European Commission

Third study on collecting most recent information for a certain number of substances with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC

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Final Report for formaldehyde

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Third study on collecting most recent information for a certain number of substances with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

Formaldehyde

8 February 2018

Final Report

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List of acronyms

ABS	Acrylonitrile butadiene styrene
ACGIH	American Conference of Governmental Industrial Hygienists
AGS	Ausschuss für Gefahrstoffe
AM	Arithmetic Mean
ANSES	Agence nationale de sécurité sanitaire de l'alimentation
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (German Federal Institute for Occupational Safety and Health)
BDO	1,4-Butanediol
BLV	Biological Limit Value
BPR	Biocidal Product Regulation
BT	Biocidal Type
CAPEX	Capital Expenditure
CAREX	CARcinogen EXposure
CBA	Cost Benefits Analysis
CDB	Current Disease Burden
C&L	Classification and Labelling
CDU	Ureacrotonaldehyde
CI	Confidence interval
CLH	Harmonised classification and labelling
Corr.	Corrosive
CMD	Carcinogens and Mutagens Directive
CoRAP	Community rolling action plan
DALY	Disability adjusted life years
DECOS	Dutch Expert Committee on Occupational Safety
DNEL	Derived No Effect Level for substances
DNPH	2,4-dinitrophenylhydrazine
DPP	Differential pulse polarography
DRR	Dose response relationship
ECHA	European Chemicals Agency
EPI	Emulsion Polymer Isocyanates
EPRMA	European Phenolic Resin Manufacturers Association
ERR	Exposure Risk Relationship
EU	European Union
FABI	Formaldehyde Biocide Interest Group
FDB	Future Disease Burden
FID	Flame Ionisation Detector
FinJem	Finnish Job-Exposure Matrix
FRF	Fast-release fertiliser
GC	Gas chromatography
GM	Geometric mean
HB	Health or risk based
HPLC	High Performance Liquid Chromatography
HSE	Health and Safety Executive
HMTA	hexamethylenetetraamine
IA	Impact Assessment
IARC	International Agency for Research on Cancer
IBDU	Urea-isobutyraldehyde
Irrit.	Irritation
ISO	The International Organization for Standardization
LC	Liquid chromatography

LEV	Local Exhaust Ventilation
LFC	Lowest Feasible Concentration
LOAEC	Local Observed Adverse Effect Level
LoD	Limit of Detection
LoQ	Limit of Quantification
MAK	German Committee for the determination of occupational exposure limits
MCA	Multi-Criteria Analysis
MDF	Medium Density Fibrewood
MDI	Methylene bis (dephenyl di-isocyanate)
MF	Melamine formaldehyde
mg/m^3	Milligram per cubic metre
MS	Member States
NIOSH	National Institute for Occupational Safety and Health
NOAEL	No Observed Adverse Effect Level
NPC	Nasopharyngeal cancer
NRC	National Research Council
OEL	Occupational Exposure Limit
OELV	Occupational Exposure Limit Value
OPEX	Operational Expenditure
OSB	Oriented Strandboard
OSH	Occupational health and safety
OSHA	Occupational Safety and Health Administration
Penta	Pentaerythritol
PF	Phenol formaldehyde
POM	Polyoxymethylene
PPE	Personal Protection Equipment
ppm	*parts per million*
PROC	The process categories
PV	Present value
PVA	Polyvinyl acetate
RAC	Committee for Risk Assessment
R&D	Research and Development
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
Regex	Registry of Subjects Occupationally Exposed to Carcinogens
Resp.	Respiratory
RIVM	Netherlands National Institute for Public Health and the Environment (Netherlands)
RMM	Risk Management Measures
RMOA	Risk Management Option Analysis
RPE	Respiratory Protection Equipment
SARF	Scottish Aquaculture Research Forum
SCC	Squamous cell carcinoma
SCOEL	Scientific Committee on Occupational Exposure Limits
SCU	Sulfur coated fertilisers
SEA	Socio-economic analysis
SEG	Similar exposed groups
Sens.	Sensitiser
SE/T	Influenced by socio-economic
SME	Small and medium-sized enterprise
STEL	Short Term Exposure Limit
SU	Sector of Use
SUMER	Medical Monitoring Survey of Professional Risks
TLV	Threshold Limit Value
Tox.	Toxicity

TWA	Time weighted average
UF	Urea formaldehyde
UV	Ultraviolet
VOLY	Value of a life year lost
VSL	Value of a statistical life
VSLY	Value of a statistical life year
WHO	World Health Organisation
WTP	Willingness to pay

Executive summary

The Carcinogens and Mutagens Directive (Directive 2004/37/EC), hereinafter the CMD, protects workers from exposure to carcinogens or mutagens at work. The aim of this study is to support the European Commission's Impact Assessment of a potential Occupational Exposure Limit Value (OELV) for formaldehyde.

