	€19,198	€17,891	€11,265	€11,265	€4,639	€4,639
Companies – administrative burden € million	€3,848	€3,848	€3,848	€3,848	€2,423	€2,423	€998	€998
Member State authorities - transposition costs € million	€1	€1	€1	€1	€1	€1	€1	€1
Total € million	€339,271	€110,856	€35,016	€30,405	€14,515	€13,699	€5,637	€5,637

Source: Study team

6.9 Other costs

6.9.1 REACH Restriction training costs

ECHA estimate that the REACH Restriction training cost for workplaces using diisocyanates will be €114 million per year (ECHA, 2021a). The study team believes that this is only the cost of providing the training materials and the trainers for face-to-face training; it does not appear to include the cost of employees' time whilst being trained or the cost of administering the training. The study team believes that no additional cost for risk management measures is included, but rather the expectation is that current RPE and other risk management measures are used properly.

During a site visit, a company explained that the REACH Restriction training time differs between the several types of users and that it would take between 45 minutes and four hours to complete. The training also needs to be repeated every five years and to be documented.

6.9.2 Medical surveillance costs

In section 4.11.3, the best practice of medical surveillance is considered, and the two approaches explained: questionnaire and medical checks. Enterprises already need to carry out medical surveillance in accordance with national arrangements (CAD article 10). However, the Working Party on Chemicals (WPC) may wish to consider mandating medical surveillance at an EU level as it is for lead under the CAD. If medical surveillance is mandated, it is likely to mean that companies need to have employees using diisocyanates medically checked.

The introduction of medical surveillance is beyond the scope of this study; however, the study team has put together rough cost estimates of the cost of medical surveillance to help the WPC in its considerations. These costs are not included further in the aggregated costs associated with the introduction of an OEL or STEL.

The study team estimates that medical surveillance based upon medical checks would consist of three cost elements:

- Occupational nurse or doctor
- Employee's time taken out of work
- Manager's time to arrange nurse and employee's appointments

Several further assumptions are required:

- The occupational nurse/doctor sees the employee twice, first to take tests and then to give results.
- Each visit takes 15 minutes, and the nurse/doctor requires a further half an hour per employee to report the results.
- The occupational nurse/doctor, manager and employee are all charged at €500/day.

The estimated costs assuming all companies implement medical surveillance shown in Table 6-39 and are based upon detailed costing provided during a site visit. Three of the four diisocyanates sites visited as part of the study provide medical checks on an annual basis.

Table 6-39 Estimated medical surveillance PV costs over 40 years by size of company

	Small	Medium	Large
Employees requiring medical surveillance	2	30	200
Nurse/doctor - days/year	1	4	30
Employees time out to have medical surveillance - days/year	0.33	1.5	15
Manager's time to set up medical surveillance - days/year	2	5	20
Total days per year	3.33	10.5	65
Cost to set up medical surveillance for one year	€1,665	€5,250	€32,500
Cost of annual medical surveillance discounted over 40 years	€34,273	€108,069	€668,996
Number of companies	2,445,213	16,778	3,533
Total cost over 40 years	**€83,804,785,149**	**€1,813,209,134**	**€2,363,518,213**

Source: Study team

If medical surveillance is mandated under the CAD, it would probably only be required for companies exceeding a given exposure concentration somewhat lower than the OEL/STEL. This would reduce the number of companies required to implement medical surveillance, for the higher OEL options, this would be a substantial reduction.

The costs of medical surveillance are not estimated for all possible OEL options but they could be. Table 6-2 contains the numbers of companies allocated to each exposure levels enabling an estimate of the number of companies operating above a given exposure level. If medical surveillance was mandated for 8-hour TWA exposure concentrations exceeding (say) 6 µg NCO/m³, this means that two groups of companies in sectors C13 Textiles and C14 Apparel or 526 companies are over this level. The costs can be estimated as in Table 6-40.

Table 6-40 Estimated medical surveillance PV costs over 40 years by size of company if only for companies exceeding 6 µg NCO/m³

Sector & exposure levels	Small	Medium	Large	Total
C13 Textiles				
9.4055 µg NCO/m³	144	4	1	149
C14 Apparel				
9.4055 µg NCO/m³	367	8	2	377
Companies operating with exposure over 6 µg NCO/m³	511	12	3	526
Cost of annual medical surveillance discounted over 40 years	€34,273	€108,069	€668,996	
Total cost over 40 years	**€17,513,503**	**€1,296,828**	**€2,006,988**	**€20,817,319**

Source: Study team

7. Market effects

This section comprises the following subsections:

- Section 7.1: Overall impact
- Section 7.2: Single market
- Section 7.3: Innovation and growth
- Section 7.4: Competitiveness of EU businesses
- Section 7.5: Employment

7.1 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/STEL 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 OEL/STELs at a cost that maintains profitability.

The likely costs that would be incurred at each of the OEL/STEL options considered in this study are set out in section 6 above. These have then been modelled to predict the likely number of companies (or business units) that would discontinue operations.

Table 7-1 provides estimates of the compliance costs that are estimated to be incurred on a per company basis (discounted at 4% over 40 years). 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 compliance as enterprises are already achieving the OEL/STEL level.

Table 7-1 PV compliance costs (RMMs) per company to comply with OELs over 40 years, additional to the baseline

Sector	Cost of compliance per business OEL µg NCO /m^3							
	0.025	0.1	0.5	1	3	6	10	17.5
C13 Textiles	€408,924	€231,767	€51,390	€22,499	€8,178	€1,098	€0	€0
C14 Apparel	€206,567	€122,908	€30,811	€14,075	€4,265	€953	€0	€0
C15 Leather	€238,555	€55,332	€0	€0	€0	€0	€0	€0
C16 Wood	€193,664	€49,575	€1,811	€0	€0	€0	€0	€0
C20 Chemicals	€1,785,777	€334,097	€63,786	€58,055	€3,074	€0	€0	€0
C22.21 Rigid foam	€2,073,460	€661,112	€38,907	€0	€0	€0	€0	€0
C22.29 Flexible foam	€2,325,146	€422,985	€86,606	€86,553	€0	€0	€0	€0
C22. Other	€868,504	€125,207	€2,500	€0	€0	€0	€0	€0
C26 Computers	€321,196	€84,427	€7,748	€3,847	€0	€0	€0	€0
C27 Electrical equipment	€377,454	€71,515	€7,544	€3,082	€0	€0	€0	€0
C28 Machinery	€1,270,370	€73,732	€58,344	€773	€0	€0	€0	€0
C29 Motor vehicles	€5,946,499	€529,152	€282,665	€279,905	€0	€0	€0	€0
C30 Transport	€2,120,986	€506,558	€96,792	€97,527	€0	€0	€0	€0
C31 Furniture	€222,304	€26,126	€9,761	€830	€0	€0	€0	€0
C33 Machinery repair	€401,249	€110,621	€19,941	€18,649	€604	€0	€0	€0
F41.2 Construction	€63,412	€18,363	€1,624	€696	€0	€0	€0	€0
F42 Civil engineering	€166,155	€63,625	€4,420	€3,289	€0	€0	€0	€0
F43 Specialised construction	€68,893	€26,968	€1,623	€1,089	€0	€0	€0	€0
F43.29 Other installation	€67,592	€22,707	€1,496	€872	€0	€0	€0	€0
G45.2 Vehicle repair	€88,474	€47,460	€5,366	€2,737	€1,770	€0	€0	€0
S95 Repairs	€38,763	€3,693	€0	€0	€0	€0	€0	€0

Source: Study team

Table 7-2 PV compliance costs (RMMs) per company to comply with OELs over 40 years, additional to the baseline

Sector	Cost of compliance per business OEL µg NCO /m^3							
	0.025	0.1	0.5	1	3	6	10	17.5
C13 Textiles	€10,223	€5,794	€1,285	€562	€204	€27	€0	€0
C14 Apparel	€5,164	€3,073	€770	€352	€107	€24	€0	€0
C15 Leather	€5,964	€1,383	€0	€0	€0	€0	€0	€0
C16 Wood	€4,842	€1,239	€45	€0	€0	€0	€0	€0
C20 Chemicals	€44,644	€8,352	€1,595	€1,451	€77	€0	€0	€0
C22.21 Rigid foam	€51,836	€16,528	€973	€0	€0	€0	€0	€0
C22.29 Flexible foam	€58,129	€10,575	€2,165	€2,164	€0	€0	€0	€0
C22. Other	€21,713	€3,130	€63	€0	€0	€0	€0	€0
C26 Computers	€8,030	€2,111	€194	€96	€0	€0	€0	€0
C27 Electrical equipment	€9,436	€1,788	€189	€77	€0	€0	€0	€0
C28 Machinery	€31,759	€1,843	€1,459	€19	€0	€0	€0	€0
C29 Motor vehicles	€148,662	€13,229	€7,067	€6,998	€0	€0	€0	€0
C30 Transport	€53,025	€12,664	€2,420	€2,438	€0	€0	€0	€0
C31 Furniture	€5,558	€653	€244	€21	€0	€0	€0	€0
C33 Machinery repair	€10,031	€2,766	€499	€466	€15	€0	€0	€0
F41.2 Construction	€1,585	€459	€41	€17	€0	€0	€0	€0
F42 Civil engineering	€4,154	€1,591	€110	€82	€0	€0	€0	€0
F43 Specialised construction	€1,722	€674	€41	€27	€0	€0	€0	€0
F43.29 Other installation	€1,690	€568	€37	€22	€0	€0	€0	€0
G45.2 Vehicle repair	€2,212	€1,187	€134	€68	€44	€0	€0	€0
S95 Repairs	€969	€92	€0	€0	€0	€0	€0	€0

Source: Study team
Note: The PV40 values in this study are converted into annual values by dividing the PV40 values by 40, for more detail about annualised costs, see the methodological note.

7.2 Single market

7.2.1 Competition

The initial screening of impacts on competition to focus the analysis on those impacts likely to be the most significant are shown in Table 7-3. The most significant impacts are further explored in the following paragraphs.

Table 7-3 Screening of competition impacts

Impacts	Key questions	Yes/No
Existing firms	Additional costs?	Yes
	Scale of costs significant?	Yes
	Old firms affected more than new?	Unknown
	Location influences?	No
	Some firms will exit the market?	Yes
	Are competitors limited in growth potential?	No
	Increased collusion likely?	Unknown
New entrants	Restrict entry?	Possibly
Prices	Increased prices for consumers	Possibly
Non-price impacts	Product quality/variety affected?	No
	Impact on innovation	Yes
Upstream and downstream market	Will OELs affect vertically integrated companies more or less than non-integrated ones?	Unknown
	Will OELs encourage greater integration and market barriers?	Unknown
	Will OELs affect bargaining power of buyers or suppliers?	Unknown

7.2.1.1 Additional costs and their significance

The estimated cost of compliance with the OEL options are shown in section 6 and Table 6-22 outlines the PV costs over 40 years. These estimates are based on the number of companies that would be required to make changes on-site to bring exposure levels in line with each OEL option or would be forced out of business if they were unable to comply. These costs will have an impact on individual companies and wider industry sectors when compared with turnover at both the company and sector level.

Section 4.8 explains how the number of companies with exposed workers was estimated. These are summarised in Table 4-57, broken down by sector and size class.

Based on the estimates of the numbers of small, medium, and large companies, as well as Eurostat data on the turnover of companies in different size classes and sectors where diisocyanates are used, the likely significance of the compliance costs modelled in Section 6 is estimated. In the sectors where SMEs are active, clearly the costs represent a significantly higher percentage of turnover than for large companies. Table 7-4 below shows that at the most stringent OEL of 0.025 µg NCO/m^3, costs are likely to represent a more significant percentage of turnover (over 40 years) of companies with exposed workers, with several companies likely to face costs of up to 3.5% of turnover. The highest level of costs as a proportion of turnover for the different size categories are 3.5% for small companies in C33, and 3.2% for medium companies in the C30 sector.

This table shows that at the lowest OELs, companies would experience substantial loss to their turnover due to compliance costs suggesting the OEL is not feasible for most.

Negative percentages for small companies in C22.29 are due to negative overall costs for risk management measures due to the model switching companies from RPE, which has higher long-term costs, compared with local extraction ventilation, which has higher initial investment costs but lower running costs and can be less expensive over 40 years. This is explained further in the methodological note. This is also the cause for negative costs for large companies in C28 at an OEL/STEL of 0.1 µg NCO/m^3, and C33 at 0.5 µg NCO/m^3. At a level of 3 µg NCO/m^3, C33 displays negative percentages for similar reasons.

Table 7-4 RMM compliance costs PV over 40 years as a percentage of company turnover by OEL options and sector

Sector	Compliance costs (RMMs) as a percentage of company turnover		
	Small	Medium	Large
OEL 0.025 µg NCO/m^3			
C13 Textiles	2.37%	2.00%	0.33%
C14 Apparel	2.92%	2.22%	0.32%
C15 Leather	1.37%	1.03%	0.19%
C16 Wood	1.66%	0.86%	0.15%
C20 Chemicals	1.19%	1.12%	0.12%
C22.21 Rigid foam	0.43%	0.57%	0.85%
C22.29 Flexible foam	0.37%	1.34%	0.18%
C22. Other	1.20%	1.16%	0.17%
C26 Computers	0.67%	0.40%	0.07%
C27 Electrical equipment	0.52%	0.36%	0.07%
C28 Machinery	2.23%	2.22%	0.19%
C29 Motor vehicles	3.22%	3.22%	0.29%
C30 Transport	3.41%	3.27%	0.28%
C31 Furniture	1.99%	1.89%	0.18%
C33 Machinery repair	3.25%	2.98%	0.01%
F41.2 Construction	0.93%	0.20%	0.03%
F42 Civil engineering	0.79%	0.46%	0.01%
F43 Specialised construction	1.60%	0.26%	0.06%

Sector	Compliance costs (RMMs) as a percentage of company turnover		
	Small	Medium	Large
F43.29 Other installation	1.04%	0.27%	0.01%
G45 Vehicle repair	2.07%	0.46%	0.08%
S95 Repairs	1.86%	0.22%	0.12%
OEL 0.1 µg NCO/m³			
C13 Textiles	1.37%	1.09%	0.21%
C14 Apparel	1.78%	1.25%	0.20%
C15 Leather	0.32%	0.21%	0.06%
C16 Wood	0.52%	0.10%	0.04%
C20 Chemicals	0.24%	0.20%	0.02%
C22.21 Rigid foam	0.03%	0.12%	0.31%
C22.29 Flexible foam	-0.58%	0.29%	0.04%
C22. Other	0.16%	0.15%	0.03%
C26 Computers	0.22%	0.08%	0.02%
C27 Electrical equipment	0.12%	0.04%	0.02%
C28 Machinery	0.17%	0.14%	-0.01%
C29 Motor vehicles	0.52%	0.42%	0.02%
C30 Transport	1.12%	0.87%	0.04%
C31 Furniture	0.31%	0.14%	0.01%
C33 Machinery repair	1.19%	0.63%	-0.19%
F41.2 Construction	0.28%	0.05%	-0.01%
F42 Civil engineering	0.34%	0.25%	-0.03%
F43 Specialised construction	0.63%	0.08%	0.01%
F43.29 Other installation	0.37%	0.06%	-0.06%
G45 Vehicle repair	1.12%	0.19%	0.03%
S95 Repairs	0.17%	0.05%	0.02%
OEL 0.5 µg NCO/m³			
C13 Textiles	0.32%	0.22%	0.06%
C14 Apparel	0.47%	0.28%	0.05%
C15 Leather	0.00%	0.00%	0.00%
C16 Wood	0.02%	0.00%	0.00%
C20 Chemicals	0.04%	0.04%	0.00%
C22.21 Rigid foam	0.00%	0.00%	0.02%
C22.29 Flexible foam	-0.04%	0.05%	0.01%
C22. Other	0.00%	0.00%	0.00%
C26 Computers	0.02%	0.01%	0.00%
C27 Electrical equipment	0.01%	0.00%	0.00%
C28 Machinery	0.10%	0.10%	0.01%
C29 Motor vehicles	0.15%	0.15%	0.01%
C30 Transport	0.18%	0.16%	0.01%

Sector	Compliance costs (RMMs) as a percentage of company turnover		
	Small	Medium	Large
C31 Furniture	0.09%	0.09%	0.01%
C33 Machinery repair	0.18%	0.13%	-0.01%
F41.2 Construction	0.03%	0.00%	0.00%
F42 Civil engineering	0.03%	0.01%	0.00%
F43 Specialised construction	0.04%	0.01%	0.00%
F43.29 Other installation	0.02%	0.00%	0.00%
G45 Vehicle repair	0.13%	0.01%	0.00%
S95 Repairs	0.00%	0.00%	0.00%
OEL 1 µg NCO/m³			
C13 Textiles	0.14%	0.09%	0.03%
C14 Apparel	0.22%	0.12%	0.02%
C15 Leather	0.00%	0.00%	0.00%
C16 Wood	0.00%	0.00%	0.00%
C20 Chemicals	0.04%	0.04%	0.00%
C22.21 Rigid foam	0.00%	0.00%	0.00%
C22.29 Flexible foam	0.00%	0.05%	0.01%
C22. Other	0.00%	0.00%	0.00%
C26 Computers	0.01%	0.00%	0.00%
C27 Electrical equipment	0.01%	0.00%	0.00%
C28 Machinery	0.00%	0.00%	0.00%
C29 Motor vehicles	0.15%	0.15%	0.01%
C30 Transport	0.16%	0.15%	0.01%
C31 Furniture	0.01%	0.00%	0.00%
C33 Machinery repair	0.15%	0.14%	0.00%
F41.2 Construction	0.01%	0.00%	0.00%
F42 Civil engineering	0.02%	0.01%	0.00%
F43 Specialised construction	0.03%	0.00%	0.00%
F43.29 Other installation	0.01%	0.00%	0.00%
G45 Vehicle repair	0.07%	0.01%	0.00%
S95 Repairs	0.00%	0.00%	0.00%
OEL 3 µg NCO/m³ (only sectors where there are costs are shown)			
C13 Textiles	0.05%	0.04%	0.01%
C14 Apparel	0.06%	0.04%	0.01%
C33 Machinery repair	0.02%	-0.01%	-0.01%
G45 Vehicle repair	0.04%	0.00%	0.00%
OEL 6 µg NCO/m³ (only sectors where there are costs are shown)			
C13 Textiles	0.01%	0.00%	0.00%
C14 Apparel	0.02%	0.01%	0.00%

Source: Calculations based on Eurostat data for average company turnover

Note: OEL 10 µg NCO/m³ and OEL 17.5 µg NCO/m³ are not included as the values for these options are zero.

The significance of costs arising from having to comply with OELs reduces as the OEL increases, and at an OEL of 3 µg NCO/m^3 or above, costs as a percentage of turnover represent a small amount across most sectors and company sizes. At the higher OELs of 17.5 µg NCO/m^3 and 10 µg NCO/m^3 costs are negligible as most enterprises are already achieving this level. However, the above analysis does not take into consideration the need for companies to undertake additional monitoring of exposure levels and the associated administrative burden. These costs are significant and will be incurred at the same rate by all companies with workers exposed, irrespective of the required OEL. The monitoring costs are described in detail in section 6.4.3 and the administrative burden costs in section 6.5. The additional costs of risk management measures, monitoring and administrative burden as a percentage of turnover by company size and sector are shown in Table 7-5.

Table 7-5 Cost of RMM compliance, monitoring and administrative burden PV over 40 years, as a percentage of company turnover by size of enterprise by sector by OEL option

Sector	RMM compliance, monitoring and administrative burden as a percentage of company turnover		
	Small	Medium	Large
OEL 0.025 µg NCO/m^3			
C13 Textiles	2.48%	2.00%	2.50%
C14 Apparel	3.14%	2.24%	0.83%
C15 Leather	1.46%	1.04%	0.65%
C16 Wood	1.81%	0.87%	0.14%
C20 Chemicals	1.21%	1.12%	0.31%
C22.21 Rigid foam	0.47%	0.57%	0.31%
C22.29 Flexible foam	0.41%	1.34%	0.72%
C22. Other	1.24%	1.17%	0.31%
C26 Computers	0.72%	0.41%	0.08%
C27 Electrical equipment	0.58%	0.36%	0.06%
C28 Machinery	2.26%	2.23%	1.10%
C29 Motor vehicles	3.26%	3.23%	0.13%
C30 Transport	3.46%	3.28%	0.31%
C31 Furniture	2.13%	1.90%	1.52%
C33 Machinery repair	3.36%	2.99%	1.78%
F41.2 Construction	1.08%	0.21%	0.17%
F42 Civil engineering	0.85%	0.47%	0.14%
F43 Specialised construction	1.81%	0.27%	0.25%
F43.29 Other installation	1.18%	0.28%	0.20%
G45 Vehicle repair	2.29%	0.47%	0.20%
S95 Repairs	2.29%	0.23%	0.20%
OEL 0.1 µg NCO/m^3			
C13 Textiles	1.48%	1.10%	3.10%
C14 Apparel	2.00%	1.27%	1.70%
C15 Leather	0.41%	0.23%	0.53%

Sector	RMM compliance, monitoring and administrative burden as a percentage of company turnover		
	Small	Medium	Large
C16 Wood	0.66%	0.11%	0.18%
C20 Chemicals	0.26%	0.20%	0.11%
C22.21 Rigid foam	0.07%	0.12%	0.39%
C22.29 Flexible foam	-0.54%	0.30%	0.18%
C22. Other	0.20%	0.16%	0.11%
C26 Computers	0.27%	0.08%	0.07%
C27 Electrical equipment	0.17%	0.05%	0.04%
C28 Machinery	0.20%	0.14%	0.16%
C29 Motor vehicles	0.55%	0.43%	0.04%
C30 Transport	1.18%	0.88%	0.19%
C31 Furniture	0.46%	0.15%	0.59%
C33 Machinery repair	1.29%	0.64%	1.55%
F41.2 Construction	0.43%	0.06%	0.84%
F42 Civil engineering	0.41%	0.26%	0.18%
F43 Specialised construction	0.85%	0.10%	3.05%
F43.29 Other installation	0.52%	0.08%	1.68%
G45 Vehicle repair	1.34%	0.20%	4.55%
S95 Repairs	0.61%	0.07%	6.43%
OEL 0.5 µg NCO/m^3			
C13 Textiles	0.43%	0.23%	0.07%
C14 Apparel	0.68%	0.30%	0.06%
C15 Leather	0.09%	0.01%	0.01%
C16 Wood	0.17%	0.01%	0.01%
C20 Chemicals	0.07%	0.04%	0.01%
C22.21 Rigid foam	0.04%	0.01%	0.03%
C22.29 Flexible foam	0.00%	0.06%	0.02%
C22. Other	0.04%	0.01%	0.01%
C26 Computers	0.07%	0.01%	0.00%
C27 Electrical equipment	0.07%	0.01%	0.00%
C28 Machinery	0.13%	0.11%	0.01%
C29 Motor vehicles	0.19%	0.16%	0.01%
C30 Transport	0.23%	0.16%	0.01%
C31 Furniture	0.23%	0.10%	0.02%
C33 Machinery repair	0.29%	0.14%	-0.01%
F41.2 Construction	0.17%	0.01%	0.00%
F42 Civil engineering	0.09%	0.02%	0.00%
F43 Specialised construction	0.26%	0.02%	0.01%
F43.29 Other installation	0.17%	0.02%	0.00%

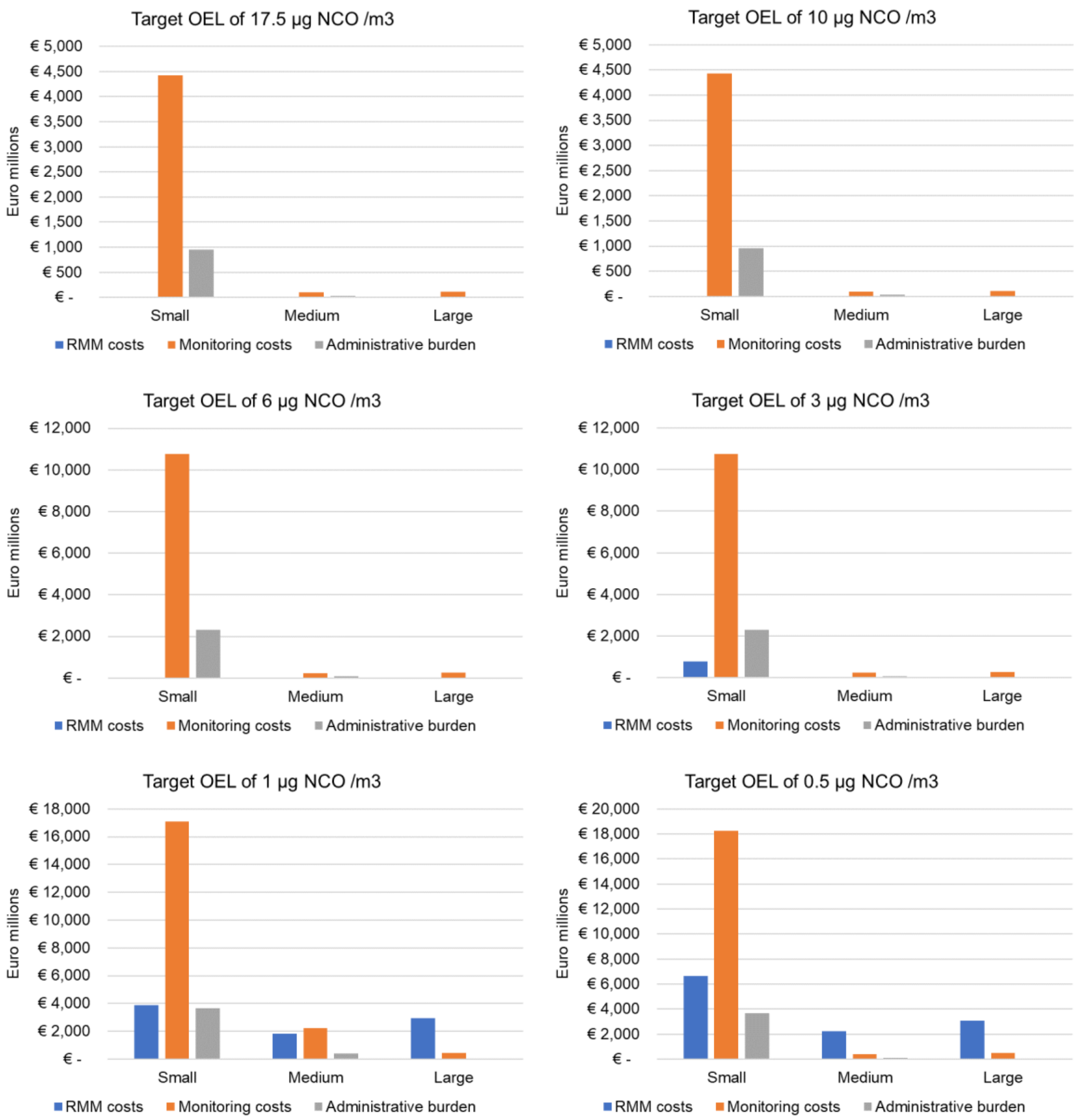
Sector	RMM compliance, monitoring and administrative burden as a percentage of company turnover		
	Small	Medium	Large
G45 Vehicle repair	0.35%	0.02%	0.01%
S95 Repairs	0.44%	0.01%	0.01%
OEL 1 µg NCO/m³			
C13 Textiles	0.25%	0.10%	0.04%
C14 Apparel	0.42%	0.14%	0.03%
C15 Leather	0.08%	0.01%	0.01%
C16 Wood	0.14%	0.01%	0.00%
C20 Chemicals	0.06%	0.04%	0.01%
C22.21 Rigid foam	0.04%	0.01%	0.01%
C22.29 Flexible foam	0.04%	0.06%	0.01%
C22. Other	0.04%	0.01%	0.00%
C26 Computers	0.06%	0.01%	0.00%
C27 Electrical equipment	0.06%	0.01%	0.00%
C28 Machinery	0.03%	0.01%	0.00%
C29 Motor vehicles	0.19%	0.16%	0.01%
C30 Transport	0.21%	0.16%	0.01%
C31 Furniture	0.15%	0.01%	0.01%
C33 Machinery repair	0.26%	0.15%	0.00%
F41.2 Construction	0.15%	0.01%	0.00%
F42 Civil engineering	0.08%	0.02%	0.00%
F43 Specialised construction	0.23%	0.01%	0.00%
F43.29 Other installation	0.15%	0.01%	0.00%
G45 Vehicle repair	0.27%	0.02%	0.00%
S95 Repairs	0.41%	0.01%	0.01%
OEL 3 µg NCO/m³			
C13 Textiles	0.11%	0.04%	0.01%
C14 Apparel	0.19%	0.06%	0.01%
C15 Leather	0.05%	0.01%	0.00%
C16 Wood	0.09%	0.01%	0.00%
C20 Chemicals	0.02%	0.00%	0.00%
C22.21 Rigid foam	0.02%	0.00%	0.00%
C22.29 Flexible foam	0.02%	0.00%	0.00%
C22. Other	0.02%	0.00%	0.00%
C26 Computers	0.03%	0.00%	0.00%
C27 Electrical equipment	0.03%	0.00%	0.00%
C28 Machinery	0.02%	0.00%	0.00%
C29 Motor vehicles	0.02%	0.00%	0.00%
C30 Transport	0.03%	0.00%	0.00%

Sector	RMM compliance, monitoring and administrative burden as a percentage of company turnover		
	Small	Medium	Large
C31 Furniture	0.09%	0.01%	0.00%
C33 Machinery repair	0.09%	0.00%	-0.01%
F41.2 Construction	0.09%	0.01%	0.00%
F42 Civil engineering	0.04%	0.01%	0.00%
F43 Specialised construction	0.13%	0.01%	0.00%
F43.29 Other installation	0.09%	0.01%	0.00%
G45 Vehicle repair	0.17%	0.01%	0.00%
S95 Repairs	0.26%	0.01%	0.00%
OEL 6 µg NCO/m³			
C13 Textiles	0.07%	0.01%	0.01%
C14 Apparel	0.15%	0.02%	0.01%
C15 Leather	0.05%	0.01%	0.00%
C16 Wood	0.09%	0.01%	0.00%
C20 Chemicals	0.01%	0.00%	0.00%
C22.21 Rigid foam	0.02%	0.00%	0.00%
C22.29 Flexible foam	0.02%	0.00%	0.00%
C22. Other	0.02%	0.00%	0.00%
C26 Computers	0.03%	0.00%	0.00%
C27 Electrical equipment	0.03%	0.00%	0.00%
C28 Machinery	0.02%	0.00%	0.00%
C29 Motor vehicles	0.02%	0.00%	0.00%
C30 Transport	0.03%	0.00%	0.00%
C31 Furniture	0.09%	0.01%	0.00%
C33 Machinery repair	0.06%	0.01%	0.00%
F41.2 Construction	0.09%	0.01%	0.00%
F42 Civil engineering	0.04%	0.01%	0.00%
F43 Specialised construction	0.13%	0.01%	0.00%
F43.29 Other installation	0.09%	0.01%	0.00%
G45 Vehicle repair	0.13%	0.01%	0.00%
S95 Repairs	0.26%	0.01%	0.00%
OEL 10 µg NCO/m³			
C13 Textiles	0.03%	0.00%	0.00%
C14 Apparel	0.05%	0.01%	0.00%
C15 Leather	0.02%	0.00%	0.00%
C16 Wood	0.04%	0.00%	0.00%
C20 Chemicals	0.01%	0.00%	0.00%
C22.21 Rigid foam	0.01%	0.00%	0.00%
C22.29 Flexible foam	0.01%	0.00%	0.00%

Sector	RMM compliance, monitoring and administrative burden as a percentage of company turnover		
	Small	Medium	Large
C22. Other	0.01%	0.00%	0.00%
C26 Computers	0.01%	0.00%	0.00%
C27 Electrical equipment	0.01%	0.00%	0.00%
C28 Machinery	0.01%	0.00%	0.00%
C29 Motor vehicles	0.01%	0.00%	0.00%
C30 Transport	0.01%	0.00%	0.00%
C31 Furniture	0.04%	0.00%	0.00%
C33 Machinery repair	0.03%	0.00%	0.00%
F41.2 Construction	0.04%	0.00%	0.00%
F42 Civil engineering	0.02%	0.00%	0.00%
F43 Specialised construction	0.05%	0.00%	0.00%
F43.29 Other installation	0.04%	0.00%	0.00%
G45 Vehicle repair	0.05%	0.00%	0.00%
S95 Repairs	0.11%	0.00%	0.00%
OEL 17.5 µg NCO/m^3			
C13 Textiles	0.03%	0.00%	0.00%
C14 Apparel	0.05%	0.01%	0.00%
C15 Leather	0.02%	0.00%	0.00%
C16 Wood	0.04%	0.00%	0.00%
C20 Chemicals	0.01%	0.00%	0.00%
C22.21 Rigid foam	0.01%	0.00%	0.00%
C22.29 Flexible foam	0.01%	0.00%	0.00%
C22. Other	0.01%	0.00%	0.00%
C26 Computers	0.01%	0.00%	0.00%
C27 Electrical equipment	0.01%	0.00%	0.00%
C28 Machinery	0.01%	0.00%	0.00%
C29 Motor vehicles	0.01%	0.00%	0.00%
C30 Transport	0.01%	0.00%	0.00%
C31 Furniture	0.04%	0.00%	0.00%
C33 Machinery repair	0.03%	0.00%	0.00%
F41.2 Construction	0.04%	0.00%	0.00%
F42 Civil engineering	0.02%	0.00%	0.00%
F43 Specialised construction	0.05%	0.00%	0.00%
F43.29 Other installation	0.04%	0.00%	0.00%
G45 Vehicle repair	0.05%	0.00%	0.00%
S95 Repairs	0.11%	0.00%	0.00%

Source: Study team estimates using Eurostat data

Figure 7-1 below provides a comparison of the compliance costs that are likely to be incurred by companies to reduce exposure to the required OEL options (including discontinuation of operations in some cases) with those that may arise from increased monitoring requirements. It shows that for SMEs, the burden from having to monitor is proportionately higher at all other OELs than for any other company size. At an OEL of higher than 6 µg NCO/m^3, there are no compliance (RMM) costs as companies already achieve this level. However, the cost monitoring and administrative burden are incurred at these levels and these costs make up a significant amount of investment for small companies.



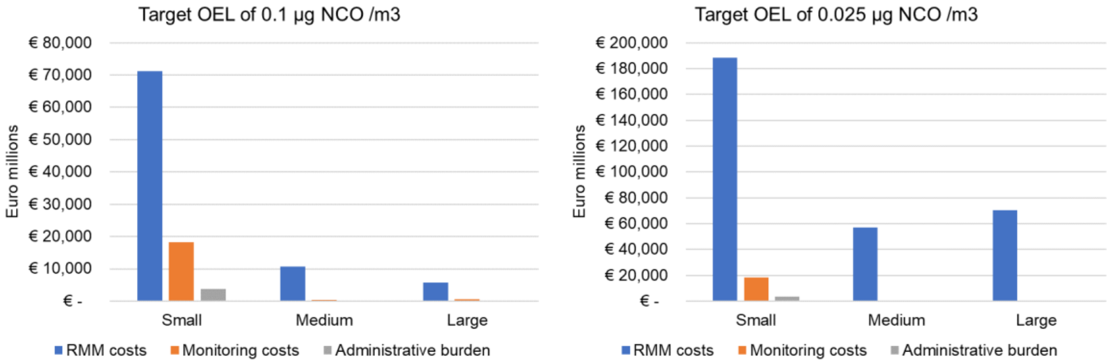


Figure 7-1 Comparison of risk management, monitoring costs and administrative burden costs required to meet OEL options by company size

Source: Study team estimates based on Eurostat

7.2.1.2 Firms exiting the market

The model developed for this study estimates the following distribution of companies or business units, broken down by sector that would discontinue diisocyanate related activities potentially leading to them ceasing trading. For each option in the model, it chooses the risk management measures RMM that can achieve the required OEL options at the lowest cost. Discontinuation of the company (or part of the company) is one of the RMM options, usually with the highest cost. Therefore, generally, the model only chooses discontinuation if no other RMM can achieve the OEL options. The model assumes that small and medium enterprises that indicate discontinuation would result in the entire company going out of business. The logic being that small and medium organisations are more likely to experience closure if their sole operation becomes unfeasible. In contrast, the study team estimates that large enterprises who will be forced into discontinuation would close only 10% of their operations, leading to a 10% loss of turnover. Large companies are more likely to discontinue divisions, lines or specific operations which would not result in the full closure of the business but the discontinuation of the line/process using diisocyanates. More details about the calculation of discontinuations are given in the methodological note. Table 7-6 outlines the number of companies that the model estimates will cease trading.

Section 6.4.1.3 outlines the consultation survey results on the lowest technically and economically feasible OEL options. Comparison of the consultation results with the modelled costs and discontinuations, suggests the study's model overestimates the ability of companies to operate at the lower OEL options. For example, the study model suggests C20, C22.21, and C22.29 would not result in discontinuation until an OEL of 0.1 µg/m³ (or lower), in other words companies would be able to operate at lower OEL than consultation results suggest. For this reason, far fewer companies may be expected to find the lower OEL options technically or economically feasible and there could be a greater number of discontinuations than modelled.

Table 7-6 Estimates of companies or business units that will discontinue operation under different OEL options

Sector	0.025 µg NCO/m^3			0.1 µg NCO/m^3			0.5 µg NCO/m^3			1 µg NCO/m^3			3 µg NCO/m^3		
	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L
C13 Textiles	763	23	4	403	12	2	72	2	0	29	1	0	14	0	0
C14 Apparel	1,948	40	10	1,029	21	5	184	4	1	73	2	0	37	1	0
C15 Leather	1,799	64	9	90	3	0	0	0	0	0	0	0	0	0	0
C16 Wood	346	5	4	30	0	0	0	0	0	0	0	0	0	0	0
C20 Chemicals	201	21	7	32	3	1	6	1	0	6	1	0	0	0	0
C22.29 Flexible foam	4	3	5	0	0	1	0	0	0	0	0	0	0	0	0
C22.21 Rigid foam	24	16	5	5	3	1	1	1	0	1	1	0	0	0	0
C22 Other	926	96	43	91	9	4	0	0	0	0	0	0	0	0	0
C26 Computers	293	19	6	0	0	0	0	0	0	0	0	0	0	0	0
C27 Electrical equipment	284	33	13	0	0	0	0	0	0	0	0	0	0	0	0
C28 Machinery	2,015	130	22	94	6	1	94	6	1	0	0	0	0	0	0
C29 Motor vehicles	5,605	675	473	652	79	55	267	32	23	267	32	23	0	0	0
C30 Transport	5,388	351	117	1,368	89	30	251	16	5	251	16	5	0	0	0
C31 Furniture	4,580	84	15	214	4	1	214	4	1	0	0	0	0	0	0
C33 Machinery repair	2,484	38	6	644	10	2	116	2	0	116	2	0	0	0	0
F41.2 Construction	3,025	22	2	0	0	0	0	0	0	0	0	0	0	0	0
F42 Civil engineering	163	7	2	102	4	1	0	0	0	0	0	0	0	0	0
F43 Specialised construction	6,394	26	3	0	0	0	0	0	0	0	0	0	0	0	0
F43.29 Other installation	25	0	0	0	0	0	0	0	0	0	0	0	0	0	0
G45 Vehicle repair	17,183	29	5	6,444	11	2	0	0	0	0	0	0	0	0	0
S95 Repairs	701	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	**54,151**	**1,683**	**750**	**11,199**	**257**	**106**	**1,206**	**68**	**32**	**744**	**54**	**29**	**51**	**1**	**0**

Source: Study team calculations
Note: Totals may not be the sum of all sectors due to rounding. OELs greater than 3 NCO/m^3 result in no discontinuations.

At the lowest OEL options, modelling predicts high levels of discontinuation amongst companies resulting in many companies exiting the market. For example, at an OEL of 0.025 µg NCO/m^3, modelling predicts approximately 57,000 companies exiting the market, and at an OEL of 0.1 µg NCO/m^3 approximately 11,500 companies would exit the market. In contrast, OELs between 0.5 µg NCO/m^3 and 3 µg NCO/m^3 result in fewer, yet still sizable discontinuations in most sectors. At level of 0.5 µg NCO/m^3 modelling predicts approximately 1,300 companies, and at 1 µg NCO/m^3 approximately 800 would exit the market. At 3 µg NCO/m^3 approximately 50 exit the market, and there are no discontinuations at higher OEL options.

In terms of the market significance of these discontinuations, Table 7-6 illustrates the share that the number of companies discontinuing represents of both the total number of companies in the sector and of the number of companies with exposed workers. The estimates show that at an OEL of 0.025 µg NCO/m^3, the highest percentage of companies discontinuing in relation to the sector is 43% for C30 transport and 40% for C29 motor vehicles. Even at a slightly higher of OEL of 0.1 µg NCO/m^3, the percentage for C30 is 11% and for C29 is 5%. This number reflects the difficulty that some operators in the transport and motor vehicle sectors would face in achieving the lower OELs; they would either have to discontinue or make significant investment.

In contrast, most other sectors show comparatively lower levels of discontinuation; particularly at the 1 µg NCO/m^3 level and higher. However, these levels of discontinuation are still considered relatively high, suggesting that the moderate OEL options would still have severe negative impacts against businesses. These figures would suggest that there would be major impacts on these sectors and other companies taking up the small gap in the market left by vacating enterprises. Interpretation of the option data suggests that OELs continue to result in high levels of discontinuation in all options at or below 1 µg NCO/m^3. At 3 µg NCO/m^3 or higher, the proportion of companies discontinuing is significantly less, and it is not expected that there would be any significant impacts at the sector level.

As shown in Table 7-7 below, at an OEL of 3 µg NCO/m^3, the proportion of enterprises that are likely to discontinue within sectors as well as in comparison to the number of enterprises with workers exposed to diisocyanates is estimated to be much lower. The sector with the highest proportion of enterprises likely to discontinue at 3 µg NCO/m^3 is C14 apparel (0.03%), with the discontinuations representing less than 0.5% of companies with workers exposed to diisocyanates.

Information regarding the capacity of other companies using diisocyanates to increase production and fill the potential gap in the market for specialised products has not been identified during the study. However, with such high proportions of companies using diisocyanates discontinuing at lower levels, it would be more difficult for others to fill any gaps and impacts on prices and availability of certain products are likely to arise.

Table 7-7 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
OEL 0.025 µg NCO/m^3					
C13 Textiles	58,878	2,982	790	1.34%	26.50%
C14 Apparel	125,000	7,538	1,998	1.60%	26.50%

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
C15 Leather	19,700	18,715	1,872	9.50%	10.00%
C16 Wood	33,108	3,085	355	1.07%	11.50%
C20 Chemicals	8,424	1,472	228	2.71%	15.50%
C22.21 Rigid foams	6,000	143	12	0.21%	8.61%
C22.29 Flexible foams	23,902	234	45	0.19%	19.25%
C22 Other	24,760	6,983	1,065	4.30%	15.25%
C26 Computers	36,417	9,104	319	0.88%	3.50%
C27 Electrical equipment	42,350	9,441	330	0.78%	3.50%
C28 Machinery	80,000	6,770	2,166	2.71%	32.00%
C29 Motor vehicles	17,047	14,292	6,753	39.61%	47.25%
C30 Transport	13,486	12,137	5,856	43.43%	48.25%
C31 Furniture	122,361	17,494	4,680	3.82%	26.75%
C33 Machinery repair	22,004	5,240	2,528	11.49%	48.25%
F41.2 Construction	677,446	609,701	3,049	0.45%	0.50%
F42 Civil engineering	85,210	4,301	172	0.20%	4.00%
F43 Specialised construction	2,191,277	1,284,501	6,423	0.29%	0.50%
F43.29 Other installation	99,570	5,000	25	0.03%	0.50%
G45 Vehicle repair	453,092	430,437	17,217	3.80%	4.00%
S95 Repairs	33,664	15,953	701	2.08%	4.40%
OEL 0.1 µg NCO/m^3					
C13 Textiles	58,878	2,982	418	0.71%	14.00%
C14 Apparel	125,000	7,538	1,055	0.84%	14.00%
C15 Leather	19,700	18,715	94	0.48%	0.50%
C16 Wood	33,108	3,085	31	0.09%	1.00%
C20 Chemicals	8,424	1,472	37	0.44%	2.50%
C22.21 Rigid foams	6,000	143	1	0.02%	0.94%
C22.29 Flexible foams	23,902	234	10	0.04%	4.25%
C22 Other	24,760	6,983	105	0.42%	1.50%
C26 Computers	36,417	9,104	0	0.00%	0.00%
C27 Electrical equipment	42,350	9,441	0	0.00%	0.00%
C28 Machinery	80,000	6,770	102	0.13%	1.50%
C29 Motor vehicles	17,047	14,292	786	4.61%	5.50%
C30 Transport	13,486	12,137	1,487	11.03%	12.25%
C31 Furniture	122,361	17,494	219	0.18%	1.25%
C33 Machinery repair	22,004	5,240	655	2.98%	12.50%

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
F41.2 Construction	677,446	609,701	0	0.00%	0.00%
F42 Civil engineering	85,210	4,301	108	0.13%	2.50%
F43 Specialised construction	2,191,277	1,284,501	0	0.00%	0.00%
F43.29 Other installation	99,570	5,000	0	0.00%	0.00%
G45 Vehicle repair	453,092	430,437	6,457	1.43%	1.50%
S95 Repairs	33,664	15,953	0	0.00%	0.00%
OEL 0.5 µg NCO/m^3					
C13 Textiles	58,878	2,982	75	0.13%	2.50%
C14 Apparel	125,000	7,538	188	0.15%	2.50%
C15 Leather	19,700	18,715	0	0.00%	0.00%
C16 Wood	33,108	3,085	0	0.00%	0.00%
C20 Chemicals	8,424	1,472	7	0.09%	0.50%
C22.21 Rigid foams	6,000	143	0	0.00%	0.00%
C22.29 Flexible foams	23,902	234	2	0.01%	0.75%
C22 Other	24,760	6,983	0	0.00%	0.00%
C26 Computers	36,417	9,104	0	0.00%	0.00%
C27 Electrical equipment	42,350	9,441	0	0.00%	0.00%
C28 Machinery	80,000	6,770	102	0.13%	1.50%
C29 Motor vehicles	17,047	14,292	322	1.89%	2.25%
C30 Transport	13,486	12,137	273	2.03%	2.25%
C31 Furniture	122,361	17,494	219	0.18%	1.25%
C33 Machinery repair	22,004	5,240	118	0.54%	2.25%
F41.2 Construction	677,446	609,701	0	0.00%	0.00%
F42 Civil engineering	85,210	4,301	0	0.00%	0.00%
F43 Specialised construction	2,191,277	1,284,501	0	0.00%	0.00%
F43.29 Other installation	99,570	5,000	0	0.00%	0.00%
G45 Vehicle repair	453,092	430,437	0	0.00%	0.00%
S95 Repairs	33,664	15,953	0	0.00%	0.00%
OEL 1 µg NCO/m^3					
C13 Textiles	58,878	2,982	30	0.05%	1.00%
C14 Apparel	125,000	7,538	75	0.06%	1.00%
C15 Leather	19,700	18,715	0	0.00%	0.00%
C16 Wood	33,108	3,085	0	0.00%	0.00%
C20 Chemicals	8,424	1,472	7	0.09%	0.50%
C22.21 Rigid foams	6,000	143	0	0.00%	0.00%

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
C22.29 Flexible foams	23,902	234	2	0.01%	0.75%
C22 Other	24,760	6,983	0	0.00%	0.00%
C26 Computers	36,417	9,104	0	0.00%	0.00%
C27 Electrical equipment	42,350	9,441	0	0.00%	0.00%
C28 Machinery	80,000	6,770	0	0.00%	0.00%
C29 Motor vehicles	17,047	14,292	322	1.89%	2.25%
C30 Transport	13,486	12,137	273	2.03%	2.25%
C31 Furniture	122,361	17,494	0	0.00%	0.00%
C33 Machinery repair	22,004	5,240	118	0.54%	2.25%
F41.2 Construction	677,446	609,701	0	0.00%	0.00%
F42 Civil engineering	85,210	4,301	0	0.00%	0.00%
F43 Specialised construction	2,191,277	1,284,501	0	0.00%	0.00%
F43.29 Other installation	99,570	5,000	0	0.00%	0.00%
G45 Vehicle repair	453,092	430,437	0	0.00%	0.00%
S95 Repairs	33,664	15,953	0	0.00%	0.00%
OEL 3 µg NCO/m^3					
C13 Textiles	58,878	2,982	15	0.03%	0.50%
C14 Apparel	125,000	7,538	38	0.03%	0.50%

Source: Study team calculations based on Eurostat data
Note: Only OEL options showing discontinuations are shown. OEL options of 6 NCO/m^3, 10 µg NCO/m^3 and 17 µg NCO/m^3 only have zero values.

7.2.1.3 Existing firms and new entrants

The analysis presented indicates that the absolute number of firms likely to exit the market in all sectors identified as using diisocyanates compounds is relatively high for all OEL options beneath 3 µg NCO/m^3, although most companies will continue their operations. This is because many organisations are already operating at lower levels of exposure.

The significant capital expenditures required for start-ups (to ensure that exposure to diisocyanates is lower than the required OEL) 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, the additional investments (as a proportion of turnover identified above) are generally lower at OELs of 3 µg NCO/m^3 and above, and consequently it is not envisaged that the introduction OELs at of 3 µg NCO/m^3 or above will have a significant impact on new entrants compared with existing firms. In contrast, significant levels of investment are required for companies at the lower OELs which would indicate these levels would prevent new entrants into the market. Table 7-4 above, outlines compliance costs as a percentage of company turnover over the 40-year period. This table indicates that significant investment is needed at lower OELs to meet compliance, Figure 7-1 also shows that on average, companies will have greater compliance (RMM) costs than monitoring and administrative burden costs at OELs below 0.5 µg NCO/m^3. Subsequently, high compliance costs in terms of upfront purchases are likely to act as a barrier for the entry of new companies. In addition, this figure also displays high levels of monitoring and administrative burden costs to be incurred by new entrants at all levels which will also act as a barrier to market entry.

Given the significant impact of costs and discontinuations upon small businesses, it is likely that some degree of market concentration will occur (other companies will take on this share of the market and workers of those discontinuing). This is more likely to occur in sectors where alternative substances are not viable (resulting in no option but discontinuation), and in sectors providing specialised services (such as spray foam) in which the number of potential employers reduces.

7.2.1.4 Consumers

Information presented in Table 4-56 illustrates that the sectors included in this study are primarily made up of mature markets. As shown below, sectors have either matured to the point of having a higher percentage of large companies, or in sectors where large enterprises are not common (i.e., low percentage in the Table 4-56) the nature of the sector implies large companies are less likely to exist despite the level of maturity. For example, the C33 machinery repair is a mature market but large firms are not common due to the nature of the work. It is therefore unlikely that consumers would experience significant increases to prices due to the OELs as it is assumed mature markets would absorb the costs.

However, information presented in Table 4-56 also illustrates that most of the markets with workers exposed to diisocyanates are primarily employed by small and medium sized companies. Exposure to materials/substances containing diisocyanates in small companies is understood to be primarily short-term use. Where this is the case, small companies are more likely to be able to meet the proposed OEL options with an increased use of RPE. As RPE has low initial costs, but high recurrent costs, it is likely that small companies would be more likely to absorb these costs and the increase would be factored into charges for consumers.

The lower OEL options modelled predict significant discontinuations, particularly for smaller businesses who would be unable to meet the OELs and their compliance costs. As a result of these discontinuations, it is also likely that there would be significantly fewer companies operating within industry resulting in lesser capacity for demand to be filled, and subsequently ad higher risk of price increases for consumers.

7.2.2 Internal market

Table 4-1 and Table 4-2 show the different OELs /STELs identified as being applicable in EU Member States, with a wide range of values and conditions under which they apply. Table 4-3 provides the range of minimum OELs currently applied in Member States. These values range from 1 µg NCO/m^3 (lowest) to 500 µg NCO/m^3 (highest) with a median of 17.4 µg NCO/m^3.

The OEL/STEL options considered in this study 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 EU OEL/STELs should reduce the diversity of national OEL/STELs identified in section 4.2 of this report and the resulting simplification would be particularly beneficial to companies operating in more than one Member State as they would be faced with a reduced range of requirements to which they would have to adhere. This would reduce the need to research OEL/STEL requirements across the EU for companies wishing to operate in more than one Member State, saving on both research costs as well as design costs through facilitating the adoption of common solutions to reduce exposure across plants in different locations instead of having to design facilities to meet with different OEL requirements.

Table 4-1 and Table 4-2 show that the majority of Member States operate at an OEL/STEL around to the baseline of this study (many have an OEL of 17 µg NCO/m^3 for some or all diisocyanates). The only Member States with OELs lower than this are: Denmark, Ireland, Poland and Sweden.

It is possible to determine the number of companies operating in more than one Member State across the sectors identified where worker exposure to diisocyanates exists. However, Table 4-56 shows that a relatively high proportion of the companies in these sectors are small and medium sized. A higher percentage of large companies exist in C22.21 rigid foams and C22.29 flexible foams (12%), however the total number of enterprises in these two sectors are small (143 enterprises for C22.21, and 234 for C22.29). Small companies are less likely to have multiple operations cross the EU. However, where large companies exist in the identified sectors, there are likely to be several companies that will benefit greatly from the simplification of Member State regulations across the EU if this occurs as a result of the introduction of EU OEL/STELs.

7.3 Innovation and growth

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 7-8 provides estimates of average R&D expenditures for small, medium and large companies in the sectors with workers exposed to diisocyanates, based on Eurostat data. Clearly significant investment is being made in large enterprises across the different sectors.

Table 7-8 Average annual R&D expenditure per company, by company size, by sector (€)

Sector	Average annual R&D expenditure per company (€)		
	Small	Medium	Large
C13 Textiles	€ 41	€ 53,042	€ 1,615,008
C14 Apparel	€ 10	€ 16,854	€ 731,934
C15 Leather	€ 29	€ 17,810	€ 1,441,962
C16 Wood	€ 2	€ 7,091	€ 100,113
C20 Chemicals	€ 1,064	€ 262,917	€ 8,594,090
C22.21 Rigid foam	€ 2,045	€ 53,484	€ 1,338,275

Sector	Average annual R&D expenditure per company (€)		
	Small	Medium	Large
C22.29 Flexible foam	€ 1,250	€ 32,685	€ 817,835
C22. Other	€ 26	€ 4,259	€ 82,217
C26 Computers	€ 174	€ 65,346	€ 2,967,301
C27 Electrical equipment	€ 110	€ 22,537	€ 791,750
C28 Machinery	€ 3,112	€ 723,615	€ 52,720,495
C29 Motor vehicles	€ 861	€ 142,889	€ 7,399,598
C30 Transport	€ 69	€ 27,679	€ 2,613,670
C31 Furniture	€ 3	€ 5,948	€ 221,976
C33 Machinery repair	€ 254	€ 622,713	€ 37,611,842
F41.2 Construction	€ 3	€ 7,883	€ 1,321,576
F42 Civil engineering	€ 399	€ 203,112	€ 11,049,317
F43 Specialised construction	€ 1	€ 6,801	€ 924,998
F43.29 Other installation	€ 328	€ 1,263,701	€ 168,934,716
G45.2 Vehicle repair	€ 8	€ 331,244	€ 25,152,464
S95 Repairs	€ 0	€ 76,631	€ 3,152,833

Source: Eurostat (2018)
Note: 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 diisocyanates, 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)

Better Regulation Tool #21 indicates that “All compliance costs divert resources from other purposes, potentially including research and innovation”. Table 7-9 below, presents the average costs of RMM compliance, monitoring, and administrative burden per company (by size and sector) minus expected R&D funds available to meet each OEL option over 40 years. This table provides an overview of the most extreme option; assuming that enterprises would input 100% of their R&D expenditure into meeting compliance costs. It is recognised that enterprises are not realistically going to place this level of R&D funding into meeting costs. Such funding may be essential to the continuity of the business or alternatively enterprises may source compliance costs from other sources. This option should only be seen to be demonstrative of the extreme impact different OELs could have on funds available for R&D.

The negative values (red) represent where compliance costs (RMM, monitoring and administrative burden) exceed the monetary value of funds available for R&D. The positive values (black) represent instances where R&D funds exceed the compliance costs, resulting in excess money available for R&D.

As shown in the below table, in the event available R&D funds were entirely used to meet compliance costs, small businesses would cease R&D operations in most sectors at OELs of 6 µg NCO/m^3 or lower. In general, medium enterprises would cease R&D operations at the lowest OEL with some sectors able to conduct R&D beyond an OEL/STEL of 0.1 µg NCO/m^3. Large organisations have much more funding available for R&D and are less affected for all OEL options. In general, R&D funding would experience a significant negative impact at the lowest OEL level of 0.025 µg NCO/m^3.

Although this is an extreme option, it demonstrates that at the lower OELs compliance would still represent an overall increase in costs for most businesses; most businesses are small. In parallel with Table 7-4 (regarding compliance costs as a percentage of turnover), businesses are further likely to incur significant compliance costs and R&D expenditures may be put under pressure as a result.

The pressure on R&D expenditures may also be exacerbated by the fact that the regulatory environment is becoming stricter, and companies may be concerned about the future use of diisocyanates as an input in their production process. Even if the final OELs implemented were at the mid to higher end of the range of OEL option, where fewer impacts are anticipated, the perception that other more stricter limits might be imposed in the future could well emerge, leading to a lack of confidence in the future of the substance. This perception could then lead to a further reduction in R&D expenditures to develop new and more efficient products.

Table 7-9 Average R&D expenditure minus average costs of RMM compliance, monitoring, and administrative burden per company, by company size, by sector as PV discounted over 40 years (in €)

Sector	Small	Medium	Large
OEL 0.025 µg NCO/m^3			
C13 Textiles	-€203,379	-€5,510,224	-€7,474,367
C14 Apparel	-€129,102	-€2,885,665	€2,133,145
C15 Leather	-€149,476	-€1,990,786	€12,879,783
C16 Wood	-€111,642	-€2,907,462	-€2,519,770
C20 Chemicals	-€450,859	-€5,662,743	€143,645,670
C22.21 Rigid foam	-€64,001	-€1,146,959	€20,986,020
C22.29 Flexible foam	-€67,326	-€4,585,856	€1,493,725
C22. Other	-€281,112	-€4,495,986	-€8,621,177
C26 Computers	-€129,835	-€516,125	€55,484,222
C27 Electrical equipment	-€92,470	-€961,227	€12,731,629
C28 Machinery	-€586,065	€5,271,608	€1,027,265,498
C29 Motor vehicles	-€786,801	-€12,998,364	€129,513,706
C30 Transport	-€568,966	-€13,616,093	€11,232,167
C31 Furniture	-€131,577	-€4,973,625	-€23,211,323
C33 Machinery repair	-€271,099	€3,598,438	€718,749,780

Sector	Small	Medium	Large
F41.2 Construction	-€66,548	-€608,818	€17,692,966
F42 Civil engineering	-€113,850	€2,736,159	€221,619,370
F43 Specialised construction	-€74,617	-€589,719	€11,739,526
F43.29 Other installation	-€66,350	€25,305,310	€3,469,779,457
G45.2 Vehicle repair	-€94,095	€5,373,921	€509,460,237
S95 Repairs	-€47,144	€922,497	€60,957,848
OEL 0.1 µg NCO/m³			
C13 Textiles	-€121,119	-€2,527,951	-€17,211,656
C14 Apparel	-€82,178	-€1,488,167	-€11,556,166
C15 Leather	-€41,439	-€146,661	€15,961,658
C16 Wood	-€40,842	-€244,533	-€3,978,408
C20 Chemicals	-€80,374	€3,402,762	€165,211,331
C22.21 Rigid foam	€27,199	€614,177	€19,316,190
C22.29 Flexible foam	€0	-€480,967	€13,013,996
C22. Other	-€43,895	-€523,169	-€1,864,111
C26 Computers	-€45,634	€963,910	€56,177,666
C27 Electrical equipment	-€26,241	€269,152	€14,074,473
C28 Machinery	€6,318	€14,267,161	€1,076,426,889
C29 Motor vehicles	-€118,731	€816,176	€144,414,048
C30 Transport	-€192,724	-€3,215,243	€27,793,392
C31 Furniture	-€28,109	-€283,105	-€6,327,160
C33 Machinery repair	-€101,318	€10,833,084	€725,923,549
F41.2 Construction	-€26,287	-€66,978	-€19,589,086
F42 Civil engineering	-€50,409	€3,379,844	€219,892,042
F43 Specialised construction	-€35,079	-€114,314	-€71,202,855
F43.29 Other installation	-€25,240	€25,815,976	€3,419,989,832
G45.2 Vehicle repair	-€54,969	€6,208,802	€329,242,195
S95 Repairs	-€12,529	€1,387,981	-€62,069,087
OEL 0.5 µg NCO/m³			
C13 Textiles	-€34,421	€339,311	€32,098,480
C14 Apparel	-€27,987	-€85,596	€14,090,163
C15 Leather	-€8,381	€333,878	€29,518,257
C16 Wood	-€10,198	€108,011	€1,853,089
C20 Chemicals	-€4,307	€4,997,252	€176,231,294
C22.21 Rigid foam	€33,243	€1,053,144	€26,960,399
C22.29 Flexible foam	€25,410	€436,175	€16,508,229
C22. Other	-€9,000	€46,787	€1,502,685
C26 Computers	-€8,924	€1,280,993	€60,778,650
C27 Electrical equipment	-€8,648	€413,125	€16,035,197

Sector	Small	Medium	Large
C28 Machinery	€25,548	€14,416,848	€1,084,397,343
C29 Motor vehicles	-€29,217	€2,149,965	€149,621,331
C30 Transport	-€36,816	-€135,159	€52,154,677
C31 Furniture	-€14,284	-€138,072	€4,287,617
C33 Machinery repair	-€18,885	€12,379,657	€0
F41.2 Construction	-€10,469	€116,503	€27,055,986
F42 Civil engineering	-€4,558	€4,117,235	€227,277,127
F43 Specialised construction	-€10,513	€93,029	€18,859,262
F43.29 Other installation	-€3,712	€25,963,539	€3,476,601,917
G45.2 Vehicle repair	-€14,092	€6,747,649	€517,343,019
S95 Repairs	-€8,967	€1,544,431	€64,727,979
OEL 1 µg NCO/m³			
C13 Textiles	-€19,361	€758,310	€32,639,333
C14 Apparel	-€17,168	€141,556	€14,544,963
C15 Leather	-€7,895	€336,795	€29,537,704
C16 Wood	-€8,448	€116,215	€1,922,450
C20 Chemicals	-€1,897	€5,021,807	€176,320,438
C22.21 Rigid foam	€33,595	€1,070,977	€27,403,816
C22.29 Flexible foam	€16,680	€442,038	€16,560,234
C22. Other	-€7,962	€57,933	€1,554,139
C26 Computers	-€6,754	€1,299,140	€60,869,991
C27 Electrical equipment	-€7,082	€426,888	€16,115,867
C28 Machinery	€54,569	€14,854,448	€1,084,911,988
C29 Motor vehicles	-€28,372	€2,158,034	€149,668,574
C30 Transport	-€33,078	-€115,330	€51,937,070
C31 Furniture	-€9,140	€85,092	€4,429,389
C33 Machinery repair	-€15,787	€12,359,956	€773,928,159
F41.2 Construction	-€9,101	€125,141	€27,096,012
F42 Civil engineering	-€3,697	€4,129,210	€227,337,877
F43 Specialised construction	-€9,520	€101,551	€18,899,163
F43.29 Other installation	-€2,638	€25,971,467	€3,476,642,627
G45.2 Vehicle repair	-€11,024	€6,768,989	€517,432,600
S95 Repairs	-€8,481	€1,547,349	€64,747,426
OEL 3 µg NCO/m³			
C13 Textiles	-€8,474	€945,871	€33,027,514
C14 Apparel	-€7,694	€265,053	€14,873,579
C15 Leather	-€4,751	€347,804	€29,588,771
C16 Wood	-€5,304	€127,225	€1,973,518
C20 Chemicals	€15,359	€5,379,374	€176,750,551

Sector	Small	Medium	Large
C22.21 Rigid foam	€36,739	€1,081,987	€27,454,883
C22.29 Flexible foam	€20,373	€653,936	€16,744,223
C22. Other	-€4,819	€68,942	€1,605,207
C26 Computers	-€1,756	€1,326,104	€60,980,242
C27 Electrical equipment	-€3,073	€445,089	€16,207,394
C28 Machinery	€58,708	€14,873,273	€1,084,900,971
C29 Motor vehicles	€12,371	€2,921,936	€152,196,913
C30 Transport	-€3,929	€550,914	€53,702,519
C31 Furniture	-€5,292	€103,693	€4,481,458
C33 Machinery repair	-€2,154	€0	€0
F41.2 Construction	-€5,288	€143,511	€27,111,216
F42 Civil engineering	€2,869	€4,161,339	€227,308,136
F43 Specialised construction	-€5,318	€121,258	€18,949,639
F43.29 Other installation	€1,410	€25,988,250	€3,476,589,634
G45 Vehicles repair	-€6,935	€6,788,646	€517,513,726
S95 Repairs	-€5,337	€1,558,358	€64,798,494
OEL 6 µg NCO/m³			
C13 Textiles	-€5,151	€1,063,744	€33,107,047
C14 Apparel	-€5,784	€319,170	€14,947,081
C15 Leather	-€4,751	€347,804	€29,588,771
C16 Wood	-€5,304	€127,225	€1,973,518
C20 Chemicals	€16,561	€5,392,110	€176,779,563
C22.21 Rigid foam	€36,739	€1,081,987	€27,454,883
C22.29 Flexible foam	€20,373	€653,936	€16,744,223
C22. Other	-€4,819	€68,942	€1,605,207
C26 Computers	-€1,756	€1,326,104	€60,980,242
C27 Electrical equipment	-€3,073	€445,089	€16,207,394
C28 Machinery	€58,708	€14,873,273	€1,084,900,971
C29 Motor vehicles	€12,371	€2,921,936	€152,196,913
C30 Transport	-€3,929	€550,914	€53,702,519
C31 Furniture	-€5,292	€103,693	€4,481,458
C33 Machinery repair	-€126	€12,796,710	€773,964,892
F41.2 Construction	-€5,288	€143,511	€27,111,216
F42 Civil engineering	€2,869	€4,161,339	€227,308,136
F43 Specialised construction	-€5,318	€121,258	€18,949,639
F43.29 Other installation	€1,410	€25,988,250	€3,476,589,634
G45 Vehicles repair	-€5,189	€6,798,286	€517,550,884
S95 Repairs	-€5,337	€1,558,358	€64,798,494
OEL 10 µg NCO/m³			

Sector	Small	Medium	Large
C13 Textiles	-€1,364	€1,083,891	€33,201,121
C14 Apparel	-€1,997	€339,144	€15,027,456
C15 Leather	-€1,608	€358,813	€29,639,839
C16 Wood	-€2,161	€138,234	€2,024,586
C20 Chemicals	€19,704	€5,403,120	€176,830,630
C22.21 Rigid foam	€39,882	€1,092,996	€27,505,951
C22.29 Flexible foam	€23,517	€664,945	€16,795,290
C22. Other	-€1,675	€79,951	€1,656,274
C26 Computers	€1,388	€1,337,114	€61,031,309
C27 Electrical equipment	€70	€456,099	€16,258,461
C28 Machinery	€61,851	€14,884,283	€1,084,952,039
C29 Motor vehicles	€15,514	€2,932,945	€152,247,981
C30 Transport	-€785	€561,923	€53,753,587
C31 Furniture	-€2,148	€114,702	€4,532,525
C33 Machinery repair	€3,017	€12,807,719	€774,015,960
F41.2 Construction	-€2,145	€154,521	€27,162,283
F42 Civil engineering	€6,013	€4,172,348	€227,359,204
F43 Specialised construction	-€2,174	€132,267	€19,000,707
F43.29 Other installation	€4,553	€25,999,259	€3,476,640,702
G45 Vehicles repair	-€2,046	€6,809,296	€517,601,952
S95 Repairs	-€2,194	€1,569,367	€64,849,561
OEL 17.5 µg NCO/m³			
C13 Textiles	-€1,364	€1,083,891	€33,201,121
C14 Apparel	-€1,997	€339,144	€15,027,456
C15 Leather	-€1,608	€358,813	€29,639,839
C16 Wood	-€2,161	€138,234	€2,024,586
C20 Chemicals	€19,704	€5,403,120	€176,830,630
C22.21 Rigid foam	€39,882	€1,092,996	€27,505,951
C22.29 Flexible foam	€23,517	€664,945	€16,795,290
C22. Other	-€1,675	€79,951	€1,656,274
C26 Computers	€1,388	€1,337,114	€61,031,309
C27 Electrical equipment	€70	€456,099	€16,258,461
C28 Machinery	€61,851	€14,884,283	€1,084,952,039
C29 Motor vehicles	€15,514	€2,932,945	€152,247,981
C30 Transport	-€785	€561,923	€53,753,587
C31 Furniture	-€2,148	€114,702	€4,532,525
C33 Machinery repair	€3,017	€12,807,719	€774,015,960
F41.2 Construction	-€2,145	€154,521	€27,162,283
F42 Civil engineering	€6,013	€4,172,348	€227,359,204

Sector	Small	Medium	Large
F43 Specialised construction	-€2,174	€132,267	€19,000,707
F43.29 Other installation	€4,553	€25,999,259	€3,476,640,702
G45 Vehicles repair	-€2,046	€6,809,296	€517,601,952
S95 Repairs	-€2,194	€1,569,367	€64,849,561

Source: Study team

7.4 Competitiveness of EU businesses

7.4.1 Cost competitiveness

The introduction of harmonised OEL/STELs will have an impact on companies' cost competitiveness but will be more significant for the lower OEL/STEL options. 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 not using diisocyanates and with any companies already compliant at this level.