Formaldehyde is used in a wide variety of sectors with information on its uses gathered from literature review and consultation. Formaldehyde has been identified as being used in the following sectors: agriculture, forestry and fishing; manufacture of food products; manufacture of textiles; manufacture of wood and products of wood and cork, except furniture; manufacture of paper and paper products; manufacture of chemicals and chemical products; manufacture of basic pharmaceutical products and pharmaceutical preparations; manufacture of rubber and plastic products; manufacture of electrical equipment; manufacture of machinery and equipment; manufacture of motor vehicles, trailers and semi-trailers; manufacture of furniture; water supply, sewage, waste management and remediation; construction of buildings; photographic activities; scientific research and development; veterinary activities; higher education; human health activities; and funeral services. The number of occupational exposed workers to formaldehyde has been calculated as 990,000 workers in the EU, with the highest number of exposed workers in health services, dentistry, schools and universities, and in the manufacture of furniture.

The costs and benefits (relative to the baseline) estimated in this report for the different reference OELVs are summarised below.

Table 0-1: Summary of monetised costs and benefits

Reference OELV	PV benefits over 60 years (€2017)	PV costs over 60 years (€2017)
A: 0.6 mg/m^3 (0.5 ppm)	€1–5.1 billion	€0.07 billion
B: 0.37 mg/m^3 (0.3 ppm)	€1–5.1 billion	€1.72 billion
C: 0.15 mg/m^3 (0.12 ppm)	€1–5.1 billion	€10.34 billion
Monetised costs and benefits	Avoided NPC Avoided sensory irritation	RMMs Discontinuation of business Transposition costs
Significant non-monetised costs and benefits	Simplification of rules for companies operating in several Member States	None

RMMs: Risk Management Measures; NPC: Nasopharyngeal cancer
Source: Derived by the study team.

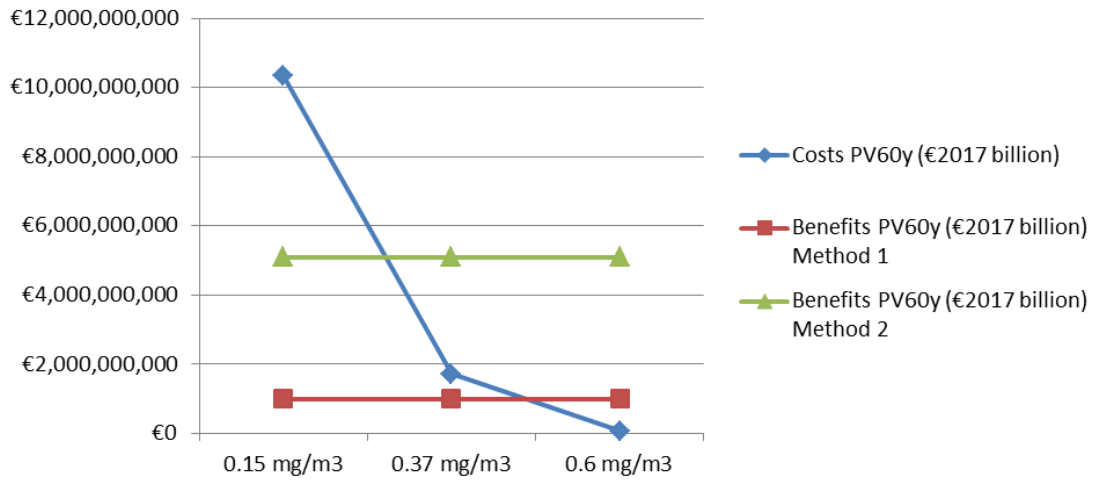


Figure 0-1: Costs vs Benefits: Scenario 3 (measured concentrations) P75
Source: Derived by the study team.

The table below summarises both the monetised impacts as well as those that are assessed qualitatively.