In the Member State authority consultation, the results of which are in Table 6-18 for OELs, and Table 6-17 for STELs, approximately 60-80% of Member States think that all OEL options from 0.025 to 6 µg NCO/m^3 will have a moderate or significant negative impact upon competitiveness, with the proportion believing this will be significant increasing as the OEL options lower. Broadly, they believe the impact of STELs on competitiveness at levels of twice the OELs are slightly more negative compared with the OELs.

7.4.2 Capacity to innovate

Potential impacts on companies' capacity to innovate have been outlined in Section 7.3 above. Primarily, 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/STELs.

7.4.3 International competitiveness

If EU companies are required to comply with stricter OEL/STELs than those in effect in third countries, they will be at a disadvantage when compared to their competitors from third countries with higher OEL/STELs who will be able to operate without incurring large capital and operating costs. In certain cases, where they have existing plants in third countries, EU companies working with diisocyanates might have the incentive to shift EU operations away from the EU. As identified in Table 4-57 above, small and medium companies form a significant proportion of companies operating in a number of sectors where companies have workers exposed to diisocyanates. Such companies are more likely to operate on national scale and have fewer opportunity to transfer operations to existing plants outside the EU. However, as most exposed workers are in small companies in the construction and vehicle repair sectors and as these cannot easily move outside the EU, they have less risk of being disadvantaged against competitors outside the EU.

Table 4-1 in section 4 provides detailed information on OEL/STELs in a selection of other countries outside the EU and a summary of the OELs and STELs in these countries is shown in Table 7-10 and Table 7-11. These countries have OEL/STELs which are generally similar to or significantly higher than the OEL/STELs options in this study. Countries often have different compliance rules and methods to define exposure and it also not possible to determine how the sample is derived: this makes comparison difficult.

However, such locations may provide an incentive for large EU based companies to relocate their operations, particularly if they already have facilities in these countries and perceive that the costs of adapting existing operations within the EU to comply with the OEL/STELs will have excessive negative impacts on their profitability. Again, however, the costs that adaptation measures represent at the highest OEL/STELs are not considered particularly significant for large companies based on the calculations modelled in this study, and the cost of relocation may exceed that of taking the necessary measures to comply with whatever OEL/STEL is introduced.

Table 7-10 Summary of highest and lowest OELs for diisocyanates in competitor countries

Country	Lowest OEL for diisocyanate µg NCO/m³	Diisocyanate with lowest OEL	Highest OEL for diisocyanate µg NCO/m³	Diisocyanate with highest OEL
Australia	20	Diisocyanates µg/m³	20	Diisocyanates µg/m³
Canada, Ontario	17	HDI IPDI 4,4'-MDI 2,2'-MDI 2,4-TDI	17	HDI IPDI 4,4'-MDI 2,2'-MDI 2,4-TDI
Canada, Québec	17	HDI IPDI 4,4'-MDI 2,2'-MDI TDI	17	HDI IPDI 4,4'-MDI 2,2'-MDI TDI
China	15	HDI	48	2,4-TDI
Israel	17	HDI IPDI 4,4'-MDI 2,4-TDI	17	HDI IPDI 4,4'-MDI 2,4-TDI
Japan - JSOH	17	HDI 4,4'-MDI TDI	68	TDI
Norway	0.005 (ppm)	Diisocyanates ppm	17	HDI IPDI 4,4'-MDI 2,4-TDI
Russia	24	2,4-TDI	168	4,4'-MDI
South Korea	17	HDI IPDI	19	2,4-TDI
Switzerland	20	Diisocyanates µg/m³	20	Diisocyanates µg/m³
Turkey	-	-	-	-
United Kingdom	20	Diisocyanates µg/m³	20	Diisocyanates µg/m³
USA, NIOSH	16	1,5-NDI	17	HDI IPDI 4,4'-MDI
USA, OSHA	67	4,4'-MDI	198,469	IPDI

Source: Consultation data

Table 7-11 Summary of highest and lowest STELs for diisocyanates in competitor countries

Country	Lowest STEL for diisocyanate µg NCO/m³	Diisocyanate with lowest STEL	Highest STEL for diisocyanate µg NCO/m³	Diisocyanate with highest STEL
Australia	-	-	70	Diisocyanates µg/m³
Canada, Ontario	69	HDI IPDI 2,2'-MDI 2,4-TDI	84	4,4'-MDI
Canada, Québec	-	-	68	TDI
China	34	4,4'-MDI	97	2,4-TDI
Israel	68	IPDI 2,4-TDI	71	4,4'-MDI
Norway	-	-	10	Diisocyanates µg/m³
South Korea	-	-	72	2,4-TDI
Switzerland	-	-	20	Diisocyanates µg/m³
United Kingdom	-	-	70	Diisocyanates µg/m³
USA, NIOSH	35	2,2'-MDI	70	HDI
USA, OSHA	67	4,4'-MDI	68	2,4-TDI

Source: Consultation data

Table 7-12 provides an overview of the factors affecting competition in specific sectors. Where relevant, the factors that may influence companies to move their operations outside of the EU are provided under Market impacts. For most sectors (except for construction), relocation is often caused by a lack of alternatives, or harmful alternatives, which are also regulated within the EU. Other factors include high levels of competition for some sectors, particularly sectors relating to chemicals where international organisations already pose a significant threat to EU companies' competition.

Table 7-12 Information on aspects affecting competitive position of EU firms

Sector	Factors influencing outcomes from OEL options	Description
C13 Textiles C14 Apparel C15 Leather	Market trends	Demand for goods in Europe is strong and the market is continuously growing, therefore, diisocyanate use may continue to grow in these sectors. The growth in diisocyanate use and the growth of the market sectors might be balanced by efforts to improve the circular economy within these sectors.
	Alternatives	Although there are some adhesives that could be alternatives, some of the alternatives are also harmful and others have slower reaction times, offer lower elasticity and greater susceptibility to water.
	Market impacts from EU companies complying with stricter OELs	Although a significant amount of clothing and footwear are imported into the EU, the textiles sector has radically changed in recent years to maintain competitiveness by moving towards high value-added products and more specialised products. The need to comply with stricter OEL/STELs and implement RMMs may cause some manufacturers to seek alternative substances/technologies or cause some to relocate their manufacturing operations in growing markets just outside of the EU such as Russia and Turkey as well as historically strong markets like the UK. Other global markets located further from the EU may also be competitive.
C16 Wood	Market trends	The wood sector is an important European sector and will help the EU towards meeting the objectives of the European Green Deal. About 70% of the wood in the EU is used in construction and furnishings. The properties of wood make it suitable for a range of applications in the construction industry; it has an energy saving potential through its natural thermal insulation properties as well as the sequestration and storage of carbon. These properties are particularly favourable compared with the energy and emissions required to produce cement and steel. The demand for diisocyanates in the wood sector may increase significantly in the coming years due to regulatory pressures on existing substances used as wood adhesives, such as formaldehyde.
	Alternatives	Although there are some adhesives that could be alternatives, some of the alternatives are also harmful and others have slower reaction times, offer lower elasticity and greater susceptibility to water.

Sector	Factors influencing outcomes from OEL options	Description
		Diisocyanates are also seen as being a less hazardous alternative to existing substances used in the wood sector such as formaldehyde. There may also not be enough pMDI available on the market to replace the amount of formaldehyde used.
	Market impacts from EU companies complying with stricter OELs	Parts of the wood sector are already facing challenges from alternative adhesives that are also subject to regulatory pressure. The need to comply with stricter OELs and implement additional RMMs may cause some manufacturers to cease operations, seek alternative substances/technologies (if possible) or relocate their manufacturing operations out of the EU.
C20 Chemicals	Market trends	The chemicals sector is one of the largest manufacturing sectors in Europe. The EU27 is the second largest region in terms of chemical sales in the world, however, the market share of the EU27 has fallen (Cefic, 2021). There are several diisocyanate manufacturers and product formulators in Europe. The proximity of manufacturers and formulators to customers is beneficial in offering security of supply chains. This is particularly important to customers requiring regular and just-in-time deliveries of diisocyanates. Durable and high-performance polyurethane coating and resin solutions are already used to protect motor vehicles and other forms of transport, but they may also be increasing used to protect wind turbines and cable systems. As several markets are expanding, the chemicals market is also expected to expand in to meet the demand.
	Alternatives	A huge range of uses means this is a complex issue. However, regulatory processes on several other substances such as formaldehyde, mean that the numbers of alternatives for some sectors are reducing.
	Market impacts from EU companies complying with stricter OELs	Highly competitive and could move to other parts of the world, particularly countries close to Europe like Russia, Turkey, Ukraine and the UK. Saudi Arabia, China, Japan and South Korea are also competitive countries that manufacture diisocyanates.
	Market trends	The European rigid foam market helps to meet the demands of end users in several sectors including construction, electrical appliances, packaging, motor vehicles and public transport. The Covid-19

Sector	Factors influencing outcomes from OEL options	Description
C22.21 Rigid foam		global pandemic has temporarily reduced the demand in these sectors, but the demand is likely to return and grow in the coming years. Increase in the demand for foams in the construction industry will also be driven by European Green Deal and light weight foams will also be used in modern electric vehicles. The close proximity of foam manufactures to their customers is important to the supply chains. Foams are big and bulky which makes them unsuitable for transporting long distances.
	Alternatives	Alternatives may consist of polyester fill, cotton, down, wool, and other similar materials. Although these alternatives could replace foams, it is unlikely these will be suitable for all sectors. Market availability of the alternatives may also be a challenge and the costs might be more expensive than diisocyanate based products. Some of the alternatives have other disadvantages depending on the application.
	Market impacts from EU companies complying with stricter OELs	Highly competitive and could move to other parts of the world, particularly countries close to Europe like Russia, Turkey, Ukraine and the UK.
C22.29 Flexible foam	Market trends	The European foam market helps to meet the demands of end users in several sectors including construction, bedding and furniture, motor vehicles and public transport. The Covid-19 global pandemic has temporarily reduced the demand in these sectors, but the demand is likely to return and grow in the coming years. Increase in the demand for foams in the construction industry will also be driven by European Green Deal. Light weight foams are also in demand in modern electric vehicles because they are lighter and counteract the weight of the batteries. The close proximity of foam manufacturers is important to the supply chains. Some foam customers are based on the just-in-time production principle (e.g. car manufactures) and slabstock foams are big and bulky which makes them unsuitable for transporting long distances.
	Alternatives	Both TDI and MDI are used in the manufacture of foams. TDI is typically used to manufacture flexible foams for use in transportation, furniture, bedding, carpet underlay, packaging. Alternatives to flexible

Sector	Factors influencing outcomes from OEL options	Description
		polyurethane foams produced with TDI are natural latex foam, polyester fill, cotton, down, wool, and other similar materials. Although these alternatives could replace the use of flexible polyurethane foams is some sectors, it is unlikely these will be suitable for all sectors. Market availability of the alternatives may also be a challenge and the costs might be more expensive than diisocyanate based products. Some of the alternatives have other disadvantages (such as size and performance) depending on the application and some individuals are allergic to some of the alternatives.
	Market impacts from EU companies complying with stricter OELs	Highly competitive and could move to other parts of the world, particularly countries close to Europe like Russia, Turkey, Ukraine and the UK. The size and weight of some mattresses' foams would added to the transport costs in the event of a relocation, however, the cost of transporting the end product is less significant in the cases of vacuum packed mattress.
C22. Other	Market trends	The demand for plastic and rubber is also expected to be maintained while the EU's adoption of a European strategy for plastics in January 2018 forms part of the EU's circular economy action plan and builds on existing EU measures to reduce plastic waste. As of 2019 the EU made the decision to ban single use plastics, which may push some plastic production overseas. The plastics strategy is a key element of Europe's transition towards a carbon neutral and circular economy.
	Alternatives	There are different types of plastic and rubber that are produced without diisocyanates, typically the type of plastic or rubber used is specifically chosen for its physical and technical properties. In the packaging industry, solvents can be used for packaging lamination, however, solventless lamination are cheaper and have a lower carbon front print.
	Market impacts from EU companies complying with stricter OELs	Considering the additional regulations already placed on plastic production, companies may already be considering relocation outside of the EU, this may be a further push towards relocation.

Sector	Factors influencing outcomes from OEL options	Description
C26 Computers C27 Electrical equipment C28 Machinery	Market trends	The overall market demand for electronics and electrical equipment continues to grow in Europe and globally. Therefore, as diisocyanates are used in the manufacture of these sectors, this market trend will cause demand for diisocyanates to increase. In terms of electrical equipment such as refrigeration units, the market is moving towards demanding more energy efficient products. The diisocyanate used in these products help maintain strong seals and thus provide high levels of energy efficiency. This market trend would thus again cause demand for diisocyanates to increase to meet production demand of appropriate consumer and industrial products. Production of renewable energy is becoming the growing market trend in the energy sector; this push would include the creation and expansion of offshore wind farm sites that require additional underwater electrical cables. Polyurethanes are one of the substances used to manufacture underwater cables. The push for green energy would therefore increase demand. New EU rules which demand manufacturers and importers make their goods repairable for 10 years after being placed on the market may also have an impact on demand for these chemicals. It is possible that new designs and cost saving approaches taken by manufacturers following the introduction of these rules means that fewer items such as adhesives or sealants are used in goods. This would extend the life span of electrical products leading to lower demand over time, causing a fall in demand for diisocyanates. However, it could be argued that the need for manufacturers to supply a stock of replacement parts may result in more products containing diisocyanates needing to be manufactured.
	Alternatives	Although there are some adhesives, coatings and sealants that do not contain diisocyanates which could be alternatives, some of the alternatives involve hazardous production processes or contain harmful substances. Some of the alternative adhesives have slower reaction times, offer lower elasticity and greater susceptibility to water. Some alternative coatings do not offer the same level of technical performance as polyurethane coatings and although some potential alternative sealants have been identified, such as silanes, these have not widely been tested and they might be 3-4 times more expensive.
	Market impacts from EU companies complying with stricter OELs	Typically, Europe and the rest of the world has relied on Asia for the manufacture and supply of electrical components. However, there is a growing demand for more manufacturing to take place outside of Asia, spurred on by the global chip shortages that have arisen from reductions in production in

Sector	Factors influencing outcomes from OEL options	Description
		nations such as China due to Covid-19. Therefore, markets having to operate under stricter OEL/STELs in Europe might be disincentivised from moving or establishing new computer manufacturing facilities within the EU. In addition, stricter OEL/STELs have the potential to cause existing manufacturing within Europe to move to avoid these regulations and better meet growing demand. As a result, stricter OEL/STELs could be counterproductive to the EUs own ambitious target of doubling production of cutting-edge chips to 20% of global value (European Commission, 2021a). Similarly, manufacturers of consumer goods and machinery may also seek to relocate outside of the jurisdiction of stricter OEL/STELs to continue manufacturing energy efficient products as they currently are. Stricter rules could also hamper the move towards green energy; if there are limitations on manufacturing equipment for green energy such as under water electrical cables there is less incentive to move towards such energy sources.
C29 Motor vehicles C30 Transport	Market trends	The EU is a world leader in the production of motor vehicles and other transport including aircraft, trains and marine vessels. Diisocyanates, and parts made using diisocyanates, are widely used in the sector presently. Demand for lower emissions and more sustainable transport is leading to lighter transport solutions and polyurethanes are helping to achieve this. The transition to more sustainable transport will probably see demands for diisocyanates maintained or increase as new generations of vehicles are produced including hybrid and electrical vehicles across all sectors. In some cases, where welding once took place in the manufacturing of motor vehicles, this activity has been replaced with using adhesives as they offer additional advantages.
	Alternatives	Comment for alternatives to adhesives, coatings and sealants as for C28 machinery above.
	Market impacts from EU companies complying with stricter OELs	Large European vehicle manufacturers are already multinational corporations, having elements of the production process distributed across the EU27 and worldwide. Where possible, companies may choose to relocate elements of production involving diisocyanates to existing plants outside of the EU to avoid stricter regulatory activity. Some activities, like vehicle paint spraying and coating operations are not practical to export outside of the EU27 and then reimport. The import of US vehicles into the EU increased during 2020, despite imports from all other countries falling, suggesting that consumers

Sector	Factors influencing outcomes from OEL options	Description
		demand may move towards US vehicles, should this be the cheaper option. Other competitive markets from which the EU imports include Turkey, Japan, South Korea, South Africa and Mexico (ACEA, 2020). Diisocyanates are also used in other forms of transport. where there are other global competitors and trends. Europe has a strong aircraft manufacturing industry; a competitor is North America and due to increased demand in Asia some production has shifted to Asia. Stricter OEL/STELs and increased costs may mean some manufacturing is relocated outside of Europe.
C31 Furniture	Market trends	There are several mattress and furniture manufactures located in the EU. Foams, coatings and adhesives are used in other types of furniture by manufactures in the EU. Furniture market demand is typically driven by consumer demand and the housing renovation and increasing demand for residential dwelling has helped to maintain the market demand for furniture. As part of the Green Deal, furniture manufacture is becoming more circular, promoting remanufacturing and repair over new production.
	Alternatives	Comment for alternatives to adhesives, coatings, and sealants as for C28 machinery above. Alternative foams are described above in sector C22.29.
	Market impacts from EU companies complying with stricter OELs	Companies producing their own foam may consider decide to purchase their foam instead of manufacturing it or they may reconsider relocating outside of the EU. Although the European furniture manufacturing industry is strong, lower production costs in other parts of the world like China, mean the furniture sector is competitive and increases in costs from regulatory measures may impact the competitiveness of EU manufactures.
C33 Machinery repair	Market trends	The market trends for machinery repair are likely to be similar to those for machinery as stated previously. The right to repair has the potential to both increase market demand due to a supply of replacement parts becoming mandatory as well as reduce demand through innovation and redesigns of machinery requiring less components and thus fewer repairs. However, if the market moves towards more demand for computer chip manufacturing and more production of electrical equipment such as

Sector	Factors influencing outcomes from OEL options	Description
		underwater power cables, more facilities and thus more machinery could be established within Europe. There could be a market trend of more machinery repairs being required in the future due to more production taking place in the continent causing a subsequent rise in demand for replacement parts made from diisocyanates.
	Alternatives	Comment for alternatives to adhesives, coatings, and sealants as for C28 machinery above.
	Market impacts from EU companies complying with stricter OELs	Industrial machinery is important to businesses and large and cumbersome to move, so it is unlikely that machinery repairs by themselves would relocate outside of the EU due to stricter OEL/STELs. Companies want repair facilities and replacement parts to be nearby and easily available to keep down time of machinery to a minimum. However, if manufacturers of components or electrical equipment move out of Europe due to stricter OEL/STELs, it is possible that machinery repair facilities and services may also relocate.
F41.2 Construction F42 Civil engineering F43 Specialised construction F43.29 Other installation	Market trends	The construction sectors all play an important role towards the EU meeting the objectives of the European Green Deal. More energy efficient residential and non-residential buildings will be built, and existing buildings may be renovated. Several CASE related products or products manufactured with diisocyanates (e.g. insulated sandwich panels) are used as part of the construction process. Insulating foams can quickly and conveniently be sprayed into existing buildings. Light density foams can be produced with enough strength to be used in the civil engineering sector. Wood and adhesives can also replace some uses of steel and cement. The market demand for diisocyanates in the construction sector is expected to increase.
	Alternatives	Comment for alternatives to adhesives, coatings, and sealants as for C28 machinery above.
	Market impacts from EU companies complying with stricter OELs	Construction and civil engineering will not be relocated got the obvious location reasons; however, property developers may choose to invest outside of the EU to avoid increased costs or pass the demands onto consumers. This may have the potential to reduce the demand for construction.

Sector	Factors influencing outcomes from OEL options	Description
G45.2 Vehicle repair	Market trends	The market demand of diisocyanates is expected to follow market trends. Polyurethane coatings offer a high level of protection, however, if assisted or fully automated driving becomes more common within Europe, the demand for repairs may decrease. Again, the right to repair may also see some products re-designed and fewer diisocyanates being used.
	Alternatives	Comment for alternatives to adhesives, coatings, and sealants as for C28 machinery above.
	Market impacts from EU companies complying with stricter OELs	Stricter OEL/STELs are not likely to cause any relocation, due to consumers not wishing to send damaged vehicles overseas for repairs. However, certain components may be imported from outside the EU, such as new seats or replacement panels (rather than respraying).
S95 Repairs	Market trends	The right to repair may also see some products re-designed and less diisocyanates being used, however, diisocyanate products will continued to be used for several years and market demand may increase following the Covid-19 pandemic.
	Alternatives	Comment for alternatives to adhesives, coatings, and sealants as for C28 machinery above.
	Market impacts from EU companies complying with stricter OELs	There will be some diversification in the market's response to stricter OELs in terms of repairs as mentioned in above sections. However, exposure in the repair sector is expected to be low. Some goods might be covered by right to repair legislation while others will not be. Any additional costs from an OEL might be passed onto customers. Although some items could be exported for repair, the demand for this might be low. Consumers may decide against repairing items and purchase new ones instead. Repairs for goods may continue within Europe with the costs passed onto consumers, however manufacturers of repair parts might import repair parts for consumers under the right to repair legislation.

Source: Study team

Consultation carried out during this study asked companies to reflect on the implications of the introduction of four proposed OEL/STEL options and what they would mean for the competitive position of their company. The figures below summarise the responses received from companies. Respondents did not feel the OEL/STEL options would result in positive impacts regarding their ability to compete against EU, or non-EU markets. At the highest STEL/OEL options (12 and 6 µg NCO/m³) respondents indicated a limited/no impact upon companies' competitiveness within the EU market. Negative impacts increase each time OEL/STELs are reduced. More stark are the negative impacts associated with all OEL/STEL levels regarding competition against non-EU markets.

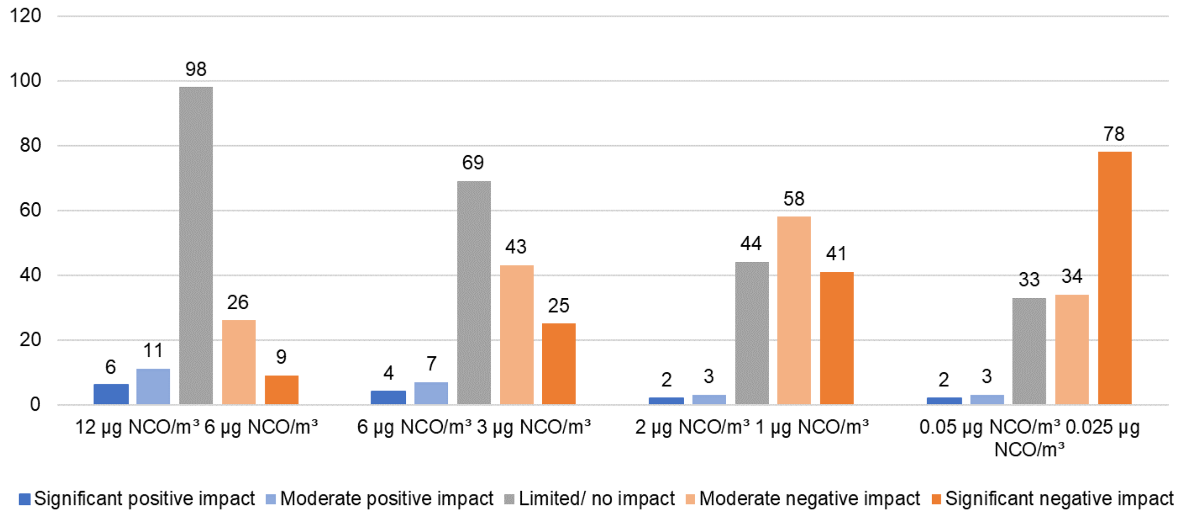


Figure 7-2 Anticipated impact of OEL/STEL options impact on companies' competitive ability against companies within the EU

Source: Consultation survey

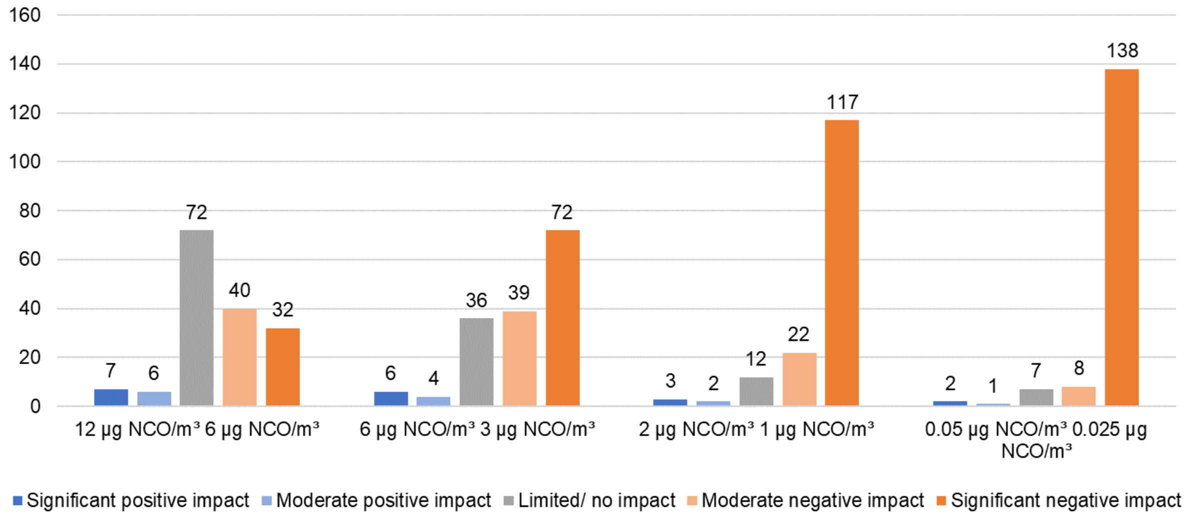


Figure 7-3 Anticipated impact of OEL/STEL options impact on companies' competitive ability against companies outside of the EU

Source: Consultation survey

7.5 Employment

Under the proposed OEL options, employment conditions and workers health are expected to improve. This is covered in further detail regarding the benefits for each of the OEL options in section 5.

However, employment impacts will result from companies forced to cease operations involving diisocyanates if they cannot comply with the OEL/STELs. The numbers of workers potentially impacted at the different OELs are presented in Table 7-13 below.

The impacts associated with the potentially temporary loss of employment can be monetised based on the approach set out in (ECHA, 2016) and adapted from (Haveman R, H. and Weimer, D., 2015) and (Duborg, 2016). The impacts include the following components:

- The value of output/wages lost during the period of unemployment;
- The costs of job search, hiring and firing employees;
- The "scarring effect", i.e. the impact of being made unemployed on future employment and earnings; and
- The value of leisure time during the period of unemployment.

Analysis carried out earlier in this report has indicated that approximately 2,465,525 companies are working with diisocyanates and have employees potentially exposed to the substance. If an enterprise is unable to meet the prescribed OELs for those workers, they would be forced to close specific operations using diisocyanates and these workers would lose their jobs. The table below summarises the numbers of jobs of potentially exposed workers that would be lost at each OEL option and estimates the social costs of the impacts outlined above.

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.

Table 7-13 Number of workers and social cost made unemployed by companies discontinuing by OEL option

OEL options µg NCO/m^3	Total no. of firms with workers exposed to diisocyanates	No. firms or business units that would have to discontinue	Total workers in firms or units discontinuing	Total social cost (based on annual salary of €30,000)
0.025 µg NCO/m^3	2,465,525	56,584	417,674	€34 billion
0.1 µg NCO/m^3		11,562	64,029	€5 billion
0.5 µg NCO/m^3		1,305	15,623	€1.3 billion
1 µg NCO/m^3		827	13,796	€1.1 billion
3 µg NCO/m^3		53	104	€8.5 million
6 µg NCO/m^3		0	-	€ 0
10 µg NCO/m^3		0	-	€ 0
17.5 µg NCO/m^3		0	-	€ 0

Source: Study team calculations and Eurostat data

Notes: 1. The total number of firms and firms discontinuing includes all sectors considered under the study.

2. In most cases, employment data by company size 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 diisocyanates, and the same ratio of small/medium/large firms has been applied to total employment figures for the relevant sub-sectors.

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 most recent Eurostat data)

4. Social cost calculated as follows: €30,000 x job losses x ratio of social cost per job loss over annual pre-displacement wage; ratio = 2.72; €30,000 = gross salary per worker (Duborg, 2016 Table A7)

5. These costs are over-estimated by approximately 10% as the companies in Member States that already comply with OELs are not excluded, see section 4.2.5.

8. Distributional effects

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 section comprises the following subsections:

- Section 8.1: Businesses
- Section 8.2: SMEs
- Section 8.3: Workers
- Section 8.4: Consumers
- Section 8.5: Taxpayers/public authorities
- Section 8.6: Specific Member States/regions
- Section 8.7: Different timeframes for costs and benefits

8.1 Businesses

The burden of the cost of continuing to trade for those enterprises that are not forced to close is shown in Table 6-33, disaggregated by OEL options. The number of companies predicted to discontinue in described in Table 7-6. The benefits for employers are based upon the reduced cost of having an employee become ill with asthma and/or skin irritation: how they relate to Method 2 and the benefit to employers is given in section 5.5.

The average benefits per enterprise for companies that continue in business are shown in Table 8-1 below. The benefits are based on workforce with a turnover of 5%, which effectively means that on average workers spend 20 years working in an environment with diisocyanate compounds.

Comparing the costs and benefits to employers in the table below it is clear that that RMM compliance, monitoring costs and administrative burden over a period of 40 years are significantly higher than the value of benefits returned to an enterprise in each OEL option.

Table 8-1 Costs and benefits to EMPLOYERS (PV over 40 years, constant discount rate, OEL options relative to the baseline – Method 2)

OEL Options	0.025 µg NCO/m³	0.1 µg NCO/m³	0.5 µg NCO/m³	1 µg NCO/m³	3 µg NCO/m³	6 µg NCO/m³	10 µg NCO/m³	17.5 µg NCO/m³
Total benefits for employers (avoided disruption)	€614 million	€461 million	€59 million	€18 million	€400,000	€0	€0	€0
Total RMM compliance, Monitoring, and administrative costs	€339 billion	€111 billion	€35 billion	€30 billion	€15 billion	€14 billion	€6 billion	€6 billion
Number of companies minus those discontinuing	2,408,940	2,453,962	2,464,220	2,464,698	2,465,472	2,465,525	2,465,525	2,465,525
Benefits (avoided disruption) per enterprise	€255	€188	€24	€0.16	€0	€0	€0	€0
Compliance, monitoring and admin costs per enterprise	€140,838	€45,174	€14,209	€12,335	€5,887	€5,556	€2,286	€2,286

Source: Study team

8.2 SMEs

The numbers of small, medium and large enterprises likely to have workers exposed to diisocyanate compounds to some degree in the EU is estimated in Table 4-57. Table 7-6 in Section 7.2.1.2 provides estimates of the number of companies likely to cease trading because of the introduction of the OELs across sectors at each of the different OEL options, broken down by size of company. More companies cease trading as the OEL options decrease.

The average costs of compliance, monitoring, and administrative burden by size of company are shown in Table 8-2, together with the number of discontinuations by size of company at each of the different OEL options.

Table 8-2 Costs for EMPLOYERS by size of company (PV over 40 years, constant discount rate, OEL options relative to the baseline)

Sector	Small	Medium	Large
Number of companies	2,445,213	16,778	3,533
OEL 0.025 µg NCO/m^3			
Total RMM compliance costs, monitoring costs, and administrative burden	€210 billion	€58 billion	€71 billion
Cost per company	€86,018	€3,446,456	€20,129,523
Cost per company as a percentage of turnover	1.69%	0.99%	0.19%
Discontinuations	54,151	1,683	750
OEL 0.1 µg NCO/m^3			
Total RMM compliance costs, monitoring costs, and administrative burden	€93 billion	€11 billion	€6 billion
Cost per company	€38,097	€676,230	€1,798,281
Cost per company as a percentage of turnover	0.75%	0.19%	0.36%
Discontinuations	11,199	257	106
OEL 0.5 µg NCO/m^3			
Total RMM compliance costs, monitoring costs, and administrative burden	€29 billion	€3 billion	€4 billion
Cost per company	€11,694	€166,816	€1,025,504
Cost per company as a percentage of turnover	0.23%	0.05%	0.04%
Discontinuations	1,206	68	32
OEL 1 µg NCO/m^3			

Sector	Small	Medium	Large
Total RMM compliance costs, monitoring costs, and administrative burden	€25 billion	€2 billion	€3 billion
Cost per company	€10,080	€138,175	€973,054
Cost per company as a percentage of turnover	0.2%	0.04%	0.01%
Discontinuations	744	54	29
OEL 3 µg NCO/m³			
Total RMM compliance costs, monitoring costs, and administrative burden	€14 billion	€341 million	€313 million
Cost per company	€5,668	€20,344	€88,675
Cost per company as a percentage of turnover	0.11%	0.01%	0%
Discontinuations	51	1	0
OEL 6 µg NCO/m³			
Total RMM compliance costs, monitoring costs, and administrative burden	€13 billion	€316 million	€308 million
Cost per company	€5,347	€18,845	€87,300
Cost per company as a percentage of turnover	0.11%	0.01%	0%
Discontinuations	0	0	0
OEL 10 µg NCO/m³			
Total RMM compliance costs, monitoring costs, and administrative burden	€5 billion	€129 million	€126 million
Cost per company	€2,200	€7,707	€35,747
Cost per company as a percentage of turnover	0.04%	0%	0%
Discontinuations	0	0	0
OEL 17.5 µg NCO/m³			
Total RMM compliance costs, monitoring costs, and administrative burden	€5 billion	€129 million	€126 million
Cost per company	€2,200	€7,707	€35,747
Cost per company as a percentage of turnover	0.04%	0%	0%
Discontinuations	0	0	0

Source: Study team

As noted in Tool #22 "The SME test" in the Better Regulation toolbox, SMEs generally tend to *"find it more difficult to access capital, and their cost of capital is often higher than for larger businesses."* In addition, the regulatory climate surrounding diisocyanates means that the long-term future of companies using it may be perceived by finance companies as being inherently more risky than other investment opportunities, thereby increasing the difficulty that SMEs might face in securing any finance, or at least having a premium placed on it with the potential threat of further regulation in the future.

Many of the RMMs required to meet the OEL/STELs involve significant capital expenditure, putting SMEs at a disadvantage due to the likely higher cost of finance, if they can secure it. In section 7, there are estimates of the likely significance of the costs of compliance (RMM), monitoring, and administrative burden, which are modelled in Section 6. In particular, Table 7-5 shows that at the lowest OELs, costs are likely to represent a more significant percentage of overall turnover of companies with exposed workers, with several companies facing costs of up to 3.4% of turnover over 40 years.

Table 8-2 and Figure 7-1 provide a comparison of the costs by company size that are likely to be incurred for companies to reduce exposure to the required OELs (including discontinuation of operations in some cases) with those that may arise from increased monitoring requirements and administrative burden. For small companies, the total burden of these costs is significantly higher than for the other company sizes at the proposed OELs. This is largely because small companies make up the majority of companies in the sectors included in this study.

Whilst there are many companies operating in these sectors that will need to invest in compliance measures, there is also a large proportion of companies operating with low levels of exposure below the higher limits. Consequently, whilst many will not incur costs to adapt their operations to be compliant, they will still incur the significant costs of demonstrating their compliance through increased monitoring.

Overall, the cost of monitoring and administrative burden for small companies is a significant proportion of their turnover for all OEL options.

In the Member State authority consultation, the results of which are in Table 6-18 for OELs, and Table 6-17 for STELs, nearly all Member States think that all OEL options from 0.025 to 6 µg NCO/m^3 will have a moderate or significant negative impact upon SMEs: as the OEL options lower, an increasing proportion believe that this will be significantly negative. Broadly, they believe the impact on SMEs of the STEL options (compared with the OELs) are less negative at the highest STEL option of 6 µg NCO/m^3 and slightly more negative at the lowest STEL options.

8.3 Workers

As estimated in section 7.2.1.2, it is anticipated that a substantial number of companies might close at the lower OEL. As a result, employees working in these enterprises would lose their jobs. 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.

Analysis carried out earlier in this report has indicated that 2,465,525 companies are working with diisocyanates and have employees exposed to diisocyanates, and if an enterprise is unable to meet the prescribed OELs for those workers, they would be forced to close specific operations using diisocyanates and these workers would lose their jobs.

Table 7-13 summarises the numbers of jobs of potentially exposed workers that would be lost at differing OELs, together with the social cost of this unemployment. At an OEL of 0.025 µg NCO/m^3, 417,674 jobs would be lost with an approximate social cost of €34 billion, at an OEL of 0.1 µg NCO/m^3, 64,029 jobs would be lost with an approximate social cost of €5 billion, and at an OEL of 0.5 µg NCO/m^3 15,623 jobs would be lost with an approximate social cost of €1.3 billion.

However, the actual cost is probably significantly higher than these figures, since the jobs lost used in the calculations only consider those workers who are potentially exposed to diisocyanate compounds. If the whole company had to close (and not just the operations involving potential exposure to diisocyanate compounds,) all employees at the company would lose their positions. Furthermore, it has not been possible to identify upstream and downstream effects on employment resulting from the employment losses in the sectors using diisocyanate compounds. Multiplier effects could lead to additional losses in employment for suppliers and customers of those companies going out of business, although it is noted that since most companies would continue operations, even at the strictest OELs, it would be expected that these effects would most likely be temporary as previous employees at those companies exiting the market would be absorbed in other companies.

There are considerable benefits to workers and their families, and these are based upon lost earnings, productivity loss, healthcare, and informal care: how they relate to Method 1 and 2 is explained in section 5.

The costs and benefits for workers and their families (relative to the baseline) are summarised in Table 8-3 for Method 1 and Method 2, for the different OEL options. The benefits are the avoided costs of ill health, and the costs are the distress burden of unemployment.

Table 8-3 Comparison of the costs and benefits to WORKERS & THEIR FAMILIES (M1 & M2) (PV over 40 years, for OEL options, relative to the baseline)

OEL Options	0.025 µg NCO/m³	0.1 µg NCO/m³	0.5 µg NCO/m³	1 µg NCO/m³	3 µg NCO/m³	6 µg NCO/m³	10 µg NCO/m³	17.5 µg NCO/m³
Number of workers	4,226,582	4,226,582	4,226,582	4,226,582	4,226,582	4,226,582	4,226,582	4,226,582
Benefits (avoided ill health) (M1)	€1.4 billion	€1.1 billion	€133 million	€38 million	€1 million	€0	€0	€0
Benefits (avoided ill health) (M2)	€4 billion	€3 billion	€370 million	€104 million	€2.2 million	€0	€0	€0
Costs (unemployment distress)	€34 billion	€5 billion	€1.3 billion	€1.1 billion	€8.5 million	€0	€0	€0
Benefits (avoided ill health) per worker (M1)	€338	€254	€31	€9	€0.19	€0	€0	€0
Benefits (avoided ill health) per worker (M2)	€945	€709	€88	€25	€1	€0	€0	€0
Costs (unemployment distress) per worker	€8,064	€1,236	€302	€266	€2	€0	€0	€0

Source: Study team

8.4 Consumers

No significant impacts on consumers have been identified. Most sectors are highly competitive, and costs are unlikely to be passed onto the consumer, particularly from sectors that have competitors just over the EU's borders in Turkey, Ukraine, Russia and the United Kingdom.

8.5 Taxpayers/public authorities

The benefits for taxpayers and public authorities are based upon the reduced cost of healthcare and loss of tax revenue due to morbidity. How these costs relate to Method 1 and Method 2 is explained in section 5.1.2.

There are no direct costs to the taxpayers and public authorities, but indirectly there is a cost due to lower tax revenues if company's profitability is reduced or they employ fewer staff.

The costs (transposition) and benefits (avoided costs) for the public sector (relative to the baseline) are summarised in Table 8-4 below for the different OEL options. The benefits of avoided healthcare costs and loss of tax revenue are in section 5.4. Indirect benefits from avoiding the cost of implementing an OEL are presented in section 5.8.2 and the transposition costs in section 6.7.

Table 8-4 Comparison of the costs and benefits to the PUBLIC SECTOR (PV over 40 years, OEL options relative to the baseline)

Benefits and costs	**OEL options µg NCO/m³ - € millions**							
	0.025	**0.1**	**0.5**	**1**	**3**	**6**	**10**	**17.5**
Benefits								
Avoided costs of healthcare and avoided loss of tax revenue	€1,700	€1,300	€156	€44	€1	-	-	-
Avoided costs of implementing OELs and STELs	€2	€2	€2	€2	€2	€2	€2	€2
Costs								
Transposition costs	€1	€1	€1	€1	€1	€1	€1	€1

Source: Study team

8.6 Specific Member States/regions

Of the 27 EU Member States, research carried out for this study has confirmed that 19 have an OEL or STEL for at least one form of diisocyanate and therefore, eight have none. The following member States have no OEL or STEL of any kind for diisocyanates: Cyprus, Czech Republic, Greece, Luxembourg, Malta, Netherlands, Portugal, and Slovakia.

However, a further complication is that Member States with diisocyanates OELs and STELs are not consistent regarding the level of OEL, or the type of diisocyanate covered. Sometimes Member States have significantly different OELs and STELs for different diisocyanates. Some Member States only have one OEL or STEL for a specific diisocyanates; others have OELs and STELs for chosen diisocyanates, which could all be different; still others have one OEL or STEL covering all diisocyanates. A summary of this information is found in section 4.2. Table 4-4 shows whether each Member State has an OEL or STEL for two of the commonest diisocyanates, MDI and TDI, and if this is well below the baseline or approximately on or above the baseline. The baseline is 17.5 µg NCO/m^3 and any limit value of 15 µg NCO/m^3 is taken as being approximately on or above the baseline.

Six Member States have at least one OEL or STEL that is lower than the baseline: Croatia, Hungary, Ireland, Poland, Slovenia, and Sweden. In addition, Germany has an OEL at the baseline, but its STEL has two levels, a higher tolerated level, which is the same as the STEL baseline and the lower accepted level, which is the same as its OEL.

8.7 Different timeframes for costs and benefits

This section explores the impact of the proposed OEL and STEL over the modelled period of 40 years, outlining when and how costs and benefits are anticipated to occur. In short, and EU-wide OEL or STEL will not produce benefits or costs until it is ratified; and the earliest that this is likely to happen is the end of 2023. 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 and STELs pre-emptively. These companies are not considered in this section as it is not possible to identify or quantify them. Companies which are already operating at or below the proposed OEL of 17.5 µg NCO/m^3 are included in the baseline assessment.

The benefits of the proposed OEL/STEL start to occur as soon as compliance is made mandatory with benefits continuing annually as outlined in section 5. 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.

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.

9. Environmental impacts

This section considers the environmental impacts of new occupational exposure limits (OELs), and short-term exposure limits (STELs) for diisocyanates.

9.1 Persistent, bio-accumulative, and toxic (PBT) screening

The table below outlines the persistent, bio-accumulative, and toxic (PBT) assessment status of diisocyanates. To be classified as PBT, all three criteria must be fulfilled. The following table outlines the PBT status and harmonised classification for each selected diisocyanate, which are listed in Table 1-2.

Table 9-1 PBT and harmonised classification status of diisocyanates

Di-isocyanate	P	B	T	PBT	Harmonised classification	Notes
HDI (Hexamethylene Di-isocyanate) (822-06-0)	Y	N	N	N	Known skin and respiratory sensitiser	-
IPDI (3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate) (4098-71-9)	Y	N	N	N	Known skin and respiratory sensitiser	Toxic to aquatic life
4,4’-MDI (4,4'-methylenediphenyl Di-isocyanate) (101-68-8)	N	N	Y	N	Suspected carcinogenic; Known skin and respiratory sensitiser	-
2,4'-MDI (o-(p-isocyanatobenzyl)phenyl isocyanate) (5873-54-1)	N	N	-	N	Suspected carcinogenic; Known skin and respiratory sensitiser	-
2,2’-MDI (2,2'-methylenediphenyl Di-isocyanate) (2536-05-2)	N	N	Y	N	Suspected carcinogenic; Known skin and respiratory sensitiser	-
pMDI (Polymeric MDI) (9016-87-9)	N	N	Y	N	Suspected carcinogenic; Known skin and respiratory sensitiser	-
H12-MDI (4,4'-methylenedicyclohexyl Di-isocyanate) (5124-30-1)	N	N	N	N	Yes Known skin and respiratory sensitiser	-
m-TMXDI (1,3-bis(1-isocyanato-1-methylethyl)benzene) (2778-42-9)	N	N	Y	N	No	-
m-XDI (1,3-bis(isocyanatomethyl)benzene) (3634-83-1)	-	-	Y	N	Known skin and respiratory sensitiser	Fatal if inhaled; Harmful to aquatic life
1,5-NDI (1,5-naphthylene Di-isocyanate) (3173-72-6)	Y	N	N	N	Known skin and respiratory sensitiser	Harmful to aquatic life

Di-isocyanate	P	B	T	PBT	Harmonised classification	Notes
TDI (m-tolylidene Di-isocyanate) (26471-62-5)	-	-	-	N	Suspected carcinogenic; Known skin and respiratory sensitiser	Fatal if inhaled; Harmful to aquatic life
2,4-TDI (4-methyl-m-phenylene Di-isocyanate) (584-84-9)	N	N	N	N	Suspected carcinogenic; Known skin and respiratory sensitiser	Fatal if inhaled; Harmful to aquatic life
TODI (4,4'-Diisocyanato-3,3'-di-methyl-1,1'-biphenyl) (91-97-4)	-	-	-	N	No	-

Source: ECHA Registration Dossiers (ECHA, 2021b)

9.1.1 Persistent

Most diisocyanates are not considered as having persistent qualities under REACH. Diisocyanates are highly reactive and upon release and undergo rapid abiotic degradation (hydrolysis) rendering the substance inert after a short period. Due to this rapid hydrolysis, biotic degradation is also not possible.

Hexamethylene diisocyanate is not biodegradable and is therefore classed as persistent. However, biodegradation is not relevant as immediate hydrolysis takes places with a half-life of 0.23 hours, producing polyurea which is known to be inert. 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (IPDI) and 1,5-naphthylene diisocyanate (1,5-NDI) are classed as having persistent properties (H411: toxic to aquatic life with long lasting effects). Environmental data on these substances are conclusive but are not considered sufficient for classification and subsequently environmental impacts are not known.

9.1.2 Bio-accumulative

Bioaccumulation of diisocyanates is not considered possible due to rapid (a)biotic degradation of the substances and their inability to accumulate in any environmental compartment.

9.1.3 Toxicity

Toxicity amongst diisocyanates varies according to the substance. As explained above, toxicity is not known to have environmental impacts due to rapid hydrolysis.

In general, diisocyanates are classified under CLP Regulation (1272/2008) as primarily having skin and respiratory sensitising effects. However, harmonised classification also identifies TDI (TDI, 2,4'-TDI) and MDI substances (4,4'-MDI, 2,4'-MDI, 2,2'-MDI, pMDI) as having suspected carcinogenic properties. 1,3-bis(isocyanatomethyl)benzene (m-XDI) has a toxicity classification of STOT RE Category 1 (toxic to humans or toxic effect in animal experiments after repeated exposures). IPDI, m-XDI, 1,5-NDI, TDI, 2,4-TDI are known to be toxic to aquatic life however data is not sufficient for classification.

9.1.4 PBT conclusion

In conclusion, diisocyanates do not meet the required thresholds to qualify as PBT (persistent, bio-accumulative and toxic) or vPvB (very persistent and very bio-accumulative).

9.2 Current environmental exposure

9.2.1 Sources

Diisocyanates are a group of synthetic substances and do not have natural sources.

Point sources for diisocyanates primarily occur during substance manufacture and formulation (via phosgenation of di-isocyanate molecules). However, due to diisocyanate's high reactivity with OH substance transportation and storage only occurs via a closed system (contained in airtight containers). When released into an environment containing water (for example, in relation to air, aquatic environments, and soil) diisocyanates produce a polyurea crust which is insoluble and inert. For these reasons point sources are not known to contribute to environmental impacts.

9.2.2 Background exposure to NCO

Background exposure to NCO can often be attributed to sources relating to the thermal decomposition or incomplete combustion of nitrogen containing organic materials. This relates to common releases from diesel vehicle exhaust gases (Wentzell *et al.*, 2013; Liggio *et al.*, 2017), cooking activities (Leanderson, 2019) and biomass burning (anthropogenic and natural) (Roberts *et al.*, 2011; Young *et al.*, 2012). These activities typically relate to the release of low molecular weight mono-isocyanates such as isocyanic acid (ICA) which is commonly studied to assess the background level of isocyanates.

Whilst studies regarding mono-isocyanates such as ICA were relatively common in the literature, no results were found regarding background exposure from diisocyanates. This is probably because the rapid hydrolysis of diisocyanates in the environment relating to a short environmental lifespan and as such there is little or no background exposure.

9.2.3 Environmental levels in relation to hazard data

No emissions of diisocyanates are made any of the environmental compartments (air, water, soil, sediment, and biota) for each diisocyanate substance for the reasons explained in previous sections.

9.2.4 Conclusions

In conclusion, effectively no environmental exposure of diisocyanates is currently known to occur. Exposures to air, soil, sediment, biota, and water are considered extremely rare due to the rapid hydrolysis of the substances.

9.3 Waste management and disposal

Diisocyanate substances are fully utilised during processes and do not require additional waste treatment options. In the event of diisocyanate spillage, polyurea crusts form requiring specialised clean-up and disposal, however these crusts will not contain diisocyanates.

Diisocyanates are stored and transported in airtight containers. When the use of the substance is complete, containers undergo specialised cleaning to ensure any diisocyanate residue is removed from the container; containers must be drip-free, powder free and/or paste-free. The cleaning of all containers should follow the processes and application of appropriate coding according to the European Waste Catalogue (EWC), which means that once any and all residues have been rendered from the containers, product and hazard labels should be invalidated and the container returned to appropriate recycling centres for reuse. No environmental impacts are anticipated from waste management processes.

9.4 Impact of introducing new risk management measures (RMMs) on environmental exposure

Through the analysis of consultation results, literature review and cost-benefit modelling, the study team has identified five primary RMM's currently used in operations containing diisocyanates. These are:

- partially closed systems
- open hoods over equipment or local extraction ventilation
- self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)
- half and full facemasks (negative pressure respirators)
- general dilution ventilation

Table 9-2 outlines how alternative RMM processes are likely change for each OEL and STEL option, together with the broad environmental impact of each change. The environmental impact of all RMMs are outlined in the methodological note.

The use of alternative RMMs to meet new OELs are not anticipated to contribute to environmental impacts and should generally lead to no change or possibly even lower environmental impacts. It is unlikely that the alternative RMMs will result in rogue emissions or increased waste by-products as they arrive at the same endpoint. For example, where general dilution ventilation may be replaced by an open hood system (local exhaust ventilation), the same endpoint (filters or waste containment sack) will occur, resulting in the incineration of waste.

Table 9-2 Primary and alternative RMMs for each OEL and STEL option, together with the broad environmental impact

Primary RMM	Alternative primary RMM for each OEL and STEL option				Broad environmental impacts
	12 µg NCO/m³ (STEL) 6 µg NCO/m³ (OEL)	6 µg NCO/m³ (STEL) 3 µg NCO/m³ (OEL)	2 µg NCO/m³ (STEL) 1 µg NCO/m³ (OEL)	0.05 µg NCO/m³ (STEL) 0.025 µg NCO/m³ (OEL)	
Partially closed systems	Partially closed systems	Partially closed systems	Closed systems Discontinuation	Closed system Discontinuation	Yes, reduced
Open hoods over equipment or local extraction ventilation	Open hoods Partially closed systems	Open hoods Partially closed systems	Partially closed systems Closed systems Discontinuation	Closed system Discontinuation	Yes, reduced
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	Self-contained breathing apparatus	Self-contained breathing apparatus	Self-contained breathing apparatus	Discontinuation	Yes, reduced
Half and full facemasks (negative pressure respirators)	Half and full facemasks	Half and full facemasks	Powered air-purifying respirators (FFP masks)	Discontinuation	Yes, reduced
General dilution ventilation	General ventilation	General ventilation	Open hoods over equipment	Discontinuation	Yes, reduced

Source: Consultation

9.5 Conclusions

The environmental impacts of diisocyanates relating to emissions or exposures to the environment is currently believed to be low because the substance rapidly becomes inert when exposed to moisture.

The impact of the new OELs/STELs is expected to have either no effect or possibly reduce any minor current environmental impact even further.

In the Member State authority consultation, the results of which are in Table 6-18 for OELs, and Table 6-17 for STELs, nearly half of all Member States think that all OEL and STEL options from 0.025 to 6 µg NCO/m^3 will have no impact on the environment. Nearly half of all Member States think the lowest OEL (0.025 to 1 µg NCO/m^3) and STEL options (0.05 to 2 µg NCO/m^3) will have a significant positive impact on the environment.

10. Limitations and sensitivity analysis

This section presents the limitations and uncertainties of this study, and contains the following sections:

- Section 10.1 Overview of limitations and uncertainties
- Section 10.2 Key limitations and uncertainties

10.1 Overview of limitations and uncertainties

This section presents an overview of the limitations and uncertainties of this study and considers their potential impact on the conclusions. Table 10-1 provides a summarised overview of each element and assesses their significance for the results of this study. A more detailed assessment of some of these limitations and uncertainties is provided in section 10.2.

Table 10-1 Overview of limitations and uncertainties and their effect on the costs and benefits

Limitation or uncertainty	Explanation	Estimates in this study are underestimates or overestimates	
		Costs	Benefits
Not included in the sensitivity analysis			
Inability to model peak exposures	This is the biggest cause of uncertainty, but no sensitivity analysis can be modelled. As explained in section 2.3.5 and section 5.10, the modelled benefits do not appear to reflect reality. The models suggests that above 3 µg NCO/m^3 there are no cases. Peak (short-term) exposure is believed to be particularly important in people developing occupational asthma, but this cannot currently be modelled. As a result, both the cost and benefits might be underestimated at the higher OEL options.	Under	Under
Does the DRR reflect diisocyanates and uses with higher risk than average?	It is possible that the dose response relationship (DRR) and the predicted excess risk at the lowest OEL options is suitable only for sectors and uses that use TDI and/or spray painting and that the predicted excess risk at the lowest OEL options for all other sectors and uses is lower than the DRR suggests, see section 5.10. Because these represent the large number of exposed workers, the number of cases and thus potential benefits could be overestimated. However, the study team has no evidence that the data in these two reports is not representative of all diisocyanates.	Not relevant if considering the costs to achieve OEL options for all sectors Overestimate if only TDI users or spray painting are considered.	Over
Included in the sensitivity analysis			
Many measurements below the	Where the exposure measurements are below the limit of quantification (LOQ), a default value is assigned, see section 4.5.5. In some sectors this means that the median,	Over	Over

Limitation or uncertainty	Explanation	Estimates in this study are underestimates or overestimates	
		Costs	Benefits
limit of quantification	75th, 90th and 95th percentiles are all the same value when, in reality, they are expected to decrease as a log normal distribution. Therefore, the exposure concentrations at the lower percentiles could be much lower and as there are over 4 million exposed workers and many sectors have exposure measurements below the LOQ, it is possible that the cost and benefits are overestimated.		
Impact of REACH Restriction	The REACH Restriction is estimated to reduce the number of occupational asthma cases by between 50 and 70% due to reductions in both airborne concentrations and dermal exposure, see section 4.5.3. Modelling the impact of the REACH Restriction is challenging because the cost model requires revised exposure concentrations, and these are difficult to determine. The steering group agreed with the assumption that all exposure concentrations will be reduced by 50%. As a result, both the costs and benefits could be over or underestimated.	Over or under	Over or under
Exclude some micro companies from monitoring and administrative burden	All enterprises must comply with OELs and STELs. However, in the construction sectors (F41.2, F42, F43 and F43.29) and the vehicle repair sector (G45.2), there are numerous micro companies, many of which employ one person, see section 6.8. It is possible that many will not be required to monitor their compliance. As a result, the costs of monitoring and administrative burden could be overestimated.	Over	Not relevant
Not included in the sensitivity analysis			
Two diverging dose response relationships at higher exposures	The DRR used in the model is described in section 2.3.2 and Figure 2-1, and uses the most conservative information based on the available studies. This may overestimate the benefits.	Not relevant	Over
Number of workers /companies	The number of enterprises with exposure and the number of exposed workers is challenging to calculate accurately. The number of workers is the primary determinant of the benefits and the number of companies the primary determinant of the costs. Both are related. The costs and benefits modelled under the main scenario may therefore be under- or overestimated.	Over or under	Over or under
Inactive micro companies	In some sectors such as construction and vehicle repair the average number of workers per enterprise is low (less than 2, and whilst some will be one person enterprises, others will be inactive, see section 4.8.3. As the costs are related to the number of enterprises, the costs may be overestimated.	Over	Not relevant

Limitation or uncertainty	Explanation	Estimates in this study are underestimates or overestimates	
		Costs	Benefits
Exposure concentrations are not static in the future	The study team believes that the exposure concentrations are likely to be static if an OEL is not introduced, see section 4.5.9 0. The costs and benefits modelled under the main scenario may therefore be under- or overestimated	Over or under	Over or under
The number of exposed workers is not static in the future	The study team believes that the number of exposed workers is likely to be static if an OEL is not introduced, see section 4.6.8. The costs and benefits modelled under the main scenario may therefore be under- or overestimated	Over or under	Over or under
Discount rate	The estimates in this report have all been modelled using a static discount rate of 4%. A declining discount rate allocates more weight to costs and benefits that occur after 20 years. The assessment below shows that although the costs and benefits increase (due to the lower discounting effect), the cost-benefit ratio does not change. This further shows that the costs and benefits are generally equally distributed over time.	Under	Under
Treatment period for asthma	The benefits increase with the treatment period of the endpoints. For the asthma, the treatment period is set at one year and years lived with disability of the disease is set at 30 years due to the chronic character of the disease. The true treatment period may however diverge from the assumed 30 years. Accordingly, the benefits may be under- or overestimated.	Not relevant	Over or under
Positive bias in reported data	It is possible that there is some self-selection among companies that participated in the consultation for this study or provided data for the surveys of the industry associations. Worse-performing companies are less likely to report their exposure concentrations and are probably less likely to be member of an industry association. This may underestimate both costs and benefits and has not been further assessed.	Under	Under
Transposition cost	The true transposition cost may diverge from this study's assessment. However, even if the true transposition were five-fold of what has been assessed, the change in costs would be insignificant when measured against the overall compliance costs of all OELs.	Under	Not relevant

10.2 Key limitations and uncertainties

10.2.1 Inability to model peak exposures

As indicated in section 5.10, the study team is concerned that some of the outputs of the benefits model do not appear to match reality. The benefits indicate that there is no reduction in asthma case numbers above 3 µg NCO/m^3 and therefore no benefit above this level, i.e. the same number of people are assumed to have occupational asthma is exposure levels were 3 µg NCO/m^3 as they would if levels were 17.5 µg NCO/m^3.

The reason for the lack of asthma cases changes above 3 µg NCO/m^3 is because the exposure levels 8-hour TWA are low with the average exposure for the top five percentiles all under 6 µg NCO/m^3. This is because the OELs are being modelled and not the STEL. Unfortunately, it is not possible to derive a DRR for the short-term exposures, and therefore not possible to model the impact of a STEL. Even if a DRR could be derived, the study team only identified short-term data for a couple of sectors.

There is some additional uncertainty about some of the exposure measurements used to develop the exposure distribution. Some of the exposure points appear to be based on static monitors located next to diisocyanate sources where employees would not normally be expected to be located for long periods of time and in some cases in areas employees would not normally be able to access.

In addition, the cost of compliance with STELs is not modelled and therefore costs associated with achieving STELs at higher OEL/STEL option values is not included and cannot be estimated.

This is the biggest cause of uncertainty, but no sensitivity analysis can be performed. However, there could be a significant underestimate of the costs and benefits at higher exposure levels that would be affected by a STEL.

10.2.2 Does the DRR reflect diisocyanates and uses with higher risk than average?

The RAC opinion and the derivation of the DRRs for asthma are based upon one report which is based entirely on TDI (Collins et al., 2017) and one report which is based entirely on HDI and spray painting (Pronk et al., 2009).

As described in section 4.5.4, TDI has a greater saturated vapour concentration (SVC), it is more volatile and the vapour is more likely to be breathed in by employees, making it more hazardous. Spray painting is a particularly hazardous use of diisocyanates

Therefore, it is possible that the excess risk at low exposure levels for sectors and uses that do not tend to use TDI and/or spray painting is lower than the DRR suggests and because many exposed workers operate at these low levels, the number of cases and thus potential benefits could be overestimated. The RAC opinion and the derivation of the DRRs for asthma are based upon one report which is based entirely on TDI (Collins *et al.*, 2017) and another report which is based entirely on HDI and spray painting (Pronk *et al.*, 2009).

However, the study team has no evidence that the data in these two reports is not representative of all diisocyanates and sought to consider all possible reasons for the apparent discrepancy between the expected and modelled number of cases occurring at low exposure levels.

10.2.3 Measurements below the limit of quantification (LOQ)

Where the exposure measurements are below the LOQ, a default value of 0.25 µg NCO/m^3 is assigned and then further reduced by 50% to 0.125 µg NCO/m^3 to take account of the REACH Restriction, see section 4.5.5. This is higher than the lowest option value of 0.025 µg NCO/m^3.

In this sensitivity analysis, two different approaches were taken:

- Reduce the percentile values through a given set of values

- Calculate the values of the percentiles using a log-normal distribution

After each of these calculations, all of the exposure levels are then reduced by 50% to account for the REACH Restriction.

For the first analysis, the exposure concentrations below the LOQ are assumed to reduce in this order:

- 0.25 µg NCO/m^3 (after 50% reduction 0.125 µg NCO/m^3)
- 0.1 µg NCO/m^3 (after 50% reduction 0.05 µg NCO/m^3)
- 0.05 µg NCO/m^3 (after 50% reduction 0.025 µg NCO/m^3)
- 0.025 µg NCO/m^3 (after 50% reduction 0.0125 µg NCO/m^3)

For example, if the 90th, 75th and median percentiles are below the LOQ, the default exposure levels (including the 50% reduction) are 0.125 µg NCO/m^3, 0.05 µg NCO/m^3 and 0.025 µg NCO/m^3 respectively instead of all being 0.125 µg NCO/m^3.

As shown in Table 10-2, the adjusted LOQ reduces both the benefits by 42% and the costs by 27% and increases the cost benefit ratio by a varying but relatively small amount.

For the second analysis, if at least the top two percentiles (100th and 95th) are available, and the others are all below the limit of quantification, the value of the other percentiles is calculated according to a log-normal distribution using the top two percentiles.

If only the 100th percentile is available, and all others were below the limit of quantification, the 95th percentile is assumed to be the default value for limit of quantification or 0.25 µg NCO/m^3 and the lower percentiles are all calculated according to a log-normal distribution using these two percentiles.

As shown in Table 10-2, the log normal LOQ reduces both costs and benefits substantially; the benefits by 59% and the costs by 65%. The impact upon the CBR is also marked, with the CBR at the lowest OEL option being lower than the main scenario and then all the other OEL options having a higher CBR.

Table 10-2 Sensitivity of LOQ on the cost, benefits and CBR, for each OEL option (€ million)

µg NCO/m³	0.025	0.1	0.5	1	3	6	10	17.5
Main								
Benefits M1	€3,400	€2,600	€320	€93	€2	-	-	-
Benefits M2	€6,300	€4,700	€590	€170	€4	-	-	-
Cost	€340,000	€110,000	€35,000	€30,000	€15,000	€14,000	€5,600	€5,600
CBR M1	99	43	109	329	7,200	∞	∞	∞
CBR M2	54	24	60	183	4,000	∞	∞	∞
Adjusted LOQ								
Benefits M1	€2,000	€1,500	€240	€82	€2	-	-	-
Benefits M2	€3,700	€2,700	€430	€150	€4	-	-	-
Cost	€250,000	€65,000	€35,000	€30,000	€15,000	€14,000	€5,600	€5,600
CBR M1	125	44	145	367	7,216	∞	∞	∞
CBR M2	68	24	80	205	4,033	∞	∞	∞
Adjusted log normal LOQ								
Benefits M1	€1,400	€1,000	€160	€56	€2	-	-	-
Benefits M2	€2,600	€1,800	€300	€100	€4	-	-	-
Cost	€120,000	€61,000	€35,000	€30,000	€15,000	€14,000	€5,600	€5,600
CBR M1	84	61	210	530	7,200	∞	∞	∞
CBR M2	46	33	120	300	4,000	∞	∞	∞

Source: Study team
Notes: ∞ or infinity is given because the costs are high, and the benefits are zero

10.2.4 Impact of REACH Restriction

The impact of the REACH Restriction is expected to be significant and the exposure concentrations for the impact assessment were reduced by 50% to account for it, see section 4.5.3. The estimated reduction in the number of cases is between 50% and 70% after four years, or by 2027. This is expected to occur due to reductions in both airborne inhalation and dermal exposure.

Although reducing the number of cases by 50% does not imply that airborne concentrations are all reduced by 50%, as described in section 4.5.3, the steering group agreed that the study team should assume that the Restriction has the effect of reducing all airborne concentrations by 50% in the cost model.

For the sensitivity analysis, the study team has run the benefit and cost models assuming that the REACH Restriction reduces airborne concentrations by 30% and by 70%. A 30% reduction assumes that the REACH restriction is less effective at reducing cases than ECHA anticipates. A 70% reduction is ECHA's highest estimate of the reduction in case numbers. The impact on the benefits and costs are shown in Table 10-3.

If the REACH Restriction had a 30% reduction in the number of cases, the potential benefits and costs both increase due to the increased exposure levels in the models. Overall, the CBRs are reduced for all OEL options.

If the REACH Restriction had a 70% reduction in the number of cases, the potential benefits and costs both increase due to the reduced exposure levels in the models and there are no benefits at 3 µg NCO/m^3 and above. Overall, the CBRs fluctuate considerably.

Table 10-3 Sensitivity of the REACH Restriction at 30% and 70% on the cost, benefits and CBR, for each OEL option (€ million)

µg NCO/m³	0.025	0.1	0.5	1	3	6	10	17.5
Main								
Benefits M1	€3,400	€2,600	€320	€93	€2	-	-	-
Benefits M2	€6,300	€4,700	€590	€170	€4	-	-	-
Cost	€340,000	€110,000	€35,000	€30,000	€15,000	€14,000	€5,600	€5,600
CBR M1	99	43	109	329	7,200	∞	∞	∞
CBR M2	54	24	60	183	4,000	∞	∞	∞
REACH Restriction 30% exposure reduction								
Benefits M1	€4,400	€3,500	€530	€240	€8	-	-	-
Benefits M2	€8,000	€6,400	€1,000	€430	€14	-	-	-
Cost	€350,000	€130,000	€36,000	€32,000	€15,000	€14,000	€5,600	€5,600
CBR M1	80	37	69	140	1,800	∞	∞	∞
CBR M2	44	20	38	75	1,000	∞	∞	∞
REACH Restriction 70% exposure reduction								
Benefits M1	€2,100	€1,300	€120	€7	-	-	-	-
Benefits M2	€4,000	€2,400	€230	€13	-	-	-	-
Cost	€270,000	€49,000	€33,000	€23,000	€14,000	€14,000	€5,600	€5,600
CBR M1	120	37	260	3,000	∞	∞	∞	∞
CBR M2	67	20	140	1,700	∞	∞	∞	∞

Source: Study team
Notes: ∞ or infinity is given because the costs are high, and the benefits are zero

10.2.5 Exclude micro companies from monitoring and administrative burden for construction and G45.2 sectors

In theory, all enterprises must comply with OELs and STELs. However, in the construction sectors (F41.2, F42, F43 and F43.29) and the vehicle repair sector (G45.2), there are many micro companies, many of which employ one person. The data for small companies in construction is also complicated by the high numbers of self-employed people.

Although these micro companies must comply with the risk management measures required to comply with OELs and STELs, it is possible that many will not be required to monitor their compliance. There are many micro companies in these sectors and including them in the calculation of monitoring and administrative burden increases costs substantially.

This sensitivity analysis removes all micro companies (1-9 employees) in these sectors from the calculations for monitoring and administrative burden costs. The revised numbers of small enterprises in these five sectors are shown in Table 10-4: the number of enterprises used in the analysis of monitoring costs for all other sectors are as Table 4-57.

The impacts are shown in Table 10-5. The benefits are unchanged and therefore the CBRs are all lower, but this is most pronounced for the OEL options of 1 and 3 µg NCO/m^3. The total costs at the three highest OEL options also reduce substantially.

Table 10-4 Revised distribution of enterprises with exposed workers for construction and vehicle repair sectors excluding micro companies by size of enterprise

NACE - Sector	Number of enterprises			
	Small	Medium	Large	Total
F41.2 Construction	44,361	4,433	360	49,154
F42 Civil engineering	884	172	43	1,099
F43 Specialised construction	77,579	5,138	514	83,231
F43.29 Other installation	384	28	3	414
G45 Vehicle repair	15,480	732	129	16,341
Total	**261,511**	**16,778**	**3,533**	**281,823**

Source: Study team

Table 10-5 Sensitivity of excluding micro construction and vehicle repair companies from monitoring and administrative burden on the cost, benefits and CBR, for each OEL option (€ million)

µg NCO/m³	0.025	0.1	0.5	1	3	6	10	17.5
Main								
Benefits M1	€3,400	€2,600	€320	€93	€2	-	-	-
Benefits M2	€6,300	€4,700	€590	€170	€4	-	-	-
Cost	€340,000	€110,000	€35,000	€30,000	€15,000	€14,000	€5,600	€5,600
CBR M1	99	43	109	329	7,200	∞	∞	∞
CBR M2	54	24	60	183	4,000	∞	∞	∞
Excluding micro construction and vehicle repair companies from monitoring and administrative burden								
Benefits M1	€3,400	€2,600	€320	€93	€2	-	-	-
Benefits M2	€6,300	€4,700	€590	€170	€4	-	-	-
Cost	€320,000	€91,000	€15,000	€12,000	€2,800	€2,000	€830	€830
CBR M1	93	35	48	130	1,40	∞	∞	∞
CBR M2	51	19	26	71	790	∞	∞	∞

Source: Study team

Notes: ∞ or infinity is given because the costs are high, and the benefits are zero

11. Comparing the options

The comparison of options entails the following sections:

- Section 11.1 Cost-benefit assessment (CBA)
- Section 11.2 Multi-criteria analysis (MCA)
- Section 11.3 Highlighted issues

11.1 Cost-benefit assessment (CBA)

11.1.1 Overview of the benefits for the OEL options

The table below summarises the benefits (cost savings from reduced ill health) associated with the OEL options, as also assessed in section 5 above. The cost savings due to reduced ill health are for the present value (PV) over 40 years with a static discount rate of 4%.

There could be no modelling of the impact of introducing a STEL upon the cases/benefits, see sections 2.3.5 and 5.10. Therefore, the comparison of the options concentrates on the OELs options and the benefits are underestimated particularly at the higher exposure levels.

Table 11-1 Overview of the benefits (PV cost savings due to reduced ill health and avoided costs) per OEL option

Impact	Stakeholders affected	OEL options (µg NCO/m³)							
		0.025	0.1	0.5	1	3	6	10	17.5
Direct benefits – improved well-being - health									
Reduced cases of ill health (asthma)	Workers & families	94,000	70,000	8,600	2,300	50	0	0	0
Reduced cases of ill health (irritation)	Workers & families	10,099	10,099	10,099	10,099	259	0	0	0
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€1,400 - 4,000 million	€1,000 - 3,000 million	€130 - 370 million	€38 - 100 million	€1 - 2 million	€0	€0	€0
Avoided costs	Companies	€610 million	€460 million	€59 million	€18 million	€0.4 million	€0	€0	€0
Avoided costs	Public sector	€1,670 million	€1,250 million	€160 million	€44 million	€1 million	€0	€0	€0
Social policy agenda	All	Contribution to Green Deal: Chemicals Strategy towards a toxic-free environment							
Direct benefits – improved well-being - environmental									
Environmental releases	All	No impact/limited impact							
Direct benefits – market efficiency									

Impact	Stakeholders affected	OEL options (µg NCO/m³)							
		0.025	0.1	0.5	1	3	6	10	17.5
Level playing field	Companies	A harmonisation of the OEL and STEL leads to a level playing field, as all companies across all Member States follow a more symmetric requirement. The level-playing field increases slightly with the stringency of OEL and STEL							
Indirect benefits									
Administrative simplification	Companies	Large companies, and to a lesser extent medium ones, with facilities in different Member States will experience administrative simplification, owing to a more harmonious set of compliance requirements. The sectors expected to benefit most are C20 Chemicals, C29 Motor vehicles and C30 Transport.							
Synergy	Companies	Synergies in terms of exposure reduction to 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 risk management measures applied in each enterprise.							
Corporate Social Responsibility	Companies	Work with diisocyanates may be perceived as a less risky line of work associated with health issues. 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	€1,750,000	€1,750,000	€1,750,000	€1,750,000	€1,750,000	€1,750,000	€1,750,000	€1,750,000

Source: Study team

11.1.2 Overview of the costs for the OEL options

The table below summarises the costs associated with the OEL options, as also assessed in section 6 above. The costs are for the present value (PV) over 40 years with a static discount rate of 4%.

There could be no modelling of the impact of introducing a STEL upon the costs, see sections 2.3.5 and 6.4.2. Therefore, the comparison of the options concentrates on the OELs options and the costs are an underestimate particularly at the higher exposure levels.

Table 11-2 Overview of the PV costs for 40 years per OEL option

Impact	Stakeholders affected	OEL options (µg NCO/m³)							
		0.025	0.1	0.5	1	3	6	10	17.5
Direct costs - compliance									
Risk management measures and discontinuation costs (one-off and recurrent)	Companies	€320,000 million	€88,000 million	€12,000 million	€8,700 million	€830 million	€10 million	€0 million	€0 million
Monitoring (sampling and analysis)	Companies	€19,000 million	€19,000 million	€19,000 million	€18,000 million	€11,000 million	€11,000 million	€4,600 million	€4,600 million
Direct costs - administrative burdens									
Administrative burden	Companies	€3,800 million	€3,800 million	€3,800 million	€3,800 million	€2,400 million	€2,400 million	€1,000 million	€1,000 million
Direct costs - total									
Compliance, monitoring and administrative	Companies	€140,000	€45,000	€14,000	€12,000	€5,900	€5,600	€2,300	€2,300

Impact	Stakeholders affected	OEL options (µg NCO/m^3)							
		0.025	0.1	0.5	1	3	6	10	17.5
burden costs per company									
Direct costs - enforcement costs									
Transposition costs	Public sector	€970,000	€970,000	€970,000	€970,000	€970,000	€970,000	€970,000	€970,000
Enforcement costs	Public sector	€0	€0	€0	€0	€0	€0	€0	€0
Monitoring costs	Public sector	€0	€0	€0	€0	€0	€0	€0	€0
Adjudication costs	Public sector	€0	€0	€0	€0	€0	€0	€0	€0
Indirect costs - other									
Firms exiting the market - No. of company closures	Companies	56,584	11,562	1,305	827	53	0	0	0
Employment – Jobs lost	Workers & families	417,674	64,029	15,623	13,796	104	0	0	0
Employment – Social cost	Workers & families	€34 billion	€5 billion	€1.3 million	€1.1 million	€8.5 million	0	0	0
International competitiveness	Companies	Several sectors are in price sensitive competitive markets with many competitors outside the EU							
Consumers	Consumers	Limited impacts expected							

Impact	Stakeholders affected	OEL options (µg NCO/m³)							
		0.025	0.1	0.5	1	3	6	10	17.5
Internal market Lowest to highest OEL	Companies	0.025 - 0.025	0.1 - 0.1	0.5 - 0.5	1 - 1	3 - 3	3 - 6	3 - 10	3 - 17.5
Specific MSs/regions - MSs that would have to change OELs	Public sector	All MS	All MS	All MS	All MS	All MS	All MS	All MS	All MS
Regulation	Companies	Cumulative impact of many changes in regulations, implemented or awaited							

Source: Study team

11.1.3 Cost benefit analysis for the OEL options

The table below provides a direct comparison of the costs and benefits.

Table 11-3 Cost-benefit ratios of the OEL options (all impacts over 40 years and additional to the baseline)

Impact	**OEL options (µg NCO/m³)**							
	0.025	**0.1**	**0.5**	**1**	**3**	**6**	**10**	**17.5**
Total benefits M1	€3,400 million	€2,600 million	€320 million	€93 million	€2 million	-	-	-
Total benefits M2	€6,300 million	€4,700 million	€590 million	€170 million	€4 million	-	-	-
Total costs	€340,000 million	€110,000 million	€35,000 million	€30,000 million	€15,000 million	€14,000 million	€5,600 million	€5,600 million
Cost benefit ratio M1	99	43	109	329	7,221	∞	∞	∞
Cost benefit ratio M2	54	24	60	183	4,036	∞	∞	∞

Source: Study team

Notes: ∞ or infinity is given because the costs are high, and the benefits are zero

11.2 Multi-criteria analysis (MCA)

The table below summarises the both the monetised and qualitative impacts.

Table 11-4 Multi-criteria analysis (all impacts over 40 years and additional to the baseline) per OEL option

Impact	**Stakeholders affected**	**OEL options (µg NCO/m³)**							
		0.025	**0.1**	**0.5**	**1**	**3**	**6**	**10**	**17.5**
Direct costs - compliance									
Risk management measures and discontinuation costs (one-off and recurrent)	Companies	€320,000 million	€88,000 million	€12,000 million	€8,700 million	€830 million	€10 million	€0 million	€0 million
Monitoring (sampling and analysis)	Companies	€19,000 million	€19,000 million	€19,000 million	€18,000 million	€11,000 million	€11,000 million	€4,600 million	€4,600 million
Direct costs - administrative burdens									
Company cost of administration burden	Companies	€3,800 million	€3,800 million	€3,800 million	€3,800 million	€2,400 million	€2,400 million	€1,000 million	€1,000 million
Direct costs - total									
Compliance, monitoring and administration burden costs per company	Companies	€140,000	€45,000	€14,000	€12,000	€5,900	€5,600	€2,300	€2,300

Impact	Stakeholders affected	OEL options (μg NCO/m^3)							
		0.025	0.1	0.5	1	3	6	10	17.5
Direct costs - enforcement costs									
Transposition costs	Public sector	€970,000	€970,000	€970,000	€970,000	€970,000	€970,000	€970,000	€970,000
Enforcement costs	Public sector	€0	€0	€0	€0	€0	€0	€0	€0
Monitoring costs	Public sector	€0	€0	€0	€0	€0	€0	€0	€0
Adjudication costs	Public sector	€0	€0	€0	€0	€0	€0	€0	€0
Indirect costs - other									
Firms exiting the market - No. of company closures	Companies	57,000	12,000	1,300	830	53	0	0	0
Employment – Jobs lost	Workers & families	420,000	64,000	16,000	14,000	100	0	0	0
Employment – Social cost	Workers & families	€34 billion	€5 billion	€1.3 million	€1.1 million	€8.5 million	0	0	0
International competitiveness	Companies	Several sectors are in price sensitive competitive markets with many competitors outside the EU							
Consumers	Consumers	Limited impacts expected							
Internal market	Companies	0.025 - 0.025	0.1 - 0.1	0.5 - 0.5	1 - 1	3 - 3	3 - 6	3 - 10	3 - 17.5

Impact	Stakeholders affected	OEL options (µg NCO/m³)							
		0.025	0.1	0.5	1	3	6	10	17.5
Lowest to highest OEL									
Specific MSs/regions - MSs that would have to change OELs	Public sector	All MS	All MS	All MS	All MS	All MS except SE	All MS except SE	All MS except IE, SE, PL	18 EU MS
Regulation	Companies	Cumulative impact of many changes in regulations, implemented or awaited							
Direct benefits – improved well-being - health									
Reduced cases of ill health (asthma)	Workers & families	94,000	70,000	8,600	2,300	50	0	0	0
Reduced cases of ill health (irritation)	Workers & families	10,000	10,000	10,000	10,000	260	0	0	0
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€1,400 - 4,000 million	€1,000 - 3,000 million	€130 - 370 million	€38 - 100 million	€1 - 2 million	€0	€0	€0
Direct benefits – improved well-being - safety									
Avoided costs	Companies	€610 million	€460 million	€59 million	€18 million	€0.4 million	€0	€0	€0
Avoided costs	Public sector	€1,670 million	€1,250 million	€160 million	€44 million	€1 million	€0	€0	€0
Social policy agenda	All	Contribution to Green Deal: Chemicals Strategy towards a toxic-free environment							

Impact	Stakeholders affected	OEL options (µg NCO/m³)							
		0.025	0.1	0.5	1	3	6	10	17.5
Direct benefits – improved well-being - environmental									
Environmental releases	All	No impact/limited impact							
Direct benefits – market efficiency									
Level playing field	Companies	A harmonisation of the OEL and STEL leads to a level playing field, as all companies across all Member States follow a more symmetric requirement. The level-playing field increases slightly with the stringency of OEL and STEL							
Indirect benefits									
Administrative simplification	Companies	Large companies, and to a lesser extent medium ones, with facilities in different Member States will experience administrative simplification, owing to a more harmonious set of compliance requirements. The sectors expected to benefit most are C20 Chemicals, C29 Motor vehicles and C30 Transport.							
Synergy	Companies	Synergies in terms of exposure reduction to 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 risk management measures applied in each enterprise.							
Corporate Social Responsibility	Companies	Work with diisocyanates may be perceived as a less risky line of work associated with health issues. 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	€1,750,000	€1,750,000	€1,750,000	€1,750,000	€1,750,000	€1,750,000	€1,750,000	€1,750,000

Source: Study team
Notes: All costs/benefits are incremental to the baseline (PV over 40 years)

11.3 Highlighted issues

The most important issue is the degree of uncertainty particularly regarding the benefits, but also regarding the costs. There are five factors contributing to this uncertainty surrounding the benefits:

- **STEL modelling** – The impact of introducing a STEL upon the cases/benefits could not be modelled. This probably means that cases at the higher OEL options are missing and therefore that there should be benefits as the OEL options reduce to 10 or 6 µg NCO/m^3. (See sections 2.3.5 and 5.10).
- **Limit of quantification (LOQ) –** Many exposure measurements are below the limit of quantification (LOQ) and with agreement of the steering group, are set to default to half the LOQ for all exposures below the LOQ. This probably means that the exposure levels are higher at the lower percentiles than they should be, which implies that the number of cases and the potential benefits at the lower OEL options are overestimated. This issue was addressed in the sensitivity analysis. (See section 5.10).
- **REACH Restriction** – The impact of the REACH Restriction on exposure concentrations is unknown. ECHA estimated a reduction in the number of cases of between 50 and 70% but this appears to be based on little evidence. To run the cost model, the exposure concentrations after the REACH Restriction had to be estimated, and the assumption of a 50% reduction to all levels agreed between the study team and the steering group could be incorrect. In addition, some reduction in cases is likely to be related to reduced dermal contact, but the likely proportion of the reduction is unknown. This issue was addressed in the sensitivity analysis. (See section 4.5.3).
- **DRRs relevance to all diisocyanates uses** – The RAC opinion and the derivation of the DRRs for asthma are based upon two reports: one based entirely on a TDI production facility (Collins *et al.*, 2017) and another report based entirely on HDI used in spray painting (Pronk *et al.*, 2009). TDI is known to be more hazardous than the other diisocyanates and spray painting is a hazardous use because, by definition, the diisocyanate is in aerosol form and thus more likely to be inhaled. Therefore, it seems possible that the DRR may overestimate the risk in sectors using other diisocyanates like MDI, particularly the construction sectors and G45.2 vehicle repair, and/or those sectors not involved in spray painting. However, the study team has no evidence that the data in these two reports is not representative of all diisocyanates and sought to consider all possible reasons for the apparent discrepancy between the expected and modelled number of cases occurring at low exposure levels. (See section 4.5.4).
- **Member States with OELs** – The benefits are overestimated by approximately 10% because the effect of the Member States that have already implemented OELs or STELs has not been taken into consideration. (See section 4.2.6).

The uncertainty regarding the costs is primarily due to three factors:

- **Cost of compliance with STELs** – The impact of introducing a STEL upon the costs could not be modelled, and the costs associated with achieving STELs at higher exposure values cannot be estimated. Therefore, the costs are an underestimate. (See sections 2.3.5 and 6.4.2).
- **Risk management costs** – These may be underestimated as estimates from several other sources tend to be higher. (See section 6.4.2).

- **Member States with OELs** – The benefits are overestimated by approximately 10% because the effect of the Member States that have already implemented OELs or STELs has not been taken into consideration. (See section 4.2.6).

Further issues relating to the EU strategic goals and EU Green Deal:

- **Non-EU competition** – In nearly all EU's major competitors, the OELs for diisocyanates are 17 µg NCO/m^3 or higher (China has 15 µg NCO/m^3 for HDI, but 48 µg NCO/m^3 for TDI). In many sectors, particularly C13 Textiles, C14 Apparel, C22.21 Rigid foams, C22.29 Flexible foams, C20 Chemicals and C31 Furniture, the products are price sensitive and competition from nearby countries such as Turkey, Belarus, UK, Ukraine and Russia is fierce. Saudi Arabia, China, Japan and South Korea are also competitive countries that manufacture products using diisocyanates in many sectors. (See section 7.4.3 and Table 7-12).
- **Small and medium sized companies** – The cost of compliance consisting of risk management measures, monitoring and administrative burden falls relatively heavily on small and medium sized companies at all OEL options. There is a cost of compliance at all options due to the cost of monitoring and administrative burden: the cost per company steps up considerably as the OEL reduces to 6 µg NCO/m^3 and increases again as the OEL reduces to 1 µg NCO/m^3. (See Table 6-35).
- **EU Green Deal** – Several sectors play a significant role in achieving the EU's Green Deal. All construction sectors and C16 Wood are important because considerable renovation of buildings is anticipated: wood is a favoured material due to its sustainability. Energy efficient insulation and an extensive range of building techniques depend upon polyurethane, adhesives, sealants and coatings that use diisocyanates. In addition, in C29 Motor vehicles, manufacturers of electric vehicles are increasingly considering replacing heavier materials in cars with polyurethane to offset the weight of batteries. Finally, sophisticated polyurethane coatings are used in many applications including the rotor surfaces of wind turbines. (See section 7.4.3).

Technical and regulatory issues that will affect companies implementing an OEL or STEL:

- **Lowest limit of quantification** – The ISO 17734-1 sampling and analysis method in Table 4-63 appears to be incorrect following conversations with the ISO. This implies that the lowest STEL that could currently be monitored is 3 µg NCO/m^3 and the lowest OEL is 0.2 µg NCO/m^3. (See section 4.12.3).
- **Continuous monitoring** – This is important for identifying peaks quickly and evacuating if necessary, but there are limits of detection of about 1ppb or about 3.5 µg NCO/m^3. Companies tend to set the warning at 1ppb and evacuation at 5ppb or about 17.5 µg NCO/m^3 or the OEL of many Member States. There are concerns that an OEL below 10 µg NCO/m^3 could lead some companies to remove continuous monitoring, which is expensive, because the warnings cannot be set sufficiently lower than the OEL. (See section 4.11.1).
- **Alternatives** – These are often more toxic than diisocyanates. Formaldehyde users in several sectors are waiting for details of a new REACH Restriction which, if it requires a new low limit, may cause them to switch to MDI. Epoxy resins are another alternative that are known to be able to cause skin sensitisation. The alternatives often have a lower performance with issues ranging from being more reactive, not as strong, requiring much greater volumes, and taking longer to install. There are also issues with the market availability of some alternatives. (See section 4.9 and Table 7-12).

- **Other regulations being considered** – Polyurethane manufacturers are particularly concerned about two potential changes in next year's REACH revision: Mixture Assessment Factor (MAF) and REACH registration of polymers. (See section 4.13.1)

Other issues for DG EMPL and the Working Party on Chemicals to consider:

- **Standard identification and recording of asthma caused by diisocyanates** – It is difficult to identify cases of occupational asthma caused by diisocyanates accurately as there are many causes of asthma, and there is no consistency in registering cases in the EU. Ideally, there would be a common EU approach to defining and registering cases. (See section 4.16).
- **Approach to analysing occupational asthmagens** – Sensitising substances present specific challenges as it is hard to model how sensitisation and occupational asthma occurs. Further consideration of the best approach to use when analysing occupational asthmagens is required. (See section 4.5.4).
- **Medical surveillance** – According to several stakeholders, industry had expected medical surveillance for workers to be introduced as part of the REACH Restriction. In addition to limit values, the Chemicals Agents Directive (CAD) contains provisions for appropriate medical surveillance of workers at a national level. Medical surveillance can also be mandated at an EU level under the CAD: it is already mandated for lead. Further work is beyond the scope of this study, but it is an option that could be considered. (See section 1.1, 4.11.3, and 6.9.2).

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ANNEX 1 SUMMARY OF THE CONSULTATION

The number of consultation responses for diisocyanates is summarised below.

Table A1 responses relevant to diisocyanates

Response type	Number of responses
Questionnaire responses	239
Interviews and conference calls	31
Site visits	4
Total	274

The study team had conference calls with the following industry associations:

- ISOPA/ALIPA and approximately 23 of their members involved in manufacturing and using diisocyanates
- FEICA and approximately 6 of their members
- CEPE and approximately 9 of their members
- PU Europe
- ICOMIA (international maritime industry association)
- Company, paints
- Europur
- Euromoulders
- BG Bau
- Flexible Packaging Europe and approximately 2 of their members
- European Wood Panel Federation (EPF) and approximately 8 of their members

Site visits were conducted with companies in the following sectors. These are all in the UK, due to the covid restrictions, but are representative of processes in the EU.

- C22 moulded foam plant – one company
- C22 slabstock foam plant – one company
- C22 polyurethane plant – one company
- C22 spray foam facility – one company

ANNEX 2 DIISOCYANATE QUESTIONNAIRE

Questionnaire for Companies: Diisocyanates

A consortium comprising RPA Risk & Policy Analysts (United Kingdom), COWI (Denmark), and FoBiG Forschungs- und Beratungsinstitut Gefahrstoffe (Germany) has been contracted by the European Commission's Directorate-General for Employment, Social Affairs and Inclusion to assess the impacts of establishing Occupational Exposure Limits (OELs) for a number of substances.

As part of the study, a baseline study is carried out for **"Diisocyanates".** The collected information and subsequent analyses shall support the European Commission's work in the area of possible amendments of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. This part of the study is being carried out by COWI.

This questionnaire is intended for all companies where exposure to the diisocyanates may take place.

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 for each facility or contact the study team.

The deadline for completion of the questionnaire is the 26th March 2021

This questionnaire is available in English, French, German, Italian, Polish and Spanish. However, you are welcome to **answer the questions in the European language of your choice**.

If you prefer to be interviewed in your language or if you have questions about the survey, please contact: Hannah Collins, hannah.collins@rpaltd.co.uk.

If you have any questions about the impact assessment study in general, please contact: Sophie Garrett, sophie.garrett@rpaltd.co.uk

Abbreviations used in the questionnaire:

CAD	Chemical Agents Directive 98/24/EC
NACE	NACE Revision 2, statistical classification of economic activities in the European Community https://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF , page 61 ff.
OEL	The term Occupational Exposure Limit (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.
ppb	Parts per billion
ppm	Parts per million
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.
RMM	Risk Management Measure
RPE	Respiratory protective equipment
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.
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).

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 name and type of the organisation that I represent, 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	
Please provide the name and address of the facility for which you are completing this questionnaire	
Country of facility	*Picklist of Member States and option to add "Other"*

A2) Please define the sector in which your company is active (if possible, using a NACE code(s))	
A3) How many workers are employed in your company at this facility?	
A4) How many of the workers employed in your company at this facility are exposed to diisocyanates?	
A5) Have you any experience of workers having asthma/respiratory issues resulting from occupational exposure to diisocyanates at the workplace?	
A6) 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

A7) If possible, please specify the specific diisocyanates that are relevant to your activities. If unknown, please leave blank.

Short name	Diisocyanate	*CAS No*	
HDI	Hexamethylene Diisocyanate	*822-06-0*	☐
IPDI	3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate	*4098-71-9*	☐

4,4’-MDI	4,4'-methylenediphenyl Diisocyanate	*101-68-8*	☐
2,4'-MDI	o-(p-isocyanatoben-zyl)phenyl isocyanate	*5873-54-1*	☐
2,2’-MDI	2,2'-methylenediphenyl Diisocyanate	*2536-05-2*	☐
H12-MDI	4,4'-methylenedicyclo-hexyl Diisocyanate	*5124-30-1*	☐
pMDI	Polymeric MDI	*9016-87-9*	☐
m-TMXDI	1,3-bis(1-isocyanato-1-methylethyl)benzene	*2778-42-9*	☐
m-XDI	1,3-bis(isocyanatome-thyl)benzene	*3634-83-1*	☐
1,5-NDI	1,5-naphthylene Diisocy-anate	*3173-72-6*	☐
TDI	m-tolylidene Diisocya-nate	*26471-62-5*	☐
2,4-TDI	4-methyl-m-phenylene Diisocyanate	*584-84-9*	☐
TODI	*4,4′-Diisocyanato-3,3′-dimethyl-1,1′-biphenyl*	*91-97-4*	☐
Other diisocyanate; please specify with name and CAS or EC number	*OPEN TEXT BOX*	*OPEN TEXT BOX*	☐

Note: You may have to adhere to a diisocyanate OEL even if a particular diisocyanate is not mentioned on the safety data sheet (sections 1 and 3) or on the packaging. Please also refer to the EU204 labelling and check about potential exposure to residual diisocya-nates in your application.

B) Information about airborne concentrations at your facility

If you would like to report on more than four activities, please complete additional questionnaires.

	Activity 1	Activity 2	Activity 3	Activity 4
B1) Please specify the most important activities* during which exposure to diisocyanates can occur.				
B2) Please provide the number of workers exposed during a typical working day				
**The most important activities in this context are those for which exposure to diisocyanates gives you the most concern. This could be because the activity has low levels of exposure but affects many people. Or because the activity has high levels of exposure but for short periods. Or alternatively, an activity where it is very difficult or expensive to reduce exposure at all.*				
B3) Please provide data for airborne concentrations without PPE taken in accordance with a STEL (15-minute reference period).				
B3a) Please confirm the relevant diisocyanate for the data you are entering	NCO TDI MDI HDI IPDI			
B3b) Please confirm the unit for the data you are entering	Picklist µg/m^3 mg/m^3 ppm ppb			
Lowest concentration (value)				
Highest concentration (value)				
Mean concentration (arithmetic mean; value)				
Median concentration (value)				

95th percentile concentration (value)				
Number of samples (n)				
Year of monitoring				
B4) Please state the sampling and analytical method followed	OPEN TEXT BOX			
B5) Are the workers wearing RPE during the activity?	☐ *Yes* ☐ **No**	☐ *Yes* ☐ **No**	☐ *Yes* ☐ **No**	☐ *Yes* ☐ **No**
B6) Please provide your most recent airborne concentration data taken in accordance with an OEL (8-hour Time Weighted Averages).				
B6a) Please confirm the relevant diisocyanate for the data you are entering	NCO TDI MDI HDI IPDI			
B6b) Please confirm the unit for the data you are entering	µg/m³ mg/m³ ppm ppb			
Lowest concentration (value)				
Highest concentration (value)				
Mean concentration (arithmetic mean; value)				
Median concentration (value)				
95th percentile concentration (value)				
Number of samples (n)				
Year of monitoring				

B7) Please confirm the sampling and analytical method followed	**OPEN TEXT BOX**			
B8) Are the workers wearing RPE during the activity?	☐ *Yes* ☐ *No*	☐ *Yes* ☐ *No*	☐ *Yes* ☐ *No*	☐ *Yes* ☐ *No*
B9) If you have other exposure data than 8 hour Time Weighted Averages, please specify type of value and air exposure concentration. Please, for example, provide any short-term exposure data here.				
Type of data, value	**OPEN TEXT BOX**			
B10) Please confirm the unit for the data you have just entered	**OPEN TEXT BOX**			
B11) Please confirm the sampling and analytical method followed	**OPEN TEXT BOX**			

B12**) 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 activities, please email this directly to Sophie Garrett, sophie.garrett@rpaltd.co.uk,.

B13) Which Risk Management Measures are in place to control respiratory and dermal exposure to diisocyanates in the different activities at this facility? Please tick all that you use.				
	Activity 1	**Activity 2**	**Activity 3**	**Activity 4**
Restructuring operations/processes				
Reduced amount of substance used	☐	☐	☐	☐
Reduced number of workers exposed	☐	☐	☐	☐

Rotation of workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐
Ventilation and extraction				
Closed systems	☐	☐	☐	☐
Partially closed systems	☐	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
PPE (personal protective equipment)				
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	☐	☐	☐	☐
Safety spectacles, goggles	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Gloves with a cuff, gauntlets and sleeving that covers part or all of the arm	☐	☐	☐	☐
Safety boots and shoes	☐	☐	☐	☐
Rubber boots	☐	☐	☐	☐
Conventional or disposable overalls, boiler suits, aprons	☐	☐	☐	☐
Coveralls/hazardous materials suits	☐	☐	☐	☐

Organisational and hygiene measures				
Training and education	☐	☐	☐	☐
REACH Restriction training (future)	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐
Substitution or discontinuation in the past				
Partial substitution of diisocyanates used in this activity in the past	☐	☐	☐	☐
Discontinuation of part of the activity using diisocyanates	☐	☐	☐	☐
Other measures				
Other: [ADD OPEN TEXT BOX HERE]	☐	☐	☐	☐

C) What are the lowest exposure levels that you could achieve

	Value	*Unit*
C1) What do you think is the lowest *technically possible* 15 minute STEL that can be achieved in this facility?		☐ *µg/m³* ☐ *mg/m³* ☐ *ppm* ☐ *ppb*
C2) What do you think is the lowest *economically feasible 15 minute* STEL that can be achieved in this facility?		☐ *µg/m³* ☐ *mg/m³* ☐ *ppm* ☐ *ppb*
C3) Any comments on above answer?		

	Value	*Unit*
C4) What do you think is the lowest *technically possible* 8-hour OEL that can be achieved in this facility?		☐ *µg/m³* ☐ *mg/m³* ☐ *ppm* ☐ *ppb*
C5) What do you think is the lowest *economically feasible* 8-hour OEL that can be achieved in this facility?		☐ *µg/m³* ☐ *mg/m³* ☐ *ppm* ☐ *ppb*
C6) Any comments on above answer?		
C7) Do you have to comply with EN 689?	*YES/NO*	

D) Compliance with a potential new STEL or OEL under the CAD

This section considers the Risk Management Measures (RMMs) that would have to be put in place to comply with a new STEL or OEL under the CAD.

Please complete this section for the activity with the highest exposure concentration.

The following limit values and air concentrations are the reference points for this questionnaire.	
STEL reference values	OEL reference values
Reference value 1 12 µg NCO/m^3	Reference value 1 6 µg NCO/m^3
Reference value 2 6 µg NCO/m^3 (The maximum STEL recommended by RAC)	Reference value 2 3 µg NCO/m^3 (Half of the maximum STEL recommended by RAC: RAC also recommend that the STEL is at most two times the OEL)
Reference value 3 2 µg NCO/m^3 (Two times the lowest national OEL in the EU)	Reference value 3 1 µg NCO/m^3 (This is the lowest OEL in a Member State)
Reference value 4 0.05 µg NCO/m^3 (Two times the lowest excess risk given by RAC Opinion for diisocyanates via: https://bit.ly/3gsbpWg)	Reference value 4 0.025 µg NCO/m^3 (This value represents the lowest excess risk given by RAC Opinion for diisocya-nates via: https://bit.ly/3gsbpWg)
All OELs or STELs would be accompanied by notation (skin, skin sensitisation, respiratory sensitisation)	

The following table converts the OEL and STEL reference values from ppb to µg/ m^3. There is an approximate factor

of two difference between NCO and the various diisocyanates, for example 1 µg/m3 NCO is approximately 2 µg/m3 (TDI, HDI, MDI).

Substance	Ms [g/mo]	Exposure unit	OEL and STEL reference values and their conversions						
NCO	42.0168	µg NCO / m³	0.025	0.05	1	2	3	6	12
Diisocyanate		ppb NCO Diiso	0.007	0.015	0.3	0.58	0.87	1.75	3.5
HDI	168.2	µg HDI / m³	0.1	0.1	2.0	4.0	6.0	12.0	24.0
TDI / 2,4-TDI	174.16	µg TDI / m³	0.1	0.1	2.1	4.1	6.2	12.4	24.9
mXDI	188.18	µg mXDI / m³	0.1	0.1	2.2	4.5	6.7	13.4	26.9
NDI	210.19	µg NDI / m³	0.1	0.1	2.5	5.0	7.5	15.0	30.0
IPDI	222.29	µg IPDI / m³	0.1	0.1	2.6	5.3	7.9	15.9	31.7
TMXDI	244.29	µg TMXDI / m³	0.1	0.1	2.9	5.8	8.7	17.4	34.9
4,4'-MDI / 2,4'-MDI / 2,2'-MDI	250.25	µg MDI / m³	0.1	0.1	3.0	6.0	8.9	17.9	35.7
H-MDI	262.35	µg H-MDI / m³	0.1	0.2	3.1	6.2	9.4	18.7	37.5
TODI	264.28	µg TODI / m³	0.1	0.2	3.1	6.3	9.4	18.9	37.7
pMDI	149.15	µg pMDI / m³	0.0	0.1	1.8	3.5	5.3	10.6	21.3
pMDI	149.15	µg Diiso / m³	0.1	0.2	3.5	7.1	10.6	21.3	42.6

D1) Please indicate which additional RMMs would be the most important in helping you to achieve the following STEL and OEL reference values? **All levels would be accompanied by notation (skin, skin sensitisation, respiratory sensitisation)** **There is an approximate factor of two difference between NCO and the various diisocyanates, for example 1 µg/m3 NCO is approximately 2 µg/m3 (TDI, HDI, MDI).**				
15 min STEL	**12 µg NCO/m³**	**6 µg NCO/m³**	**2 µg NCO/m³**	**0.05 µg NCO/m³**
8 h TWA OEL	**6 µg NCO/m³**	**3 µg NCO/m³**	**1 µg NCO/m³**	**0.025 µg NCO/m³**
No action required as STEL already achieved	☐	☐	☐	☐
Substitution or discontinuation				
Substitution of diisocyanates	☐	☐	☐	☐
Partial substitution of diisocyanates	☐	☐	☐	☐
Discontinuation of the activity using diisocyanates (shutdown business or part of business)	☐	☐	☐	☐
Restructuring operations/processes				
Reduced amount of substance used	☐	☐	☐	☐
Reduced number of workers exposed	☐	☐	☐	☐
Rotation of the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐

Ventilation and extraction	☐	☐	☐	☐
Closed systems	☐	☐	☐	☐
Partially closed systems	☐	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
PPE (personal protective equipment)				
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, faceshields, visors	☐	☐	☐	☐
Safety spectacles, goggles	☐	☐	☐	☐

Gloves	☐	☐	☐	☐
Gloves with a cuff, gauntlets and sleeving that covers part or all of the arm	☐	☐	☐	☐
Safety boots and shoes	☐	☐	☐	☐
Rubber boots	☐	☐	☐	☐
Conventional or disposable overalls, boiler suits, aprons	☐	☐	☐	☐
Coveralls/hazardous materials suits	☐	☐	☐	☐
Organisational and hygiene measures				
Training and education	☐	☐	☐	☐
REACH Restriction training (future)	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐

Other measures				
Other: [ADD OPEN TEXT BOX HERE]	☐	☐	☐	☐

D2) What is your estimated range of the total <u>initial investment</u> likely to be incurred at this facility to achieve the following STEL/OEL reference values?				
15 min STEL	**12 µg NCO/m³**	**6 µg NCO/m³**	**2 µg NCO/m³**	**0.05 µg NCO/m³**
8 h TWA OEL	**6 µg NCO/m³**	**3 µg NCO/m³**	**1 µg NCO/m³**	**0.025 µg NCO/m³**
< €10,000	☐	☐	☐	☐
€10,000 - €100,000	☐	☐	☐	☐
€100,000 - €1 million	☐	☐	☐	☐
€1 - 10 million	☐	☐	☐	☐
€10 - 100 million	☐	☐	☐	☐
€100 - 1 billion	☐	☐	☐	☐
Over €1 billion	☐	☐	☐	☐
Don’t know	☐	☐	☐	☐
D3) What is your estimated range of total annual *<u>recurrent costs</u>* likely to be incurred at this facility to achieve the following STEL/OEL reference values?				

15 min STEL	**12 µg NCO/m³**	**6 µg NCO/m³**	**2 µg NCO/m³**	**0.05 µg NCO/m³**
8 h TWA OEL	**6 µg NCO/m³**	**3 µg NCO/m³**	**1 µg NCO/m³**	**0.025 µg NCO/m³**
< €10,000	☐	☐	☐	☐
€10,000 - €100,000	☐	☐	☐	☐
€100,000 - €1 million	☐	☐	☐	☐
€1 - 10 million	☐	☐	☐	☐
€10 - 100 million	☐	☐	☐	☐
€100 - 1 billion	☐	☐	☐	☐
Over €1 billion	☐	☐	☐	☐
Don't know	☐	☐	☐	☐

D4) The RAC opinion sets a maximum STEL to OEL ratio of two. If the ratio was one, so the OEL and STEL were the same, what is your estimated range of the total <u>initial investment</u> in risk management measures likely to be incurred at this facility to achieve the following STEL/OEL reference values?

15 min STEL AND 8 h TWA OEL	**6 µg NCO/m³**	**3 µg NCO/m³**	**1 µg NCO/m³**	**0.025 µg NCO/m³**
< €10,000	☐	☐	☐	☐
€10,000 - €100,000	☐	☐	☐	☐

€100,000 - €1 million	☐	☐	☐	☐
€1 - 10 million	☐	☐	☐	☐
€10 - 100 million	☐	☐	☐	☐
€100 - 1 billion	☐	☐	☐	☐
Over €1 billion	☐	☐	☐	☐
Don’t know	☐	☐	☐	☐
D5) What is your estimated range of total annual *__recurrent costs__* for risk management measures likely to be incurred at this facility to achieve the following STEL/OEL reference values?				
15 min STEL AND 8 h TWA OEL	**6 µg NCO/m³**	**3 µg NCO/m³**	**1 µg NCO/m³**	**0.025 µg NCO/m³**
< €10,000	☐	☐	☐	☐
€10,000 - €100,000	☐	☐	☐	☐
€100,000 - €1 million	☐	☐	☐	☐
€1 - 10 million	☐	☐	☐	☐
€10 - 100 million	☐	☐	☐	☐
€100 - 1 billion	☐	☐	☐	☐
Over €1 billion	☐	☐	☐	☐
Don’t know	☐	☐	☐	☐

D6) How would the STEL reference values impact the competitiveness of your company…				
15 min STEL	12 µg NCO/m³	6 µg NCO/m³	2 µg NCO/m³	0.05 µg NCO/m³
8 h TWA OEL	6 µg NCO/m³	3 µg NCO/m³	1 µg NCO/m³	0.025 µg NCO/m³
versus competitors in EU	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact
versus competitors outside of EU	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact

D7) Are the future REACH Restriction training obligations likely to have an impact on exposure concentrations at your facility?	☐ Yes ☐ No
If yes, please describe the initiative and the sectors to which it applies.	

D8) Are you aware of any voluntary industry initiatives to reduce exposure to diisocyanates (e.g. Product Stewardships or Social Partner Agreements)?	☐ Yes ☐ No
If yes, please specify name of the initiative and to which sectors it applies.	

E) Impacts of COVID-19

E1) Has COVID-19 had any impact on exposure levels of diisocyanates or the numbers of workers exposed to diisocyanates at this facility? (Examples could include: COVID-19 preventative measures have reduced your exposure levels or on the number of workers exposed has reduce/increased, or some of your operations have had to close due to COVID-19)

F) Any other comments

F1) Do you have any other comments relevant to this study that you would like to make?

G) Further communication

G1) Please tick if you are happy for the study team to contact you for further clarification or discussion about your responses?	☐
G2) 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!

ANNEX 3 EXPOSURE DATA SUMMARY FROM 2000

Table 11-5 Summary of occupational exposures to diisocyanates from available sources, all OEL values in NCO µg/m³ from 2000

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C13 Textiles	MEGA database	2000-19	12		0.25	0.25	0.25	0.25			NC
C13 Textiles	MEGA database	2000-19	12		0.25	0.25	0.25	0.25			NC
C13 Textiles	MEGA database	2000-19	21		0.25	0.25	0.25	0.25			NC
C13 Textiles	MEGA database	2000-19	14		0.25	0.25	0.25	0.25			NC
C13 Textiles	MEGA database	2000-19	27		0.25	0.25	0.25	0.25			NC
C13 Textiles	MEGA database	2000-19	15		0.25	0.25	0.25	0.25			NC
C13 Textiles	MEGA database	2000-19	27		0.25	0.25	0.40	1.39			NC
C13 Textiles	MEGA database	2000-19	15		0.25	0.25	1.16	2.12			NC
C13 Textiles	MEGA database	2000-19	41		3.96	7.96	12.06	20.07			NC
C13 Textiles	MEGA database	2000-19	29		1.83	14.14	22.20	28.95			NC
C13 Textiles	MEGA database	2000-19	41		5.55	11.72	19.78	22.53			NC
C13 Textiles	MEGA database	2000-19	29		3.79	18.19	34.79	36.00			NC
C13 Textiles	MEGA database	2000-19	20		17.00	26.00	34.00	35.00			NC
C13 Textiles	MEGA database	2000-19	10		25.00	31.00	51.00	51.50			NC
C13 Textiles	MEGA database	2000-19	18		16.00	23.50	28.40	34.10			NC
C13 Textiles	MEGA database	2000-19	20		17.00	26.00	34.00	35.00			NC
C13 Textiles	MEGA database	2000-19	12		0.25	0.25	0.25	0.25			NC
C13 Textiles	MEGA database	2000-19	14		0.25	0.25	0.25	0.25			NC
C13 Textiles	MEGA database	2000-19	14		0.25	0.34	1.57	1.84			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C13 Textiles	MEGA database	2000-19	14		0.25	0.25	0.25	0.53			NC
C13 Textiles	MEGA database	2000-19	14		1.01	5.20	10.07	11.52			NC
C13 Textiles	MEGA database	2000-19	14		0.34	1.49	2.78	6.58			NC
C13 Textiles	MEGA database	2000-19	16		2.90	7.60	18.00	21.40			NC
C13 Textiles	MEGA database	2000-19	14		1.00	2.30	3.48	7.16			NC
C13 Textiles	MEGA database	2000-19	13		2.20	6.22	19.50	21.70			NC
C13 Textiles	MEGA database	2000-19	13		0.90	2.05	3.56	7.72			NC
C14 Apparel	-	-	-	-	-	-	-	-	-	-	-
C15 Leather	Brzeźnicki and Bonczarow-ska	2002	2	0.30					0.40	0.34	Y/NC
C15 Leather	FIOH	2008-16	53	0.01					0.39		NC
C15 Leather	FIOH	2008-16	53	0.002					1.88		NC
C15 Leather	MEGA database	2000-19	19		0.25	0.25	0.25	0.25			NC
C15 Leather	MEGA database	2000-19	23		0.25	0.25	0.25	0.25			NC
C15 Leather	MEGA database	2000-19	23		0.25	0.25	0.25	0.25			NC
C15 Leather	MEGA database	2000-19	14		0.25	0.25	0.25	0.25			NC
C15 Leather	MEGA database	2000-19	15		0.25	0.25	0.25	0.25			NC
C15 Leather	MEGA database	2000-19	15		0.25	0.25	0.25	0.25			NC
C15 Leather	MEGA database	2000-19	15		0.25	0.25	0.25	0.25			NC
C15 Leather	MEGA database	2000-19	33		0.25	0.25	0.25	0.25			NC
C15 Leather	MEGA database	2000-19	24		0.25	0.25	0.25	0.25			NC
C15 Leather	MEGA database	2000-19	23		0.25	0.25	0.25	0.25			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C15 Leather	MEGA database	2000-19	14		0.25	0.25	0.25	0.25			NC
C15 Leather	MEGA database	2000-19	14		0.25	0.25	0.25	0.25			NC
C16 Wood	Brzeźnicki and Bonczarowska	2008	2	<0.2					0.24	0.13	Y/NC
C16 Wood	Brzeźnicki and Bonczarowska	2012	4	<0.2							Y/NC
C16 Wood	Brzeźnicki and Bonczarowska	2007	2	<0.2							Y/NC
C16 Wood	Brzeźnicki and Bonczarowska	2012	8	<0.2							Y/NC
C16 Wood	Brzeźnicki and Bonczarowska	2002	4	<0.2					1.75	1.18	Y/NC
C16 Wood	MEGA database	2000-19	10		0.25	0.25	0.25	0.25			NC
C16 Wood	MEGA database	2000-19	40		0.25	0.25	0.25	0.25			NC
C16 Wood	MEGA database	2000-19	17		0.25	0.25	0.25	0.25			NC
C16 Wood	MEGA database	2000-19	48		0.25	0.25	0.25	0.25			NC
C16 Wood	MEGA database	2000-19	19		0.25	0.25	0.25	0.59			NC
C16 Wood	MEGA database	2000-19	47		0.25	0.25	0.34	0.75			NC
C16 Wood	MEGA database	2000-19	19		0.25	0.41	0.87	0.89			NC
C16 Wood	MEGA database	2000-19	42		0.25	0.25	0.34	0.76			NC
C16 Wood	MEGA database	2000-19	15		0.25	0.79	0.90	2.30			NC
C16 Wood	MEGA database	2000-19	39		0.25	0.25	0.30	0.84			NC
C16 Wood	MEGA database	2000-19	14		0.25	0.60	0.90	2.58			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
C16 Wood	MEGA database	2000-19	12		0.25	0.25	0.25	0.25			NC
C16 Wood	MEGA database	2000-19	11		0.25	0.25	0.25	0.25			NC
C16 Wood	MEGA database	2000-19	24		0.25	0.25	0.25	0.25			NC
C16 Wood	MEGA database	2000-19	33		0.25	0.25	0.25	0.25			NC
C16 Wood	MEGA database	2000-19	28		0.25	0.25	0.34	0.70			NC
C16 Wood	MEGA database	2000-19	36		0.25	0.25	0.25	0.25			NC
C16 Wood	MEGA database	2000-19	28		0.25	0.25	0.63	1.05			NC
C16 Wood	MEGA database	2000-19	36		0.25	0.25	0.34	0.85			NC
C16 Wood	MEGA database	2000-19	11		0.25	0.25	0.25	0.25			NC
C16 Wood	MEGA database	2000-19	11		0.25	0.25	0.25	0.25			NC
C16 Wood	MEGA database	2000-19	24		0.25	0.30	0.84	1.64			NC
C16 Wood	MEGA database	2000-19	30		0.25	0.25	0.80	1.30			NC
C16 Wood	MEGA database	2000-19	12		0.25	0.25	0.25	5.50			NC
C16 Wood	MEGA database	2000-19	11		0.25	0.25	0.25	0.25			NC
C16 Wood	MEGA database	2000-19	24		0.25	0.30	0.84	1.64			NC
C16 Wood	MEGA database	2000-19	29		0.25	0.25	0.53	0.97			NC
C16 Wood	MEGA database	2000-19	11		0.25	0.25	0.25	0.25			NC
C16 Wood	FIOH	2008-16	36	0.001					0.22		NC
C16 Wood	FIOH	2008-16	36	0.0125							NC
C16 Wood	UK HSE	2003		1.00	1.00			1.00	4.00		NC
C16 Wood	UK HSE	2003								0.25	NC
C16 Wood	UK HSE	2003								0.25	NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
C16 Wood	UK HSE	2003								2	NC
C16 Wood	UK HSE	2003								0.25	NC
C16 Wood	UK HSE	2003								0.25	NC
C16 Wood	UK HSE	2003								0.25	NC
C16 Wood	UK HSE	2003								0.25	NC
C16 Wood	Consultation	2021	8	0.10	0.42			3.10	4.43	0.76	Y
C20 Chemicals	Cassidy et al.	1987-2007	57	0.043					107	3	Y
C20 Chemicals	Cassidy et al.	1987-2007		0.043					7	1	Y
C20 Chemicals	FIOH	2008-16	58	0.005					84.92		NC
C20 Chemicals	FIOH	2008-16	58	0.002					0.14		NC
C20 Chemicals	FIOH	2008-16	58						4.60		NC
C20 Chemicals	FIOH	2008-16	57	0.002					82.51		NC
C20 Chemicals	FIOH	2008-16	57	0.002					0.17		NC
C20 Chemicals	FIOH	2008-16	57	0.005					0.02		NC
C20 Chemicals	MEGA database	2000-19	11		0.25	0.25	0.25	0.25			NC
C20 Chemicals	MEGA database	2000-19	15		0.25	0.25	0.25	0.36			NC
C20 Chemicals	MEGA database	2000-19	10		0.25	2.59	6.72	8.39			NC
C20 Chemicals	MEGA database	2000-19	15		0.25	0.25	0.60	0.85			NC
C20 Chemicals	MEGA database	2000-19	10		0.25	2.97	13.43	18.80			NC
C20 Chemicals	MEGA database	2000-19	19		0.25	0.25	1.24	1.60			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
C20 Chemicals	MEGA database	2000-19	11		0.25	3.79	13.60	28.90			NC
C20 Chemicals	MEGA database	2000-19	11		0.25	0.33	0.94	1.09			NC
C20 Chemicals	MEGA database	2000-19	12		0.25	0.25	0.25	7.19			NC
C20 Chemicals	MEGA database	2000-19	10		0.25	0.25	6.80	8.32			NC
C20 Chemicals	MEGA database	2000-19	28		0.25	0.25	0.25	0.25			NC
C20 Chemicals	MEGA database	2000-19	19		0.25	0.25	0.25	0.25			NC
C20 Chemicals	MEGA database	2000-19	33		0.25	0.25	0.70	2.67			NC
C20 Chemicals	MEGA database	2000-19	21		0.25	0.25	0.25	1.99			NC
C20 Chemicals	MEGA database	2000-19	33		0.25	0.25	3.79	6.21			NC
C20 Chemicals	MEGA database	2000-19	22		0.25	0.25	0.25	2.36			NC
C20 Chemicals	MEGA database	2000-19	25		0.25	0.25	2.35	4.83			NC
C20 Chemicals	MEGA database	2000-19	17		0.25	0.25	2.36	5.19			NC
C20 Chemicals	MEGA database	2000-19	22		0.25	0.25	2.80	5.17			NC
C20 Chemicals	MEGA database	2000-19	12		0.25	0.65	1.38	2.68			NC
C20 Chemicals	MEGA database	2000-19	12		0.25	0.25	0.25	0.25			NC
C20 Chemicals	MEGA database	2000-19	15		0.25	0.25	0.25	0.40			NC
C20 Chemicals	MEGA database	2000-19	14		0.25	0.25	0.25	0.25			NC
C20 Chemicals	MEGA database	2000-19	15		0.25	0.25	0.37	0.44			NC
C20 Chemicals	MEGA database	2000-19	14		0.25	0.25	0.25	0.20			NC
C20 Chemicals	MEGA database	2000-19	14		0.25	0.43	1.58	2.15			NC
C20 Chemicals	MEGA database	2000-19	16		0.25	0.25	0.25	0.50			NC
C20 Chemicals	MEGA database	2000-19	12		0.25	0.25	3.40	218.00			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
C20 Chemicals	MEGA database	2000-19	11		0.25	0.30	0.40	0.85			NC
C20 Chemicals	MEGA database	2000-19	12		0.25	0.25	0.25	0.38			NC
C20 Chemicals	MEGA database	2000-19	24		0.25	0.25	0.25	0.25			NC
C20 Chemicals	MEGA database	2000-19	10		0.25	0.25	0.25	0.25			NC
C20 Chemicals	MEGA database	2000-19	12		0.25	0.25	0.25	0.25			NC
C20 Chemicals	MEGA database	2000-19	29		0.25	0.25	0.34	0.65			NC
C20 Chemicals	MEGA database	2000-19	15		0.25	0.25	0.25	0.25			NC
C20 Chemicals	MEGA database	2000-19	15		0.25	0.25	0.65	1.33			NC
C20 Chemicals	MEGA database	2000-19	29		0.25	0.25	2.22	9.94			NC
C20 Chemicals	MEGA database	2000-19	17		0.25	0.25	0.35	0.51			NC
C20 Chemicals	MEGA database	2000-19	17		0.25	0.25	0.93	1.23			NC
C20 Chemicals	MEGA database	2000-19	11		2.05	7.24	7.29	9.46			NC
C20 Chemicals	MEGA database	2000-19	11		1.57	4.75	6.13	7.14			NC
C20 Chemicals	MEGA database	2000-19	30		0.25	0.70	46.00	68.00			NC
C20 Chemicals	MEGA database	2000-19	26		0.25	4.05	12.40	14.40			NC
C20 Chemicals	MEGA database	2000-19	20		0.25	1.50	300.00	410.00			NC
C20 Chemicals	MEGA database	2000-19	24		0.25	0.30	0.70	6.14			NC
C20 Chemicals	MEGA database	2000-19	16		0.25	2.20	8.34	12.60			NC
C20 Chemicals	MEGA database	2000-19	16		0.25	0.25	1.44	1.61			NC
C20 Chemicals	MEGA database	2000-19	11		4.15	12.30	14.80	17.70			NC
C20 Chemicals	MEGA database	2000-19	11		0.25	0.25	0.25	0.25			NC
C20 Chemicals	MEGA database	2000-19	10		0.25	0.25	0.25	0.25			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
C20 Chemicals	MEGA database	2000-19	14		0.25	0.25	0.25	0.25			NC
C20 Chemicals	MEGA database	2000-19	19		0.25	0.25	0.25	0.25			NC
C20 Chemicals	MEGA database	2000-19	10		0.25	0.25	0.27	0.47			NC
C20 Chemicals	MEGA database	2000-19	19		0.25	0.25	0.25	0.42			NC
C20 Chemicals	MEGA database	2000-19	16		0.25	0.25	0.25	0.50			NC
C20 Chemicals	MEGA database	2000-19	16		0.25	0.25	0.70	0.88			NC
C20 Chemicals	MEGA database	2000-19	11		0.25	0.45	0.68	0.93			NC
C20 Chemicals	MEGA database	2000-19	20		0.25	0.25	0.65	1.70			NC
C20 Chemicals	MEGA database	2000-19	12		0.25	0.25	1.48	1.82			NC
C20 Chemicals	MEGA database	2000-19	10		0.25	0.25	0.60	1.15			NC
C20 Chemicals	Gui et al		7	0.3					34.37		Y
C20 Chemicals	Hathaway et al		72						7		NC
C20 Chemicals	Hathaway et al		72						0.3		NC
C20 Chemicals	Hathaway et al		72						0.3		NC
C20 Chemicals	UK HSE	2003		1			2	2			NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							2		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							2		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	UK HSE	2003							3		NC
C20 Chemicals	UK HSE	2003							1		NC
C20 Chemicals	Middendorf et al 2017			0.07					316.0		Y
C20 Chemicals	Middendorf et al 2017		120	0.10					65.1		Y

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C20 Chemicals	Middendorf et al 2017		116	0.10					316.0		Y
C20 Chemicals	Middendorf et al 2017		101	0.10					41.0		Y
C20 Chemicals	Middendorf et al 2017			0.05					31.4		Y
C20 Chemicals	Middendorf et al 2017		44	0.05					31.4		Y
C20 Chemicals	Middendorf et al 2017		10	0.05					8.2		Y
C20 Chemicals	Middendorf et al 2017		10	0.05					0.5		Y
C20 Chemicals	Middendorf et al 2017		16	0.10					12.5		Y
C20 Chemicals	Middendorf et al 2017			0.05					308.8		Y
C20 Chemicals	Middendorf et al 2017		109	0.05					309.3		Y
C20 Chemicals	Middendorf et al 2017		98	0.10					51.6		Y
C20 Chemicals	Middendorf et al 2017		103	0.05					7.7		Y
C20 Chemicals	Middendorf et al 2017		27	0.10					113.4		Y
C20 Chemicals	CSR	1990-2009							0.15		Y
C20 Chemicals	CSR	1990-2009							2.00		Y
C20 Chemicals	CSR	1990-2009							3.50		Y
C20 Chemicals	CSR	1990-2009							0.17		Y
C20 Chemicals	CSR	1990-2009							2.00		Y
C20 Chemicals	CSR	1990-2009							0.50		Y

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C20 Chemicals	CSR	1990-2009							1.30		Y
C20 Chemicals	CSR	1990-2009							16.49		Y
C20 Chemicals	CSR	1990-2009							3.57		Y
C20 Chemicals	CSR	1990-2009							0.50		Y
C20 Chemicals	CSR	1990-2009						11.74			Y
C20 Chemicals	CSR	1990-2009							2.50		Y
C20 Chemicals	CSR	1990-2009							0.31		Y
C20 Chemicals	CSR	1990-2009							1.00		Y
C20 Chemicals	CSR	1990-2009							1.00		Y
C20 Chemicals	CSR	1990-2009							1.15		Y
C20 Chemicals	CSR	1990-2009							0.39		Y
C20 Chemicals	CSR	1990-2009							0.34		Y
C20 Chemicals	CSR	1990-2009							0.46		Y

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C20 Chemicals	CSR	1990-2009							0.60		Y
C20 Chemicals	CSR	1990-2009							1.50		Y
C20 Chemicals	CSR	1990-2009							135.89		Y
C20 Chemicals	CSR	1990-2009							4.50		Y
C20 Chemicals	CSR	1990-2009							1.00		Y
C20 Chemicals	CSR	1990-2009							0.73		Y
C20 Chemicals	CSR	1990-2009							0.27		Y
C20 Chemicals	CSR	1990-2009							0.28		Y
C20 Chemicals	CSR	1990-2009							0.30		Y
C20 Chemicals	CSR			0.043	0.34	0.92	2.22	3.3	53.1	0.001	Y
C20 Chemicals	CSR			0.39	1.59	4.20	7.14	10.6	47.5	0.004	Y
C20 Chemicals	CSR			0.19	2.36	4.83	9.26	48.3	48.3	0.006	Y
C20 Chemicals	CSR			37.06	63.21	136.55	442.9	442.9	442.9	0.13	Y
C20 Chemicals	CSR			0.97	5.21	15.63	16.12	16.1	16.1	0.008	Y

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
C20 Chemicals	CSR			0.97	43.04	100.27	212.8	212.8	212.8	0.06	Y
C20 Chemicals	CSR			0.010	2.61	6.76	14.5	14.8	14.8	0.004	Y
C20 Chemicals	Consultation	2021	89	0.27	0.72			1.94	3.57	0.57	N
C20 Chemicals	Consultation	2021	92	0.17	0.47	0.25	0.25	1.80	3.63	0.35	Y
C22 Plastics	Austin		26	<3.5					8.4	2.7	Y
C22 Plastics	Brzeźnicki and Bonczarowska	2002	2	0.30					0.91		Y/NC
C22 Plastics	Brzeźnicki and Bonczarowska	2011	20	<0.2							Y/NC
C22 Plastics	Brzeźnicki and Bonczarowska	2011	20	0.10					29.38	2.00	Y/NC
C22 Plastics	Brzeźnicki and Bonczarowska	2012	6	0.95					6.30	2.65	Y/NC
C22 Plastics	Brzeźnicki and Bonczarowska	2011	10	0.30					5.65	0.9-1.85	Y/NC
C22 Plastics	Brzeźnicki and Bonczarowska	2011	3	0.10					3.25	1.8-2.25	Y/NC
C22 Plastics	Brzeźnicki and Bonczarowska	2011	2	4.95					20.73	12.84	Y/NC
C22 Plastics	Brzeźnicki and Bonczarowska	2011	5	0.15					29.33	8.49	Y/NC
C22 Plastics	Brzeźnicki and Bonczarowska	2012	3	0.95					3.65	1.10	Y/NC

NACE Sector	*Source*	*Year*	*No. (2)*	*Low*	*50%*	*75%*	*90%*	*95%*	*High*	*AM*	*RPE (3)*
				NCO µg/m^3							
C22 Plastics	Brzeźnicki and Bonczarowska	2012	2	1.55					2.35	1.95	Y/NC
C22 Plastics	Brzeźnicki and Bonczarowska	2012	1	6.30						6.295	Y/NC
C22 Plastics	Brzeźnicki and Bonczarowska	2005	6	<0.2							Y/NC
C22 Plastics	Brzeźnicki and Bonczarowska	2005	6	3.50					6.34	4.90	Y/NC
C22 Plastics	Brzeźnicki and Bonczarowska	2012	4	<0.2							Y/NC
C22 Plastics	Creely et al		4	0.5	1.5		2.5		2.5		Y
C22 Plastics	Creely et al		5	0.5	1		16		22.6		Y
C22 Plastics	Creely et al		1	0.5	0.5		0.5		0.5		Y
C22 Plastics	Creely et al		13	0.5	0.5		28.8		65.8		Y
C22 Plastics	Creely et al		8	0.5	0.5		2.3		4.7		Y
C22 Plastics	Creely et al		7	0.5	0.5		3.2		7.2		Y
C22 Plastics	Creely et al		3	0.5	0.5		0.5		0.5		Y
C22 Plastics	Creely et al		6	0.5	0.5		1.2		1.9		Y
C22 Plastics	Creely et al		8	0.5	0.5		8.8		11.7		Y
C22 Plastics	Creely et al		6	0.5	2.9		7.7		10		Y
C22 Plastics	Creely et al		3	0.5	0.5		3.5		4.2		Y
C22 Plastics	Creely et al		2	0.5	0.5		0.5		0.5		Y
C22 Plastics	Creely et al		4	0.5	0.5		0.5		0.5		Y

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
C22 Plastics	Creely et al		23	0.5	0.5		9.5		22.6		Y
C22 Plastics	Creely et al		2	0.5	0.5		0.5		0.5		Y
C22 Plastics	Creely et al		13	0.5	0.5		1.1		4.7		Y
C22 Plastics	Creely et al		5	0.5	0.5		1.5		2.2		Y
C22 Plastics	Creely et al		2	0.5	0.5		0.5		0.5		Y
C22 Plastics	Creely et al		7	0.5	0.5		1.9		4.2		Y
C22 Plastics	Creely et al		16	0.5	0.5		18.5		65.8		Y
C22 Plastics	Creely et al		2	0.5	0.9		1.3		1.4		Y
C22 Plastics	Industry association		8						1.39	0.61	Y
C22 Plastics	Industry association		6						35.22	19.55	Y
C22 Plastics	Industry association		6						0.47	0.29	Y
C22 Plastics	Industry association		8						0.37	0.24	Y
C22 Plastics	Industry association		6						11.97	8.79	Y
C22 Plastics	Industry association		6						0.13	0.13	Y
C22 Plastics	Industry association		8						0.11	0.11	Y
C22 Plastics	Industry association		4						0.48	0.43	Y
C22 Plastics	Industry association		8						0.77	0.53	Y
C22 Plastics	Industry association		6						11.10	6.90	Y
C22 Plastics	Industry association		6						0.24	0.19	Y
C22 Plastics	Industry association		12						0.48	0.29	Y
C22 Plastics	Industry association		8						1.59	0.82	Y
C22 Plastics	Industry association		6						7.62	5.79	Y

NACE Sector	*Source*	*Year*	*No. (2)*	*Low*	*50%*	*75%*	*90%*	*95%*	*High*	*AM*	*RPE (3)*
				NCO µg/m³							
C22 Plastics	Industry association		6						0.29	0.24	Y
C22 Plastics	Industry association		8						1.06	0.48	Y
C22 Plastics	Industry association		4						0.34	0.29	Y
C22 Plastics	Industry association		4						0.19	0.14	Y
C22 Plastics	Industry association									0.38	Y
C22 Plastics	Industry association									0.83	Y
C22 Plastics	Industry association									33.29	Y
C22 Plastics	Industry association									0.54	Y
C22 Plastics	Industry association									10.17	Y
C22 Plastics	Industry association									25.65	Y
C22 Plastics	Industry association									0.01	Y
C22 Plastics	Industry association									10.77	Y
C22 Plastics	Industry association									0.58	Y
C22 Plastics	Industry association									0.28	Y
C22 Plastics	Industry association									0.01	Y
C22 Plastics	Industry association									1.31	Y
C22 Plastics	Industry association									0.02	N
C22 Plastics	Industry association									0.02	N
C22 Plastics	Industry association									0.02	N
C22 Plastics	Industry association									0.02	N
C22 Plastics	Industry association									0.25	N
C22 Plastics	Industry association									11.02	Y

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
C22 Plastics	Industry association									10.12	Y
C22 Plastics	Industry association									0.19	Y
C22 Plastics	Industry association									0.05	Y
C22 Plastics	Industry association									0.05	Y
C22 Plastics	Industry association									11.48	Y
C22 Plastics	Industry association									8.20	Y
C22 Plastics	Industry association									10.83	Y
C22 Plastics	Industry association									2.49	Y
C22 Plastics	Industry association									2.28	Y
C22 Plastics	Industry association									7.87	Y
C22 Plastics	Industry association									21.65	Y
C22 Plastics	Industry association									7.31	Y
C22 Plastics	Industry association									5.11	Y
C22 Plastics	Industry association									0.11	Y
C22 Plastics	Industry association									20.40	Y
C22 Plastics	Industry association									6.78	Y
C22 Plastics	Industry association									0.02	N
C22 Plastics	Industry association									0.01	N
C22 Plastics	Industry association									0.02	N
C22 Plastics	Industry association									0.01	N
C22 Plastics	Industry association									0.02	N
C22 Plastics	Industry association									0.02	N

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C22 Plastics	Industry association									0.03	Y
C22 Plastics	Industry association									0.03	Y
C22 Plastics	Industry association									0.01	Y
C22 Plastics	Industry association									3.25	Y
C22 Plastics	Industry association									0.01	Y
C22 Plastics	Industry association									1.53	Y
C22 Plastics	Industry association									0.05	N
C22 Plastics	Industry association									0.12	N
C22 Plastics	Industry association									201.68	Y
C22 Plastics	Industry association									43.62	Y
C22 Plastics	Industry association									35.99	Y
C22 Plastics	Industry association									23.56	Y
C22 Plastics	Industry association									21.11	Y
C22 Plastics	Industry association									17.43	Y
C22 Plastics	Industry association									17.51	Y
C22 Plastics	Industry association									92.44	Y
C22 Plastics	Industry association									13.47	Y
C22 Plastics	Industry association									364.36	Y
C22 Plastics	Industry association									1.60	N
C22 Plastics	Industry association									0.17	N
C22 Plastics	Industry association									0.01	N
C22 Plastics	Industry association									0.08	N

NACE Sector	*Source*	*Year*	*No. (2)*	*Low*	*50%*	*75%*	*90%*	*95%*	*High*	*AM*	*RPE (3)*
				NCO µg/m³							
C22 Plastics	Industry association									0.03	N
C22 Plastics	Industry association									3.50	Y
C22 Plastics	Industry association									0.09	Y
C22 Plastics	Industry association									1.52	Y
C22 Plastics	Industry association									7.41	Y
C22 Plastics	Industry association									20.23	Y
C22 Plastics	Industry association									10.77	Y
C22 Plastics	Industry association									0.92	Y
C22 Plastics	Industry association									1.37	Y
C22 Plastics	Industry association									16.99	Y
C22 Plastics	Industry association									0.55	Y
C22 Plastics	Industry association									8.89	Y
C22 Plastics	Industry association									2.46	Y
C22 Plastics	Industry association									1.58	Y
C22 Plastics	Industry association									0.92	N
C22 Plastics	Industry association									0.62	N
C22 Plastics	Industry association									0.02	N
C22 Plastics	Industry association									0.02	N
C22 Plastics	Industry association									0.03	N
C22 Plastics	MEGA database	2011-19	24		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	10		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	12		0.25	0.25	0.25	0.25			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C22 Plastics	MEGA database	2011-19	29		0.25	0.25	0.34	0.65			NC
C22 Plastics	MEGA database	2011-19	15		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	15		0.25	0.25	0.65	1.33			NC
C22 Plastics	MEGA database	2011-19	29		0.25	0.25	2.22	9.94			NC
C22 Plastics	MEGA database	2011-19	17		0.25	0.25	0.35	0.51			NC
C22 Plastics	MEGA database	2011-19	17		0.25	0.25	0.93	1.23			NC
C22 Plastics	MEGA database	2011-19	11		2.05	7.24	7.29	9.46			NC
C22 Plastics	MEGA database	2011-19	11		1.57	4.75	6.13	7.14			NC
C22 Plastics	MEGA database	2011-19	30		0.25	0.70	46.00	68.00			NC
C22 Plastics	MEGA database	2011-19	26		0.25	4.05	12.40	14.40			NC
C22 Plastics	MEGA database	2011-19	20		0.25	1.50	300.00	410.00			NC/Y
C22 Plastics	MEGA database	2011-19	24		0.25	0.30	0.70	6.14			NC
C22 Plastics	MEGA database	2011-19	16		0.25	2.20	8.34	12.60			NC
C22 Plastics	MEGA database	2011-19	16		0.25	0.25	1.44	1.61			NC
C22 Plastics	MEGA database	2011-19	11		4.15	12.30	14.80	17.70			NC
C22 Plastics	MEGA database	2011-19	11		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	10		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	14		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	19		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	10		0.25	0.25	0.27	0.47			NC
C22 Plastics	MEGA database	2011-19	19		0.25	0.25	0.25	0.42			NC
C22 Plastics	MEGA database	2011-19	16		0.25	0.25	0.25	0.50			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
C22 Plastics	MEGA database	2011-19	16		0.25	0.25	0.70	0.88			NC
C22 Plastics	MEGA database	2011-19	11		0.25	0.45	0.68	0.93			NC
C22 Plastics	MEGA database	2011-19	20		0.25	0.25	0.65	1.70			NC
C22 Plastics	MEGA database	2011-19	12		0.25	0.25	1.48	1.82			NC
C22 Plastics	MEGA database	2011-19	10		0.25	0.25	0.60	1.15			NC
C22 Plastics	MEGA database	2011-19	103		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	38		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	18		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	109		0.25	0.25	0.25	0.34			NC
C22 Plastics	MEGA database	2011-19	42		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	19		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	109		0.25	0.25	0.69	1.75			NC
C22 Plastics	MEGA database	2011-19	42		0.25	0.25	0.25	0.34			NC
C22 Plastics	MEGA database	2011-19	19		0.25	0.25	3.22	4.43			NC
C22 Plastics	MEGA database	2011-19	100		0.25	0.25	1.00	3.80			NC
C22 Plastics	MEGA database	2011-19	39		0.25	0.25	0.30	0.50			NC
C22 Plastics	MEGA database	2011-19	18		0.25	0.25	3.88	4.88			NC
C22 Plastics	MEGA database	2011-19	100		0.25	0.25	1.00	3.80			NC
C22 Plastics	MEGA database	2011-19	39		0.25	0.25	0.30	0.50			NC
C22 Plastics	MEGA database	2011-19	18		0.25	0.25	3.88	4.88			NC
C22 Plastics	MEGA database	2011-19	56		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	60		0.25	0.25	0.25	0.77			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
C22 Plastics	MEGA database	2011-19	19		0.25	1.79	6.84	7.49			NC
C22 Plastics	MEGA database	2011-19	18		0.25	0.25	1.13	4.73			NC
C22 Plastics	MEGA database	2011-19	14		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	23		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	16		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	26		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	16		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	28		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	49		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	87		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	49		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	87		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	89		0.25	0.25	0.25	2.79			NC
C22 Plastics	MEGA database	2011-19	116		0.25	0.25	0.25	0.86			NC
C22 Plastics	MEGA database	2011-19	15		0.25	0.25	0.25	3.60			NC
C22 Plastics	MEGA database	2011-19	51		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	45		0.25	0.25	0.25	1.12			NC
C22 Plastics	MEGA database	2011-19	17		0.25	3.45	7.70	9.24			NC
C22 Plastics	MEGA database	2011-19	11		0.25	0.25	4.02	5.30			NC
C22 Plastics	MEGA database	2011-19	14		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	20		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	46		0.25	0.25	0.25	0.25			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C22 Plastics	MEGA database	2011-19	73		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	32		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	12		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	40		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	13		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	42		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	14		0.25	0.25	0.66	0.87			NC
C22 Plastics	MEGA database	2011-19	46		0.25	2.75	12.40	29.10			NC/Y
C22 Plastics	MEGA database	2011-19	16		0.25	0.25	1.36	5.48			NC
C22 Plastics	MEGA database	2011-19	39		0.25	1.50	12.10	20.70			NC/Y
C22 Plastics	MEGA database	2011-19	14		0.25	0.25	0.70	0.97			NC
C22 Plastics	MEGA database	2011-19	17		0.25	0.25	0.81	0.88			NC
C22 Plastics	MEGA database	2011-19	12		0.25	7.56	9.00	9.83			NC
C22 Plastics	MEGA database	2011-19	94		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	37		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	26		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	110		0.25	0.25	0.25	0.71			NC
C22 Plastics	MEGA database	2011-19	44		0.25	0.25	0.36	0.56			NC
C22 Plastics	MEGA database	2011-19	26		0.25	0.25	0.79	0.87			NC
C22 Plastics	MEGA database	2011-19	112		0.25	0.25	0.58	1.81			NC
C22 Plastics	MEGA database	2011-19	45		0.25	0.25	0.34	5.47			NC
C22 Plastics	MEGA database	2011-19	26		0.25	0.77	1.54	2.11			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C22 Plastics	MEGA database	2011-19	28		0.58	3.57	16.60	66.59			NC/Y
C22 Plastics	MEGA database	2011-19	17		3.23	9.55	12.59	16.98			NC
C22 Plastics	MEGA database	2011-19	28		0.48	7.24	49.22	106.15			NC/Y
C22 Plastics	MEGA database	2011-19	17		0.80	3.91	9.65	17.80			NC
C22 Plastics	MEGA database	2011-19	92		0.25	1.90	12.90	31.00			NC/Y
C22 Plastics	MEGA database	2011-19	39		0.25	1.47	7.26	8.70			NC
C22 Plastics	MEGA database	2011-19	30		0.50	1.30	10.00	14.00			NC
C22 Plastics	MEGA database	2011-19	85		0.25	0.78	11.80	30.00			NC/Y
C22 Plastics	MEGA database	2011-19	34		0.25	0.35	6.66	12.20			NC
C22 Plastics	MEGA database	2011-19	24		0.25	0.85	1.32	2.68			NC
C22 Plastics	MEGA database	2011-19	58		0.25	0.25	0.25	0.31			NC
C22 Plastics	MEGA database	2011-19	17		0.25	0.25	0.36	0.56			NC
C22 Plastics	MEGA database	2011-19	68		0.25	0.37	1.20	1.99			NC
C22 Plastics	MEGA database	2011-19	26		0.25	0.25	0.56	1.52			NC
C22 Plastics	MEGA database	2011-19	68		0.25	1.01	4.37	9.00			NC
C22 Plastics	MEGA database	2011-19	26		0.25	0.37	0.96	1.91			NC
C22 Plastics	MEGA database	2011-19	49		0.25	1.72	7.12	14.70			NC
C22 Plastics	MEGA database	2011-19	15		0.30	2.35	7.35	45.70			NC/Y
C22 Plastics	MEGA database	2011-19	48		0.25	1.50	7.14	15.00			NC
C22 Plastics	MEGA database	2011-19	13		0.25	1.28	3.43	6.26			NC
C22 Plastics	MEGA database	2011-19	21		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	22		0.25	0.25	0.69	1.01			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C22 Plastics	MEGA database	2011-19	11		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	22		0.25	0.25	1.36	4.67			NC
C22 Plastics	MEGA database	2011-19	11		0.29	0.34	0.43	0.44			NC
C22 Plastics	MEGA database	2011-19	17		0.25	0.99	4.03	7.66			NC
C22 Plastics	MEGA database	2011-19	10		0.30	0.30	0.50	0.55			NC
C22 Plastics	MEGA database	2011-19	17		0.25	0.99	4.03	7.66			NC
C22 Plastics	MEGA database	2011-19	10		0.30	0.30	0.50	0.55			NC
C22 Plastics	MEGA database	2011-19	26		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	17		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	30		5.67	11.15	18.15	18.90			NC
C22 Plastics	MEGA database	2011-19	17		0.25	0.25	10.24	13.23			NC
C22 Plastics	MEGA database	2011-19	96		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	65		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	24		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	113		0.25	0.25	0.25	0.76			NC
C22 Plastics	MEGA database	2011-19	76		0.25	0.25	0.25	0.35			NC
C22 Plastics	MEGA database	2011-19	26		0.25	0.25	1.14	1.28			NC
C22 Plastics	MEGA database	2011-19	114		0.25	0.40	2.01	6.88			NC
C22 Plastics	MEGA database	2011-19	77		0.25	0.25	0.25	0.36			NC
C22 Plastics	MEGA database	2011-19	26		0.25	1.19	1.89	2.18			NC
C22 Plastics	MEGA database	2011-19	22		0.25	2.63	9.22	13.99			NC
C22 Plastics	MEGA database	2011-19	27		0.25	0.48	1.11	2.45			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C22 Plastics	MEGA database	2011-19	22		0.25	1.52	8.78	10.90			NC
C22 Plastics	MEGA database	2011-19	28		0.25	0.68	2.08	3.15			NC
C22 Plastics	MEGA database	2011-19	132		0.70	6.40	18.60	28.40			NC
C22 Plastics	MEGA database	2011-19	79		0.38	2.50	14.10	18.00			NC
C22 Plastics	MEGA database	2011-19	28		1.70	5.00	26.80	34.00			NC
C22 Plastics	MEGA database	2011-19	16		0.25	0.25	0.25	1.70			NC
C22 Plastics	MEGA database	2011-19	25		6.15	12.70	19.00	19.80			NC
C22 Plastics	MEGA database	2011-19	89		0.60	3.17	15.10	29.10			NC
C22 Plastics	MEGA database	2011-19	51		0.25	0.83	9.25	13.90			NC
C22 Plastics	MEGA database	2011-19	24		1.00	3.40	18.50	32.20			NC
C22 Plastics	MEGA database	2011-19	16		1.80	13.00	19.00	37.60			NC
C22 Plastics	MEGA database	2011-19	15		1.10	2.22	4.00	8.63			NC
C22 Plastics	MEGA database	2011-19	11		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	45		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	24		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	55		0.25	0.25	0.55	0.90			NC
C22 Plastics	MEGA database	2011-19	33		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	11		0.25	0.25	0.25	1.07			NC
C22 Plastics	MEGA database	2011-19	56		0.25	0.25	0.53	1.54			NC
C22 Plastics	MEGA database	2011-19	33		0.25	0.25	0.34	0.77			NC
C22 Plastics	MEGA database	2011-19	11		0.25	0.81	1.05	1.39			NC
C22 Plastics	MEGA database	2011-19	11		0.25	0.48	13.08	17.71			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C22 Plastics	MEGA database	2011-19	14		0.25	0.25	0.25	0.30			NC
C22 Plastics	MEGA database	2011-19	11		0.25	0.54	2.16	13.85			NC
C22 Plastics	MEGA database	2011-19	14		0.25	0.25	0.25	0.61			NC
C22 Plastics	MEGA database	2011-19	65		0.25	0.80	3.20	7.77			NC
C22 Plastics	MEGA database	2011-19	21		0.25	0.63	2.05	19.10			NC
C22 Plastics	MEGA database	2011-19	52		0.25	0.25	1.14	3.80			NC
C22 Plastics	MEGA database	2011-19	20		0.25	0.40	2.10	20.00			NC
C22 Plastics	MEGA database	2011-19	14		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	12		0.25	0.25	4.57	7.18			NC
C22 Plastics	MEGA database	2011-19	68		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	31		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	26		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	84		0.25	0.25	0.42	1.30			NC
C22 Plastics	MEGA database	2011-19	43		0.25	0.25	0.25	0.34			NC
C22 Plastics	MEGA database	2011-19	26		0.25	0.25	0.25	1.04			NC
C22 Plastics	MEGA database	2011-19	84		0.25	0.34	1.10	3.26			NC
C22 Plastics	MEGA database	2011-19	43		0.25	0.25	0.64	2.09			NC
C22 Plastics	MEGA database	2011-19	26		0.25	0.25	0.77	3.56			NC
C22 Plastics	MEGA database	2011-19	20		0.25	0.25	0.53	0.58			NC
C22 Plastics	MEGA database	2011-19	13		0.25	3.52	8.01	12.69			NC
C22 Plastics	MEGA database	2011-19	20		0.25	0.34	0.63	1.35			NC
C22 Plastics	MEGA database	2011-19	13		0.25	11.10	25.52	36.77			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C22 Plastics	MEGA database	2011-19	71		0.25	1.03	4.86	10.00			NC
C22 Plastics	MEGA database	2011-19	31		0.25	0.81	2.43	6.19			NC
C22 Plastics	MEGA database	2011-19	30		0.25	0.25	1.15	8.50			NC
C22 Plastics	MEGA database	2011-19	13		0.25	0.25	0.25	9.01			NC
C22 Plastics	MEGA database	2011-19	58		0.25	0.90	2.32	5.11			NC
C22 Plastics	MEGA database	2011-19	28		0.25	0.85	3.12	6.38			NC
C22 Plastics	MEGA database	2011-19	25		0.25	0.25	1.08	4.04			NC
C22 Plastics	MEGA database	2011-19	16		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	25		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	26		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	27		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	28		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	27		0.25	0.25	0.53	0.78			NC
C22 Plastics	MEGA database	2011-19	28		0.25	0.30	0.85	2.30			NC
C22 Plastics	MEGA database	2011-19	12		0.58	1.30	2.30	3.63			NC
C22 Plastics	MEGA database	2011-19	12		2.90	11.58	16.89	18.82			NC
C22 Plastics	MEGA database	2011-19	34		0.25	2.70	12.20	18.60			NC
C22 Plastics	MEGA database	2011-19	22		0.25	0.75	12.40	23.00			NC
C22 Plastics	MEGA database	2011-19	20		0.25	0.25	0.80	0.80			NC
C22 Plastics	MEGA database	2011-19	15		0.25	0.25	0.30	0.30			NC
C22 Plastics	MEGA database	2011-19	12		2.80	11.00	17.00	18.80			NC
C22 Plastics	MEGA database	2011-19	40		0.25	0.25	0.34	0.37			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
C22 Plastics	MEGA database	2011-19	24		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	20		0.25	0.25	1.18	1.28			NC
C22 Plastics	MEGA database	2011-19	43		0.25	0.39	1.03	1.17			NC
C22 Plastics	MEGA database	2011-19	25		0.25	0.25	0.25	0.31			NC
C22 Plastics	MEGA database	2011-19	23		0.25	1.67	2.90	3.24			NC
C22 Plastics	MEGA database	2011-19	43		0.50	1.06	2.61	2.94			NC
C22 Plastics	MEGA database	2011-19	25		0.25	0.25	0.35	0.57			NC
C22 Plastics	MEGA database	2011-19	23		0.89	2.75	7.12	7.99			NC
C22 Plastics	MEGA database	2011-19	40		0.80	1.70	4.40	4.60			NC
C22 Plastics	MEGA database	2011-19	22		0.25	0.25	0.50	0.50			NC
C22 Plastics	MEGA database	2011-19	21		1.03	3.70	9.08	12.80			NC
C22 Plastics	MEGA database	2011-19	39		0.80	1.72	4.41	4.61			NC
C22 Plastics	MEGA database	2011-19	20		0.25	0.25	0.30	0.50			NC
C22 Plastics	MEGA database	2011-19	21		1.03	3.70	9.08	12.80			NC
C22 Plastics	MEGA database	2011-19	14		0.25	0.25	0.25	0.57			NC
C22 Plastics	MEGA database	2011-19	16		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	21		0.25	0.25	0.25	0.25			NC
C22 Plastics	MEGA database	2011-19	21		0.25	0.25	0.25	0.40			NC
C22 Plastics	MEGA database	2011-19	18		0.25	0.25	0.64	1.23			NC
C22 Plastics	MEGA database	2011-19	18		0.25	0.25	0.44	0.69			NC
C22 Plastics	MEGA database	2011-19	16		0.25	0.25	0.25	1.70			NC
C22 Plastics	MEGA database	2011-19	12		0.25	0.25	0.25	2.70			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C22 Plastics	Jones et al			0.03					3.1		Y
C22 Plastics	Jones et al			0.07					0.85		Y
C22 Plastics	Jones et al			0.07					2.47		Y
C22 Plastics	Littorin		136							<3	NC
C22 Plastics	Littorin		136	2.17					13.75		NC
C22 Plastics	Littorin		136	2.61					5.15		NC
C22 Plastics	Littorin		136	0.58					2.20		NC
C22 Plastics	Littorin		136	0.07					0.17		NC
C22 Plastics	Littorin	2003	260	<0.1					38		NC
C22 Plastics	FIOH	2008-16	382	0.001					9.12		NC
C22 Plastics	FIOH	2008-16	382	0.002					0.85		NC
C22 Plastics	FIOH	2008-16	382	0.0025					0.12		NC
C22 Plastics	Rosenberg et al		6		0.12						NC
C22 Plastics	Sennbro et al		30	0.01					2.62		NC
C22 Plastics	Sennbro et al		30	0.08					6.00		NC
C22 Plastics	Sennbro et al	2000-01	7	0.00	1.41				2.99	1.58	Y
C22 Plastics	Sennbro et al	2000-01	24	0.01	1.17				0.34	1.31	Y
C22 Plastics	Sennbro et al	2000-01	9	0.10	0.62				1.27	0.58	Y
C22 Plastics	Sennbro et al	2000-01	21	0.17	0.27				0.45	0.27	Y
C22 Plastics	Sennbro et al	2000-01	6	0.69	1.34				2.13	1.38	Y
C22 Plastics	Sennbro et al	2000-01	6	0.25	0.34				3.19	0.89	Y
C22 Plastics	Sennbro et al	2000-01	4	2.89	4.47				7.22	4.81	Y

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C22 Plastics	Sennbro et al	2000-01	8	0.38	1.72				4.47	1.89	Y
C22 Plastics	Sennbro et al	2000-01	3	1.03	1.13				2.37	1.51	Y
C22 Plastics	Sennbro et al	2000-01	5	0.25	0.03				0.10	0.03	Y
C22 Plastics	Sennbro et al	2000-01	3	0.25	0.25				0.25	0.25	Y
C22 Plastics	Sennbro et al	2000-01	7	0.17	0.79				0.89	0.83	Y
C22 Plastics	Sennbro et al	2000-01	24	0.01	0.55					0.76	Y
C22 Plastics	Sennbro et al	2000-01	9	0.07	0.62				1.13	0.52	Y
C22 Plastics	Sennbro et al	2000-01	21	0.14	0.31				0.65	0.34	Y
C22 Plastics	Sennbro et al	2000-01	6	0.65	1.13				1.75	1.20	Y
C22 Plastics	Sennbro et al	2000-01	6	0.00	1.82				7.22	2.64	Y
C22 Plastics	Sennbro et al	2000-01	4	7.56	9.28				11.69	9.28	Y
C22 Plastics	Sennbro et al	2000-01	8	0.00	3.44				7.90	3.78	Y
C22 Plastics	Sennbro et al	2000-01	3	1.20	1.48				2.30	1.65	Y
C22 Plastics	Sennbro et al	2000-01	5	0.10	0.14				0.24	0.17	Y
C22 Plastics	Sennbro et al	2000-01	3	0.03	0.07				0.17	0.10	Y
C22 Plastics	Sennbro et al	2000-01	5	0.01	1.24				2.58	1.20	Y
C22 Plastics	Sennbro et al	2000-01	5	0.25	0.07				3.44	0.76	Y
C22 Plastics	Sennbro et al	2000-01	12	0.58	1.34				6.18	1.68	Y
C22 Plastics	Sennbro et al	2000-01	24	0.03	0.07				0.34	0.10	Y
C22 Plastics	Sennbro et al	2000-01	3	0.03	0.14				0.21	0.10	Y
C22 Plastics	Sennbro et al	2000-01	81	0.25					21.23		Y
C22 Plastics	Sepai and Sabbioni		1	0.40					32.8		NC

NACE Sector	*Source*	*Year*	*No. (2)*	*Low*	*50%*	*75%*	*90%*	*95%*	*High*	*AM*	*RPE (3)*
				NCO µg/m³							
C22 Plastics	Sepai and Sabbioni		1		0.25						NC
C22 Plastics	Sepai and Sabbioni		1		32.78						NC
C22 Plastics	Sepai and Sabbioni		1		0.25						NC
C22 Plastics	Sepai and Sabbioni		1		0.25						NC
C22 Plastics	Sepai and Sabbioni		1		0.25						NC
C22 Plastics	Sepai and Sabbioni		1		0.25						NC
C22 Plastics	Sepai and Sabbioni		1		0.40						NC
C22 Plastics	Sepai and Sabbioni		1		32.78						NC
C22 Plastics	Sepai and Sabbioni		1		0.40						NC
C22 Plastics	Sepai and Sabbioni		1		0.25						NC
C22 Plastics	Sepai and Sabbioni		1		32.78						NC
C22 Plastics	Sepai and Sabbioni		1		3.60						NC
C22 Plastics	Sepai and Sabbioni		1		0.25						NC
C22 Plastics	Sepai and Sabbioni		1		3.60						NC
C22 Plastics	Sepai and Sabbioni		1		0.40						NC
C22 Plastics	Sepai and Sabbioni		1		2.00						NC
C22 Plastics	Sepai and Sabbioni		1		0.40						NC
C22 Plastics	Sepai and Sabbioni		1		32.78						NC
C22 Plastics	Sepai and Sabbioni		1		0.25						NC
C22 Plastics	Sepai and Sabbioni		1		1.04						NC
C22 Plastics	Swierczynska Machura			0.10					28.5		Y
C22 Plastics	Swierczynska Machura		10	0.29					5.31	1.79	Y

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C22 Plastics	Swierczynska Machura		3	0.10					3.14	1.74	Y
C22 Plastics	Swierczynska Machura		2	4.78					20.27	12.40	Y
C22 Plastics	Swierczynska Machura		5	0.14					28.47	12.69	Y
C22 Plastics	Swierczynska Machura			<0.6							Y
C22 Plastics	Tinnerberg et al	2000-05		0.25							Y
C22 Plastics	Tinnerberg et al	2000			11.58						Y
C22 Plastics	Tinnerberg et al	2000			14.57						Y
C22 Plastics	Tinnerberg et al	2000			6.08						Y
C22 Plastics	Tinnerberg et al	2000			8.97						Y
C22 Plastics	Tinnerberg et al	2000			0.19						Y
C22 Plastics	Tinnerberg et al	2000			13.99						Y
C22 Plastics	Tinnerberg et al	2000			0.19						Y
C22 Plastics	Tinnerberg et al	2000			0.68						Y
C22 Plastics	Tinnerberg et al	2000			3.09						Y
C22 Plastics	Tinnerberg et al	2000			3.33						Y
C22 Plastics	Tinnerberg et al	2005			23.93						Y
C22 Plastics	Tinnerberg et al	2005			21.81						Y
C22 Plastics	Tinnerberg et al	2005			16.36						Y
C22 Plastics	Tinnerberg et al	2005			18.38						Y
C22 Plastics	Tinnerberg et al	2005			2.32						Y
C22 Plastics	Tinnerberg et al	2005			27.74						Y
C22 Plastics	Tinnerberg et al	2005			3.91						Y

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C22 Plastics	Tinnerberg et al	2005			1.74						Y
C22 Plastics	Tinnerberg et al	2005			25.38						Y
C22 Plastics	Tinnerberg et al	2005			4.44						Y
C22 Plastics	UK HSE	2003		<1	5			8	10		NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								4	NC
C22 Plastics	UK HSE	2003								7	NC
C22 Plastics	UK HSE	2003								8	NC
C22 Plastics	UK HSE	2003								12	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								<1	NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								2	NC
C22 Plastics	UK HSE	2003								4	NC
C22 Plastics	UK HSE	2003								5	NC
C22 Plastics	UK HSE	2003								10	NC
C22 Plastics	UK HSE	2003								5	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003		<1	1			6	12		NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								3	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								1	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003		<1	1			2	5		NC
C22 Plastics	UK HSE	2003								1	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	UK HSE	2003								1	NC
C22 Plastics	UK HSE	2003								5	NC
C22 Plastics	UK HSE	2003								<1	NC
C22 Plastics	Consultation	2021	56	1.11	1.89			3.35	20.94	1.67	Y

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C22 Plastics	Consultation	2021	77	0.25	0.48			0.43	6.82	0.34	N
C26 Computers/ C27 Electrical equipment	Brzeźnicki and Bonczarow-ska	2011	2	<0.39							Y
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	12		0.25	0.25	0.25	0.25			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	11		0.25	0.25	0.25	0.25			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	73		0.25	0.25	0.25	0.25			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	84		0.25	0.25	0.25	0.25			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	28		0.25	0.25	0.25	0.25			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	11		0.25	0.25	0.25	0.25			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	99		0.25	0.25	0.25	0.25			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	101		0.25	0.25	0.25	0.25			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	31		0.25	0.25	0.25	1.80			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	15		0.25	0.25	0.25	0.25			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	99		0.25	0.25	0.25	0.68			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	101		0.25	0.25	0.25	0.25			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	31		0.25	0.25	1.34	2.33			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	15		0.25	0.25	0.25	0.25			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	111		0.25	0.25	1.06	3.17			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	108		0.25	0.25	0.25	0.25			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	33		0.25	0.25	1.41	2.65			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	16		0.25	0.25	0.25	0.25			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	12		0.60	2.30	6.32	8.14			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	11		0.25	0.25	0.25	0.25			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	99		0.25	0.25	0.25	0.72			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	99		0.25	0.25	0.25	0.25			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	31		0.25	0.25	0.25	1.79			NC
C26 Computers/ C27 Electrical equipment	MEGA database	2011-19	15		0.25	0.25	0.25	0.25			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C26 Computers/ C27 Electrical equipment	FIOH	2008-16	43	0.101					164.5		NC
C26 Computers/ C27 Electrical equipment	FIOH	2008-16	43	0.001					0.40		NC
C26 Computers/ C27 Electrical equipment	FIOH	2008-16	43	0.01					0.22		NC
C26 Computers/ C27 Electrical equipment	FIOH	2008-16	33	0.002					0.36		NC
C26 Computers/ C27 Electrical equipment	FIOH	2008-16	33	0.0025					103.9 2		NC
C26 Computers	Consultation	2021							0.45		Y
C27 Electrical equipment	Brzeźnicki and Bonczarow-ska	2007	2	3.86					6.04	5.04	Y
C27 Electrical equipment	Brzeźnicki and Bonczarow-ska	2009	3	<0.2					0.40	0.24	Y
C27 Electrical equipment	Brzeźnicki and Bonczarow-ska	2007	1	<0.2							Y
C27 Electrical equipment	Brzeźnicki and Bonczarow-ska	2007	3	<0.39					0.40	0.40	Y
C27 Electrical equipment	Brzeźnicki and Bonczarow-ska	2007	3	<0.39							Y
C27 Electrical equipment	UK HSE	2003	28	1	1			1	7		NC
C27 Electrical equipment	UK HSE	2003								<1	NC
C27 Electrical equipment	UK HSE	2003								<1	NC
C27 Electrical equipment	UK HSE	2003								<1	NC

NACE Sector	*Source*	*Year*	*No. (2)*	*Low*	*50%*	*75%*	*90%*	*95%*	*High*	*AM*	*RPE (3)*
				NCO µg/m³							
C27 Electrical equipment	UK HSE	2003								<1	NC
C27 Electrical equipment	UK HSE	2003								<1	NC
C27 Electrical equipment	UK HSE	2003								<1	NC
C27 Electrical equipment	UK HSE	2003								<1	NC
C27 Electrical equipment	UK HSE	2003								<1	NC
C27 Electrical equipment	Consultation	2021	1	0.0067					3.35		N
C28 Machinery	Brzeźnicki and Bonczarow-ska	2012	11	<0.2					1.11	0.27	Y
C28 Machinery	Brzeźnicki and Bonczarow-ska	2012	12	<0.2					5.84	1.14	Y
C28 Machinery	Brzeźnicki and Bonczarow-ska	2012	6						0.80	0.24-0.3	Y
C28 Machinery	Brzeźnicki and Bonczarow-ska	2012	4						2.45	1.61-1.95	Y
C28 Machinery	MEGA database	2011-19	13		0.25	0.25	0.25	0.25			NC
C28 Machinery	MEGA database	2011-19	89		0.25	0.25	0.25	0.25			NC
C28 Machinery	MEGA database	2011-19	22		0.25	0.25	0.25	0.25			NC
C28 Machinery	MEGA database	2011-19	24		0.25	0.25	0.25	0.25			NC
C28 Machinery	MEGA database	2011-19	106		0.25	0.25	0.25	0.25			NC
C28 Machinery	MEGA database	2011-19	30		0.25	0.25	0.25	0.47			NC
C28 Machinery	MEGA database	2011-19	28		0.25	0.25	0.25	0.25			NC
C28 Machinery	MEGA database	2011-19	108		0.25	0.25	0.25	0.25			NC
C28 Machinery	MEGA database	2011-19	30		0.25	0.25	0.25	0.25			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
C28 Machinery	MEGA database	2011-19	28		0.25	0.25	0.70	1.85			NC
C28 Machinery	MEGA database	2011-19	96		0.25	0.25	0.25	0.52			NC
C28 Machinery	MEGA database	2011-19	22		0.25	0.25	0.25	0.85			NC
C28 Machinery	MEGA database	2011-19	22		0.25	0.25	2.54	2.55			NC
C28 Machinery	MEGA database	2011-19	10		0.25	0.25	0.25	0.25			NC
C28 Machinery	MEGA database	2011-19	94		0.25	0.25	0.25	0.53			NC
C28 Machinery	MEGA database	2011-19	22		0.25	0.25	0.25	0.85			NC
C28 Machinery	MEGA database	2011-19	22		0.25	0.25	2.54	2.55			NC
C28 Machinery	MEGA database	2011-19	13		0.25	0.25	0.25	0.25			NC
C28 Machinery	MEGA database	2011-19	10		0.25	0.25	0.25	0.25			NC
C28 Machinery	MEGA database	2011-19	16		0.25	0.25	0.25	0.25			NC
C28 Machinery	MEGA database	2011-19	14		0.25	0.25	0.29	0.58			NC
C28 Machinery	MEGA database	2011-19	16		0.25	0.25	0.25	0.34			NC
C28 Machinery	MEGA database	2011-19	14		0.25	0.25	0.95	2.77			NC
C28 Machinery	MEGA database	2011-19	15		0.25	0.25	0.40	7.62			NC
C28 Machinery	MEGA database	2011-19	11		0.25	0.63	1.45	3.57			NC
C28 Machinery	MEGA database	2011-19	13		0.25	0.25	0.25	0.31			NC
C28 Machinery	Liljelind	2006-07		0.01					1.18		NC
C28 Machinery	FIOH	2008-16	171	0.002					0.4		NC
C28 Machinery	FIOH	2008-16	171	0.002					22.7		NC
C28 Machinery	FIOH	2008-16	171	0.0025					238.8		NC
C28 Machinery	FIOH	2008-16	41	0.002					0.2		NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C28 Machinery	FIOH	2008-16	41	0.002					0.1		NC
C28 Machinery	FIOH	2008-16	41	0.0025					501.1		NC
C29 Motor vehicles	Brzeźnicki and Bonczarow-ska	2007		<0.39					0.50	0.35	Y
C29 Motor vehicles	Brzeźnicki and Bonczarow-ska	2007		<0.39							Y
C29 Motor vehicles	Creely		13	0.50	0.50		28.80		65.80		Y
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	16		0.25	0.25	0.25	0.25			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	14		0.25	0.25	0.25	0.25			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	95		0.25	0.25	0.25	0.25			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	38		0.25	0.25	0.25	0.25			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	19		0.25	0.25	0.25	0.25			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	11		0.25	0.25	0.25	0.25			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	102		0.25	0.25	0.25	0.25			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	44		0.25	0.25	0.25	0.25			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	22		0.25	0.25	0.25	0.25			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	15		0.25	0.25	0.25	0.83			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	103		0.25	0.25	0.34	0.71			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	44		0.25	0.25	0.25	0.25			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	22		0.25	0.25	0.25	1.53			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	15		0.25	0.25	1.93	5.74			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	14		0.25	0.39	0.66	0.93			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	14		0.25	0.53	2.51	4.03			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	89		0.25	0.25	1.52	7.92			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	39		0.25	0.25	0.25	0.42			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	24		0.25	0.25	4.25	4.77			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	14		0.25	0.25	0.25	5.81			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	14		0.25	0.25	35.20	67.10			NC/Y
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	12		0.25	0.25	0.25	0.25			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	75		0.25	0.25	0.40	0.98			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	37		0.25	0.25	0.25	0.46			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	19		0.25	0.25	2.03	2.43			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	12		0.25	0.25	0.25	7.27			NC
C29 / C30 / F41 / F42 / F43	MEGA database	2011-19	11		0.25	1.18	3.86	5.45			NC
C29 / C30 / G45	MEGA database	2011-19	340		0.25	0.25	1.00	2.40			NC
C29 / C30 / G45	MEGA database	2011-19	98		0.25	0.25	0.75	1.38			NC
C29 / C30 / G45	MEGA database	2011-19	123		0.25	1.98	6.00	10.44			NC
C29 / C30 / G45	MEGA database	2011-19	19		0.25	0.25	1.58	11.99			NC
C29 / C30 / G45	MEGA database	2011-19	59		0.25	0.25	2.92	5.07			NC
C29 / C30 / G45	MEGA database	2011-19	25		0.25	0.25	0.25	4.95			NC
C29 / C30 / G45	MEGA database	2011-19	19		0.25	6.99	14.93	20.11			NC
C29 / C30 / G45	MEGA database	2011-19	24		0.25	0.25	0.25	0.25			NC
C29 / C30 / G45	MEGA database	2011-19	31		0.25	0.25	0.25	0.25			NC
C29 / C30 / G45	MEGA database	2011-19	21		0.25	2.52	5.61	6.65			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
C29 / C30 / G45	MEGA database	2011-19	35		0.25	0.25	0.25	1.36			NC
C29 / C30 / G45	MEGA database	2011-19	41		0.25	0.25	2.62	3.33			NC
C29 / C30 / G45	MEGA database	2011-19	23		5.37	32.07	59.44	83.28			NC/Y
C29 / C30 / G45	MEGA database	2011-19	38		0.25	0.25	0.58	9.81			NC
C29 / C30 / G45	MEGA database	2011-19	41		0.25	0.40	1.47	8.93			NC
C29 / C30 / G45	MEGA database	2011-19	23		7.72	51.04	192.08	310.95			NC/Y
C29 / C30 / G45	MEGA database	2011-19	74		0.25	0.25	0.25	0.48			NC
C29 / C30 / G45	MEGA database	2011-19	22		0.25	0.25	3.07	4.71			NC
C29 / C30 / G45	MEGA database	2011-19	35		0.25	0.25	1.09	1.23			NC
C29 / C30 / G45	MEGA database	2011-19	71		0.25	0.25	0.25	0.62			NC
C29 / C30 / G45	MEGA database	2011-19	22		0.25	0.25	5.93	8.11			NC
C29 / C30 / G45	MEGA database	2011-19	34		0.25	0.25	1.15	1.31			NC
C29 / C30 / G45	MEGA database	2011-19	379		2.00	13.00	46.20	78.40			NC/Y
C29 / C30 / G45	MEGA database	2011-19	110		0.25	4.85	16.00	34.50			NC/Y
C29 / C30 / G45	MEGA database	2011-19	162		23.00	87.00	238.00	289.00			NC/Y
C29 / C30 / G45	MEGA database	2011-19	27		0.25	21.50	66.00	78.20			NC/Y
C29 / C30 / G45	MEGA database	2011-19	330		2.10	14.00	45.00	75.50			NC/Y
C29 / C30 / G45	MEGA database	2011-19	82		0.25	3.80	14.80	37.30			NC/Y
C29 / C30 / G45	MEGA database	2011-19	116		28.00	89.00	244.00	274.00			NC/Y
C29 / C30 / G45	MEGA database	2011-19	17		0.25	10.40	56.00	70.10			NC/Y
C29 / C30 / G45	MEGA database	2011-19	53		1.90	14.50	54.80	110.00			NC/Y
C29 / C30 / G45	MEGA database	2011-19	13		0.25	8.20	12.40	27.70			NC/Y

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C29 / C30 / G45	MEGA database	2011-19	18		8.00	25.00	41.20	45.00			NC/Y
C29 / C30 / G45	MEGA database	2011-19	34		0.25	1.00	26.00	51.30			NC/Y
C29 / C30 / G45	MEGA database	2011-19	30		0.40	5.50	17.00	28.00			NC/Y
C29 / C30 / G45	MEGA database	2011-19	20		48.00	170.00	380.00	590.00			NC/Y
C29 / C30 / G45	MEGA database	2011-19	70		0.90	7.30	25.00	53.50			NC/Y
C29 / C30 / G45	MEGA database	2011-19	11		0.85	9.70	15.70	16.40			NC/Y
C29 / C30 / G45	MEGA database	2011-19	31		1.33	19.80	66.70	97.90			NC/Y
C29 / C30 / G45	MEGA database	2011-19	90		0.25	0.25	0.25	0.75			NC
C29 / C30 / G45	MEGA database	2011-19	65		0.25	0.25	0.25	0.25			NC
C29 / C30 / G45	MEGA database	2011-19	12		0.25	2.30	3.78	4.69			NC
C29 / C30 / G45	MEGA database	2011-19	16		0.25	0.25	7.18	8.85			NC
C29 / C30 / G45	MEGA database	2011-19	16		0.25	0.25	2.91	7.49			NC
C29 / C30 / G45	MEGA database	2011-19	34		0.25	0.25	0.25	0.25			NC
C29 / C30 / G45	MEGA database	2011-19	65		0.25	0.25	0.25	0.25			NC
C29 / C30 / G45	MEGA database	2011-19	14		0.25	0.25	0.25	0.25			NC
C29 / C30 / G45	MEGA database	2011-19	13		0.25	0.25	0.25	0.25			NC
C29 / C30 / G45	MEGA database	2011-19	82		0.25	0.25	0.59	2.73			NC
C29 / C30 / G45	MEGA database	2011-19	92		0.25	0.25	0.34	0.62			NC
C29 / C30 / G45	MEGA database	2011-19	15		0.25	0.25	0.25	0.25			NC
C29 / C30 / G45	MEGA database	2011-19	15		0.25	0.25	0.25	1.13			NC
C29 / C30 / G45	MEGA database	2011-19	82		0.25	1.07	2.71	3.96			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
C29 / C30 / G45	MEGA database	2011-19	92		0.37	0.94	1.86	3.29			NC
C29 / C30 / G45	MEGA database	2011-19	15		0.25	0.25	2.07	2.94			NC
C29 / C30 / G45	MEGA database	2011-19	15		0.91	1.86	3.17	10.14			NC
C29 / C30 / G45	MEGA database	2011-19	24		0.25	0.25	0.54	0.69			NC
C29 / C30 / G45	MEGA database	2011-19	23		0.25	0.25	0.25	0.48			NC
C29 / C30 / G45	MEGA database	2011-19	13		0.25	1.07	1.16	1.16			NC
C29 / C30 / G45	MEGA database	2011-19	24		0.25	0.34	3.31	3.73			NC
C29 / C30 / G45	MEGA database	2011-19	23		0.25	0.25	0.58	3.66			NC
C29 / C30 / G45	MEGA database	2011-19	13		0.25	2.92	4.11	5.31			NC
C29 / C30 / G45	MEGA database	2011-19	154		0.25	2.05	8.26	21.30			NC
C29 / C30 / G45	MEGA database	2011-19	125		0.25	1.10	3.35	6.37			NC
C29 / C30 / G45	MEGA database	2011-19	28		1.60	4.30	50.80	164.00			NC/Y
C29 / C30 / G45	MEGA database	2011-19	15		1.90	2.93	3.90	11.40			NC
C29 / C30 / G45	MEGA database	2011-19	87		0.25	0.25	9.01	21.60			NC
C29 / C30 / G45	MEGA database	2011-19	50		0.25	0.25	1.10	2.05			NC
C29 / C30 / G45	MEGA database	2011-19	14		0.25	0.25	8.10	9.53			NC
C29 / C30 / G45	MEGA database	2011-19	70		0.35	1.80	3.10	10.50			NC
C29 / C30 / G45	MEGA database	2011-19	64		0.70	1.40	3.02	3.68			NC
C29 / C30 / G45	MEGA database	2011-19	12		0.25	1.40	2.10	2.43			NC
C29 / C30 / G45	MEGA database	2011-19	13		1.65	2.80	3.21	13.30			NC
C29 / C30 / G45	MEGA database	2011-19	19		0.25	4.35	8.17	16.70			NC
C29 / C30 / G45	MEGA database	2011-19	11		0.25	4.80	9.12	21.50			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C29 / C30 / G45	MEGA database	2011-19	10		1.70	4.40	8.20	22.10			NC
C29 Motor vehicles	FIOP	2008-16	47	0.014					0.03		NC
C29 Motor vehicles	FIOP	2008-16	47	0.008					7.96		NC
C29 Motor vehicles	FIOP	2008-16	47	0.0125					232.82		NC
C29 Motor vehicles	Schweigert		41	0.51					3.07		NC
C29 Motor vehicles	Sivaraman		1							0.26	Y
C29 Motor vehicles	Sivaraman		1							1.30	Y
C29 Motor vehicles	Sivaraman		1							0.40	Y
C29 Motor vehicles	Sivaraman		1							0.11	Y
C29 Motor vehicles	Sivaraman		1							0.14	Y
C29 Motor vehicles	Sivaraman		1							0.14	Y
C29 Motor vehicles	Sivaraman		1							0.06	Y
C29 Motor vehicles	Sivaraman		1							0.10	Y
C29 Motor vehicles	Sivaraman									0.32	Y
C29 Motor vehicles	Sivaraman									0.03	Y
C29 Motor vehicles	Sivaraman									0.08	Y
C29 Motor vehicles	Sivaraman									0.08	Y
C29 Motor vehicles	Sweigert		41	0.3					2		NC
C29 Motor vehicles	Sweigert			<0.2							NC
C29 Motor vehicles	UK HSE	2003		1	1			1	7		NC
C29 Motor vehicles	UK HSE	2003		<1	1			34	136		NC

NACE Sector	***Source***	***Year***	***No. (2)***	***Low***	***50%***	***75%***	***90%***	***95%***	***High***	***AM***	***RPE (3)***
				NCO µg/m³							
C29 Motor vehicles	UK HSE	2003								<1	NC
C29 Motor vehicles	UK HSE	2003								<1	NC
C29 Motor vehicles	UK HSE	2003								<1	NC
C29 Motor vehicles	UK HSE	2003								<1	NC
C29 Motor vehicles	UK HSE	2003								<1	NC
C29 Motor vehicles	UK HSE	2003								<1	NC
C29 Motor vehicles	UK HSE	2003								<1	NC
C29 Motor vehicles	UK HSE	2003								<1	NC
C29 Motor vehicles	UK HSE	2003								<1	NC
C29 Motor vehicles	UK HSE	2003								<1	NC
C29 Motor vehicles	UK HSE	2003								<1	NC
C29 Motor vehicles	UK HSE	2003								<1	NC
C29 Motor vehicles	UK HSE	2003								<1	NC
C29 Motor vehicles	UK HSE	2003								<1	NC
C29 Motor vehicles	UK HSE	2003								<1	NC
C29 Motor vehicles	UK HSE	2003								<1	NC
C29 Motor vehicles	UK HSE	2003								<1	NC
C30 Transport	FIOH	2008-16	47	0.014					0.03		NC
C30 Transport	FIOH	2008-16	47	0.008					7.96		NC
C30 Transport	FIOH	2008-16	47	0.0125					232.82		NC
C30 Transport	Henriks-Eckerman et al	2010-12	24	0.03					9.07		Y

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C31 Furniture	Brzeźnicki and Bonczarow-ska	2004	10	0.20							Y
C31 Furniture	FIOH	2008-16	60	0.005					51.15		NC
C31 Furniture	FIOH	2008-16	60	0.002					0.04		NC
C31 Furniture	FIOH	2008-16	60	0.02					0.82		NC
C31 Furniture	MEGA database	2000-19	10		0.25	0.25	0.25	0.25			NC
C31 Furniture	MEGA database	2000-19	40		0.25	0.25	0.25	0.25			NC
C31 Furniture	MEGA database	2000-19	17		0.25	0.25	0.25	0.25			NC
C31 Furniture	MEGA database	2000-19	48		0.25	0.25	0.25	0.25			NC
C31 Furniture	MEGA database	2000-19	19		0.25	0.25	0.25	0.59			NC
C31 Furniture	MEGA database	2000-19	47		0.25	0.25	0.34	0.75			NC
C31 Furniture	MEGA database	2000-19	19		0.25	0.41	0.87	0.89			NC
C31 Furniture	MEGA database	2000-19	42		0.25	0.25	0.34	0.76			NC
C31 Furniture	MEGA database	2000-19	15		0.25	0.79	0.90	2.30			NC
C31 Furniture	MEGA database	2000-19	39		0.25	0.25	0.30	0.84			NC
C31 Furniture	MEGA database	2000-19	14		0.25	0.60	0.90	2.58			NC
C31 Furniture	MEGA database	2000-19	12		0.25	0.25	0.25	0.25			NC
C31 Furniture	MEGA database	2000-19	11		0.25	0.25	0.25	0.25			NC
C31 Furniture	MEGA database	2000-19	24		0.25	0.25	0.25	0.25			NC
C31 Furniture	MEGA database	2000-19	33		0.25	0.25	0.25	0.25			NC
C31 Furniture	MEGA database	2000-19	28		0.25	0.25	0.34	0.70			NC
C31 Furniture	MEGA database	2000-19	36		0.25	0.25	0.25	0.25			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C31 Furniture	MEGA database	2000-19	28		0.25	0.25	0.63	1.05			NC
C31 Furniture	MEGA database	2000-19	36		0.25	0.25	0.34	0.85			NC
C31 Furniture	MEGA database	2000-19	11		0.25	0.25	0.25	0.25			NC
C31 Furniture	MEGA database	2000-19	11		0.25	0.25	0.25	0.25			NC
C31 Furniture	MEGA database	2000-19	24		0.25	0.30	0.84	1.64			NC
C31 Furniture	MEGA database	2000-19	30		0.25	0.25	0.80	1.30			NC
C31 Furniture	MEGA database	2000-19	12		0.25	0.25	0.25	5.50			NC
C31 Furniture	MEGA database	2000-19	11		0.25	0.25	0.25	0.25			NC
C31 Furniture	MEGA database	2000-19	24		0.25	0.30	0.84	1.64			NC
C31 Furniture	MEGA database	2000-19	29		0.25	0.25	0.53	0.97			NC
C31 Furniture	MEGA database	2000-19	11		0.25	0.25	0.25	0.25			NC
C33 Machinery Repair	FIOP	2008-16	41	0.002					0.2		NC
C33 Machinery Repair	FIOP	2008-16	41	0.002					0.1		NC
C33 Machinery Repair	FIOP	2008-16	41	0.0025					501.1		NC
C33 Machinery Repair	Pronk et al	2004	10	0.03	3.7				29		Y
C33 Machinery Repair	Pronk et al	2004	11	0.01	0.02				0.1		NC
C33 Machinery Repair	Pronk et al	2004	3	0.01	0.5				1		Y
C33 Machinery Repair	Pronk et al	2004	3	0.09	0.3				4.4		NC
C33 Machinery Repair	UK HSE	2003	1							<1	NC
C33 Machinery Repair	UK HSE	2003	1							2	NC
C33 Machinery Repair	UK HSE	2003	1							<1	NC
C33 Machinery Repair	UK HSE	2003	1							<1	NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
C33 Machinery Repair	UK HSE	2003	1							2	NC
C33 Machinery Repair	UK HSE	2003	1							<1	NC
F41 / F43	MEGA database	2000-19	29		0.25	1.02	2.00	3.37			NC
F41 / F43	MEGA database	2000-19	20		0.25	1.70	2.20	3.55			NC
F41 / F43	MEGA database	2000-19	24		0.25	0.25	0.25	0.25			NC
F41 / F43	MEGA database	2000-19	24		0.25	0.25	0.25	0.25			NC
F41 / F43	MEGA database	2000-19	38		0.25	1.00	2.10	3.18			NC
F41 / F43	MEGA database	2000-19	22		0.25	2.30	3.07	3.82			NC
F41 / F43	MEGA database	2000-19	29		0.25	1.45	2.19	3.99			NC
F41 / F43	MEGA database	2000-19	20		0.25	2.50	3.10	3.90			NC
F41 / F43	MEGA database	2000-19	20		0.25	0.25	0.25	0.35			NC
F43 Specialised construction	Bello	2015-16	24	0.30					41.30		Y
F43 Specialised construction	Bello	2015-16	24	0.04					4.26		Y
F43 Specialised construction	Bello	2015-16	24	<0.01					60.51		Y
F43 Specialised construction	Bello	2015-16	24	<0.01					225.96		Y
F43 Specialised construction	Bello	2015-16	24	<0.01					253.70		Y
F43 Specialised construction	Bello	2015-16	7	0.27					14.17		Y

NACE Sector	*Source*	*Year*	*No. (2)*	*Low*	*50%*	*75%*	*90%*	*95%*	*High*	*AM*	*RPE (3)*
				NCO µg/m³							
F43 Specialised construction	Bello	2015-16	7	0.01					0.12		Y
F43 Specialised construction	Bello	2015-16	7	0.003					26.70		Y
F43 Specialised construction	Bello	2015-16	7	0.05					10.95		Y
F43 Specialised construction	Bello	2015-16	7	0.34					44.60		Y
F43 Specialised construction	Bello	2015-16	15	0.47					80.86		Y
F43 Specialised construction	Bello	2015-16	15	0.07					9.54		Y
F43 Specialised construction	Bello	2015-16	15	0.003					0.87		Y
F43 Specialised construction	Bello	2015-16	15	0.17					146.81		Y
F43 Specialised construction	Bello	2015-16	15	3.20					579.10		Y
F43 Specialised construction	Bello	2015-16	5	0.003					9.07		Y
F43 Specialised construction	Bello	2015-16	5	0.01					1.41		Y
F43 Specialised construction	Bello	2015-16	5	<0.01					0.87		Y
F43 Specialised construction	Bello	2015-16	5	<0.01					1.46		Y

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
F43 Specialised construction	Bello	2015-16	5	0.09					12.00		Y
F43 Specialised construction	Creely		5	0.50	1.00		16.00		22.60		Y
F41 / F42 / 43	MEGA database	2000-19	16		0.25	0.25	0.25	0.25			NC
F41 / F42 / 43	MEGA database	2000-19	12		0.25	0.25	0.25	0.25			NC
F41 / F42 / 43	MEGA database	2000-19	16		0.25	0.25	0.98	1.07			NC
F41 / F42 / 43	MEGA database	2000-19	12		0.25	0.25	0.25	0.25			NC
F41 / F42 / 43	MEGA database	2000-19	16		0.25	0.25	0.98	1.07			NC
F41 / F42 / 43	MEGA database	2000-19	10		0.58	0.72	1.01	1.04			NC
F41 / F42 / 43	MEGA database	2000-19	10		1.11	3.16	6.27	8.20			NC
F41 / F42 / 43	MEGA database	2000-19	21		0.25	1.85	4.05	7.14			NC
F41 / F42 / 43	MEGA database	2000-19	19		0.25	0.25	1.00	1.08			NC
F41 / F42 / 43	MEGA database	2000-19	12		0.25	0.25	1.58	1.90			NC
F41 / F42 / 43	MEGA database	2000-19	16		0.25	0.25	0.71	0.80			NC
F41 / F42 / 43	MEGA database	2000-19	10		1.90	3.85	7.30	9.15			NC
F43 Specialised construction	MEGA database	2000-19	59		0.25	0.25	0.25	1.21			NC
F43 Specialised construction	MEGA database	2000-19	41		0.25	0.25	0.25	0.25			NC
F43 Specialised construction	MEGA database	2000-19	31		0.25	0.25	2.34	4.53			NC
F43 Specialised construction	MEGA database	2000-19	21		0.25	0.25	0.25	0.25			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
F43 Specialised construction	MEGA database	2000-19	16		0.25	0.25	0.25	0.25			NC
F43 Specialised construction	MEGA database	2000-19	20		0.25	0.25	0.25	0.25			NC
F43 Specialised construction	MEGA database	2000-19	24		0.25	0.25	0.59	0.79			NC
F43 Specialised construction	MEGA database	2000-19	18		0.25	0.25	0.46	1.07			NC
F43 Specialised construction	MEGA database	2000-19	23		0.25	0.77	1.20	1.33			NC
F43 Specialised construction	MEGA database	2000-19	24		0.25	0.25	0.46	0.69			NC
F43 Specialised construction	MEGA database	2000-19	18		0.25	0.25	0.25	0.25			NC
F43 Specialised construction	MEGA database	2000-19	23		0.25	0.25	0.99	1.52			NC
F43 Specialised construction	MEGA database	2000-19	13		0.25	0.25	0.25	0.25			NC
F43 Specialised construction	MEGA database	2000-19	15		0.25	0.25	0.25	0.25			NC
F43 Specialised construction	MEGA database	2000-19	13		0.25	0.25	0.25	0.57			NC
F43 Specialised construction	MEGA database	2000-19	15		0.25	0.25	0.25	0.25			NC
F43 Specialised construction	MEGA database	2000-19	74		0.25	0.25	1.66	2.45			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
F43 Specialised construction	MEGA database	2000-19	46		0.25	0.25	0.25	1.67			NC
F43 Specialised construction	MEGA database	2000-19	57		0.25	1.90	4.38	7.92			NC
F43 Specialised construction	MEGA database	2000-19	10		0.25	0.25	2.00	2.32			NC
F43 Specialised construction	MEGA database	2000-19	57		0.25	0.25	1.08	2.83			NC
F43 Specialised construction	MEGA database	2000-19	34		0.25	0.25	0.25	2.51			NC
F43 Specialised construction	MEGA database	2000-19	30		0.25	0.25	3.60	4.55			NC
F43 Specialised construction	MEGA database	2000-19	19		0.25	0.61	1.73	2.01			NC
F43 Specialised construction	MEGA database	2000-19	14		0.25	0.25	0.76	1.23			NC
F43 Specialised construction	MEGA database	2000-19	22		0.25	1.55	3.68	4.18			NC
F43 Specialised construction	MEGA database	2000-19	12		0.25	0.25	0.84	1.15			NC
F43 Specialised construction	MEGA database	2000-19	11		0.25	0.25	0.25	0.25			NC
F43 Specialised construction	Jones			0.10					0.47		Y
F43 Specialised construction	FIOP	2008-16	16	0.068							NC

NACE Sector	*Source*	*Year*	*No. (2)*	*Low*	*50%*	*75%*	*90%*	*95%*	*High*	*AM*	*RPE (3)*
				NCO µg/m^3							
F43 Specialised construction	FIOP	2008-16	16	0.008							NC
F43 Specialised construction	FIOP	2008-16	16	0.01					18.44		NC
F43 Specialised construction	UK HSE	2003								1	NC
F43 Specialised construction	UK HSE	2003								14	NC
F43 Specialised construction	UK HSE	2003								<1	NC
F43 Specialised construction	UK HSE	2003								5	NC
F43 Specialised construction	UK HSE	2003								2	NC
F43 Specialised construction	UK HSE	2003								27	NC
F43 Specialised construction	UK HSE	2003								48	NC
F43 Specialised construction	UK HSE	2003								2	NC
F43 Specialised construction	UK HSE	2003								66	NC
F43 Specialised construction	UK HSE	2003								<1	NC
F43 Specialised construction	UK HSE	2003								<1	NC

NACE Sector	*Source*	*Year*	*No. (2)*	*Low*	*50%*	*75%*	*90%*	*95%*	*High*	*AM*	*RPE (3)*
				NCO µg/m³							
F43 Specialised construction	UK HSE	2003								1	NC
F43 Specialised construction	UK HSE	2003								5	NC
F43 Specialised construction	UK HSE	2003								1	NC
G45.2 Vehicle repair	Fent et al			0.0015					23.98		Y
G45.2 Vehicle repair	Fent et al			0.2498					32.72		Y
G45.2 Vehicle repair	Fent et al			0.0003					89.43		Y
G45.2 Vehicle repair	Fent et al			0.0003					89.43		Y
G45.2 Vehicle repair	MEGA database	28			0.25	0.25	0.25	0.25			N
G45.2 Vehicle repair	MEGA database	20			0.25	0.25	0.25	0.75			*N*
G45.2 Vehicle repair	MEGA database	30			0.25	0.25	0.25	0.25			*N*
G45.2 Vehicle repair	MEGA database	19			0.25	0.25	0.68	3.31			*N*
G45.2 Vehicle repair	MEGA database	28			0.25	0.25	0.25	0.25			*N*
G45.2 Vehicle repair	MEGA database	17			0.25	0.25	0.93	6.33			*N*
G45.2 Vehicle repair	MEGA database	12			0.25	0.25	1.55	1.75			NC
G45.2 Vehicle repair	MEGA database	17			0.25	0.25	0.25	0.25			NC
G45.2 Vehicle repair	MEGA database	12			0.25	0.25	0.25	0.25			NC
G45.2 Vehicle repair	MEGA database	16			0.25	0.25	0.25	0.25			NC
G45.2 Vehicle repair	MEGA database	12			0.25	0.25	0.25	1.03			NC
G45.2 Vehicle repair	MEGA database	16			0.25	0.25	1.26	2.89			NC
G45.2 Vehicle repair	MEGA database	13			0.25	0.25	0.25	5.64			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m^3							
G45.2 Vehicle repair	MEGA database	17			0.25	2.41	16.32	20.32			NC/Y
G45.2 Vehicle repair	MEGA database	14			0.25	1.15	3.64	11.20			NC
G45.2 Vehicle repair	MEGA database	27			0.25	0.98	7.99	23.80			NC/Y
G45.2 Vehicle repair	MEGA database	14			0.25	0.25	0.25	0.60			NC
G45.2 Vehicle repair	MEGA database	10			0.25	0.25	0.30	13.20			NC
G45.2 Vehicle repair	MEGA database	16			0.25	2.50	21.60	34.80			NC/Y
G45.2 Vehicle repair	Pronk et al	2004	15	0.2	1				2.7		Y
G45.2 Vehicle repair	Pronk et al	2004	31	0.2	2.1				6.5		Y
G45.2 Vehicle repair	Pronk et al	2004	19						0.05		NC
G45.2 Vehicle repair	Pronk et al	2004	3		0.04						NC
G45.2 Vehicle repair	Reeb-Whitaker and Schoonover	2012-14							0.1		NC
G45.2 Vehicle repair	Reeb-Whitaker	2006-07	228							70	Y
G45.2 Vehicle repair	FIOH	2008-16	44	0.003					0.01		NC
G45.2 Vehicle repair	FIOH	2008-16	44	0.0025					44.91		NC
G45.2 Vehicle repair	Schreiber et al		10	0.001					0.13	0.04	NC
G45.2 Vehicle repair	Schreiber et al		16	0.49					2.67	0.49	NC
G45.2 Vehicle repair	Schreiber et al		4							10.47	NC
S95.24 Repair of furniture and home furnishings	MEGA database	2000-19	19		0.25	0.25	0.25	0.25			NC
S95.24 Repair of furniture and home furnishings	MEGA database	2000-19	23		0.25	0.25	0.25	0.25			NC

NACE Sector	Source	Year	No. (2)	Low	50%	75%	90%	95%	High	AM	RPE (3)
				NCO µg/m³							
S95.24 Repair of furniture and home furnishings	MEGA database	2000-19	23		0.25	0.25	0.25	0.25			NC
S95.24 Repair of furniture and home furnishings	MEGA database	2000-19	14		0.25	0.25	0.25	0.25			NC
S95.24 Repair of furniture and home furnishings	MEGA database	2000-19	15		0.25	0.25	0.25	0.25			NC
S95.24 Repair of furniture and home furnishings	MEGA database	2000-19	15		0.25	0.25	0.25	0.25			NC
S95.24 Repair of furniture and home furnishings	MEGA database	2000-19	15		0.25	0.25	0.25	0.25			NC
S95.24 Repair of furniture and home furnishings	MEGA database	2000-19	33		0.25	0.25	0.25	0.25			NC
S95.24 Repair of furniture and home furnishings	MEGA database	2000-19	24		0.25	0.25	0.25	0.25			NC
S95.24 Repair of furniture and home furnishings	MEGA database	2000-19	23		0.25	0.25	0.25	0.25			NC
S95.24 Repair of furniture and home furnishings	MEGA database	2000-19	14		0.25	0.25	0.25	0.25			NC
S95.24 Repair of furniture and home furnishings	MEGA database	2000-19	14		0.25	0.25	0.25	0.25			NC

Sources: (Austin, 2007), (Bello *et al.*, 2019), (Brzeźnicki and Bonczarowska, 2015), (Cassidy, Molenaar and Hathaway, 2010), (Creely *et al.*, 2006), (Fent *et al.*, 2009), *(Finnish National Institute of Occupational Health, no date),* (Gui *et al.*, 2014), *(Hathaway et al., 2014),* (Henriks-Eckerman *et al.*, 2015), (Jones *et al.*, 2017), (Liljelind *et al.*, 2010), (Littorin *et al.*, 2007), (Middendorf *et al.*, 2017), *(Pronk et al., 2006),* (Reeb-whitaker *et al.*, 2014), (Reeb-whitaker and Schoonover, 2016), (Świerczyńska-Machura *et al.*, 2015), (Tinnerberg and Mattsson, 2008), *(HSE, 2005), CSRs (confidential) and consultation responses (confidential)*
2 Number of records = number of measurements in studies, number of worker contribution scenarios from CSRs
3 Y = Yes; N = No; NC = Not Clear; V = Ventilation

ANNEX 4 EXISTING NATIONAL LIMITS

Table 11-6 OELs (µg/m³, 8-h TWA) in EU Member States and selected non-EU countries for diisocyanates (status: 18.08.2021)

EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4’-MDI	2,4'-MDI	2,2’-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³
Austria[1,2]	35	90	50			54				90		35			
Belgium[1,2]	34	46 (1)	52			55					37	37		0.005	
Bulgaria[1,3]	100														
Croatia[1,4]															20
Cyprus[1]															
Czech Republic[1]															
Denmark[1,2,5]	35	45	50			54				40		35			
Estonia[1,]														0.005	
Finland[1,2,6]															
France[1,2,7]	75	90	100							95		80			
Germany[1,2,8]	35 (1)	46 (1)	50 (1)(2)	50	50 (1)		50 (1)(2)			50		35 (1)			
Greece[1]															
Hungary[1,2,9]	35		50							90		7			
Ireland[1,2,10]	34 (1)	45 (1)	50 (1)									7 (1)			20 (1)
Italy[1,2]	1000														
Latvia[1,2,11]	50											50			
Lithuania[1,12]	30	50	50							40		40		0.005	

EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4’-MDI	2,4'-MDI	2,2’-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³
Luxembourg[1,13]															
Malta[1]															
Netherlands[1,14]															
Poland[1,2,15]	40	40	30	30	30						7	7			
Portugal[1]															
Romania[1,2,16]	50											70 (1)			
Slovakia[1,17]															
Slovenia[1,18]	35	46	50	50	50		50			50	35	35			
Spain[1,2,19]	35	46	52			55				43		36			
Sweden[1,2,20]	20	18	30							17	14	14		0.002	
Non-EU countries															
Australia[1,21]															20
Canada, Ontario[1,22]	34.4	45.46	51.18			53.65						35.62			
Canada, Québec[1,23]	34	45	51			54					36				
China[1,24]	30	50	50									100			
Israel[1]	34	45	51									36			
Japan - JSOH[1,25]	34		5								35 140 (1)				
Norway[1,2, 26]	35	45	50			50				40		35		0.005	
Russia[27]	50		500									50			

EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4’-MDI	2,4'-MDI	2,2’-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³
South Korea[1]	34	45	55									40			
Switzerland[1,2,28]															20
Turkey[29]															
United Kingdom[1,2,30]															20
USA, NIOSH[1,2,31]	35	45	50							40					
USA, OSHA[1,2,32]		525,000	200									140			

Notes:

Belgium (1) Additional indication "D" means that the absorption of the agent through the skin, mucous membranes or eyes is an important part of the total exposure. It can be the result of both direct contact and its presence in the air.

Germany (1) Inhalable fraction (2) Skin

Ireland (1) as NCO

Romania (1) Only valid for 2,4-TDI

Japan (1) Occupational exposure limit ceiling: Reference value to the maximal exposure concentration of the substance during a working day

Sources

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EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4'-MDI	2,4'-MDI	2,2'-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³

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Table 11-7 OELs (µg/m³, 15-min STEL) in EU Member States and selected non-EU countries for diisocyanates (status: 18.08.2021)

EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4’-MDI	2,4'-MDI	2,2’-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³
Austria[1,2]	35	180	100			54 (1)				180		170			
Belgium[1,2]											140 (1)	140 (1)		0.02	
Bulgaria[1,3]															
Croatia[1,4]															
Cyprus[1]															
Czech Republic[1]															
Denmark[1,2,5]	70	90	100			108				80		70			
Estonia[1,]														0.01	
Finland[1,2,6]															35
France[1,2,7]	150	180	200							190		160			
Germany[1,2,8]	35 (1)(2) 70 (1)(3)	46 (1)(2) 92 (1)(3)	50 (4)(5)(2) 100 (4)(5)(3)	50 (1) 100 (2)	50 (1)(2) 100 (1)(3)		50 (4)(5)(2) 100 (4)(5)(3)			50 (1) 100 (2)		35 (1)(2) 140 (1)(3)			
Greece[1]															
Hungary[1,2,9]	35		50							90		35			
Ireland[1,2,10]												3 (1)(2)			70 (1)(2)
Italy[1,2]															
Latvia[1,2,11]															
Lithuania[1,12]	70	90	100							90		70		0.01	

EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4'-MDI	2,4'-MDI	2,2'-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³
Luxembourg[1,13]															
Malta[1]															
Netherlands[1,14]															
Poland[1,2,15]	80		90 (1)		90						21	21			
Portugal[1]															
Romania[1,2,16]			150 (1)									150 (1)(2)			
Slovakia[1,17]															
Slovenia[1,18]															
Spain[1,2,19]												0,14			
Sweden[1,2,20]	30 (1)	46 (1)	50 (1)							44 (1)	40 (1)	40		0,005 (1)	
Non-EU countries															
Australia[1,21]															70
Canada, Ontario[1,22]	137.59	181.83	250.25			214.6						142.46			
Canada, Québec[1,23]											140 (1)				
China[1,24]		100 (1)	100 (1)									200 (1)			
Israel[1]		180 (1)	210 (1)									140 (1)			
Norway[1,2,25]															10
Russia[26]															
South Korea[1]												150			

EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4'-MDI	2,4'-MDI	2,2'-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³
Switzerland[1,2,27]															20 (1)
Turkey[28]															
United Kingdom[1,2,29]															70
USA, NIOSH[1,2,30]	140 (1)	180 (1)	200 (1)			110 (1)				170 (1)					
USA, OSHA[1,2,31]			200									140			

Notes:

Austria (1) Ceiling limit value

Belgium (1) 15 minutes average value

Germany (1) Inhalable aerosol and vapour (2) 15 minutes reference period (3) Ceiling limit value (4) Inhalable fraction and vapour (5) Skin
Ireland (1) as NCO (2) 15 minutes reference period
Poland (1) Celling limit value
Romania (1) Only valid for 2,4-TDI (2) 15 minutes average value
Sweden (1) Short-term limit value, 5 minutes average value
Canada – Québec (1) 15 minutes average value
China (1) 15 minutes average value
Israel (1) 15 minutes average value
Switzerland (1) as NCO
USA – NIOSH (1) Ceiling limit value (10 min)
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EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4'-MDI	2,4'-MDI	2,2'-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³

5: Denmark, (2018) List of limit values (HTP). Available at: https://at.dk/regler/bekendtgoerelser/graensevaerdier-stoffer-materialer-698/bilag-2/, accessed on 04.01.2021

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EU Member State / Country	Specific diisocyanates													Diisocyanates	
	HDI	IPDI	4,4'-MDI	2,4'-MDI	2,2'-MDI	H12-MDI	pMDI	m-TMXDI	m-XDI	1,5-NDI	TDI	2,4-TDI	TODI	ppm	µg/m³

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ANNEX 5 DETAILED PERCENTAGES OF ENTERPRISES AND WORKERS USING DI-ISOCYANATES

NACE Sector	Percentage of enterprises using di-isocyanates	Percentage of workers exposed to di-isocyanates
C13 Textiles		
C13	5%	15%
C13.95	10%	30%
C14 Apparel		
C14	5%	15%
C14.11	10%	30%
C14.19	10%	30%
C15 Leather		
C15.20	95%	50%
C16 Wood		
C16.21	75%	20%
C16.22	3%	20%
C16.29	5%	20%
C20 Chemicals		
C20.14	20%	15%
C20.16	10%	15%
C20.17	20%	15%
C20.30	20%	15%
C20.52	20%	10%
C20.60	25%	15%
C22 Plastics		
C22.21	7.5%	20%
C22.29	7.5%	10%
C22 other	10%	25%
C26 Computers		
C26 Computers	25%	10%
C27 Electrical equipment		

NACE Sector	Percentage of enterprises using di-isocyanates	Percentage of workers exposed to di-isocyanates
C27 Electrical equipment	20%	5%
C27.31	10%	5%
C27.51	75%	5%
C28 Machinery		
C28	5%	5%
C28.25	30%	5%
C28.30	20%	20%
C29 Motor vehicles-		
C29.10	90%	10%
C29.20	90%	20%
C29.31	20%	5%
C29.32	90%	5%
C30 Transport-		
C30.11	90%	10%
C30.12	90%	10%
C30.20	90%	10%
C30.30	90%	10%
C30.40	90%	10%
C30.91	90%	10%
C30.92	90%	10%
C30.99	90%	10%
C31 Furniture-		
C31.01	10%	10%
C31.02	40%	30%
C31.03	5%	5%
C31.09	10%	10%
C33 Machinery repair-		
C33.15	20%	20%
C33.16	35%	20%
C33.17	35%	20%

NACE Sector	Percentage of enterprises using di-isocyanates	Percentage of workers exposed to di-isocyanates
F Construction		
F41.2 Construction	90%	50%
F42 Civil engineering	5%	5%
F42.12	90%	20%
F42.13	90%	20%
F43 Specialised construction	-	-
F43.21	50%	50%
F43.22	50%	10%
F43.29	50%	75%
F43.31	50%	75%
F43.32	80%	80%
F43.33	95%	95%
F43.34	50%	25%
F43.39	50%	50%
F43.91	75%	75%
F43.99	50%	25%
F43.29 Other installation	-	75%
G45 Vehicles repair-		
G45.20	95%	50%
G45.40	95%	50%
S95 Repairs		
S95.23	95%	95%
S95.24	95%	95%

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