Table 0-2: Multi-criteria analysis (formaldehyde OELV, all costs PV 60 years)

Impact	Stakeholders affected	0.15 mg/m³ (0.12 ppm)	0.37 mg/m³ (0.3 ppm)	0.6 mg/m³ (0.5 ppm)
Economic impacts				
Compliance costs	Companies	€10.34 billion	€1.72 billion	€0.07 billion
Transposition costs	Public sector	€1.35 million	€0.95 million	€0.55 million
Benefits from reduced ill health	Reduction in cases (nasopharyngeal cancer)	*7 (over 60 years)*	*7 (over 60 years)*	*7 (over 60 years)*
	Reduction in cases (sensory irritation)	*19,234 (*on any given day)	*19,234 (*on any given day)	*19,234 (*on any given day)
	Reduction in DALYs	*115,510*	*115,510*	*115,510*
	Employers (avoided costs)	€0.03 million	€0.03 million	€0.03 million
	Public sector (avoided costs)	€181 million	€181 million	€181 million
Single market: competition	No. of company closures	*0*	*0*	*0*
Single-market: consumers	Consumers	***No impacts identified***	***No impacts identified***	***No impacts identified***
Single market: internal market	Companies	***Significant positive impact***	***Significant positive impact***	***Positive impact***

Table 0-2: Multi-criteria analysis (formaldehyde OELV, all costs PV 60 years)				
Impact	**Stakeholders affected**	**0.15 mg/m³ (0.12 ppm)**	**0.37 mg/m³ (0.3 ppm)**	**0.6 mg/m³ (0.5 ppm)**
		Reduction of highest OEL/lowest OEL ratio from 20:1 to 'no difference'	Reduction of highest OEL/lowest OEL ratio from 20:1 to 2:1	Reduction of highest OEL/lowest OEL ratio from 20:1 to 4:1
International competitiveness	Companies	Limited impact	Limited impact	Limited impact
Specific MSs/regions	MSs	All except NL	MSs impacted: BE, BG, HR, CY, CZ, DK, EL, EE, HU, IT, LV, LT, LU, MT, PL, RO, SI, ES, UK	MSs impacted: BE, BG, HR, CY, EL, IT, LU, MT, RO, ES, UK
Social impacts				
Ill health avoided (incl. intangible costs)	Workers & families	€1 billion (Method 1), €5 billion (Method 2)		
Employment	Jobs lost	No impacts identified		
	Social cost	No impacts identified		
Environmental impacts				
Environmental releases	Environment	Limited impacts under all options		
Recycling – loss of business	Recycling companies	Limited impacts under all options		
Notes: All costs/benefits are relative to the baseline (PV over 60 years). Source: Derived by the study team.				

Bearing in mind that the benefits could not be monetised for some health endpoints, it can be concluded that the lowest reference OELV at which the monetised benefits are likely to exceed the costs is around 0.37 mg/m^3. Further justification for this conclusion is provided by the sensitivity analysis in Section 9.3.

It should be noted from input received from industry in the framework of the consultation exercise of the study, that a number of sectors are either working at or to an OELV of 0.37 mg/m^3 (0.3 ppm), using a variety of risk management measures that are discussed in section 3 of the report. These include the use of local exhaust ventilation, respiratory protection equipment and the use of closed systems, amongst others. Sectors in which issues could arise are: aerospace (NACE C30.3), health (Q86), veterinary (M75) and funeral services (S96.0.3). These sectors have the highest exposure concentrations and hence drive the results. For these reasons, alternative scenarios that exclude these four sectors have been defined. Although there are differences, the data that exclude these four sectors support the same conclusion: that there is support for an OELV within the range of 0.3 ppm (0.37 mg/m^3) to 0.5 ppm (0.6 mg/m^3) on cost-benefit grounds. There is also a voluntary industry initiative in place for working to this OELV and there has also been a common letter signed by the European Trade Union Confederation and industry in 2016 asking for formaldehyde to be included in Annex III of the Carcinogen and Mutagen Directive 2004/37/EC and to include the SCOEL proposed health based values which are 0.37 mg/m^3 (0.3 ppm) for the OELV and 0.738 mg/m^3 (0.6 ppm) for a STEL (Short Term Exposure Level). Current OELVs in member states vary from 0.12 ppm (0.15 mg/m^3) to 2.1 ppm (2.5 mg/m^3), with most in the range of 0.3 ppm (0.37 mg/m^3) to 0.5 ppm (0.6 mg/m^3). An OELV of 0.15 mg/m^3 (0.12 ppm) may not be achievable for some sectors.

The key uncertainties that could significantly impact on the conclusion are summarised below.

Table 0-3: Overview of the key limitations/uncertainties and their significance			
Limitation or uncertainty	**Explanation**	**Estimates in this study are U (underestimates) or O (overestimates)**	
		Costs	**Benefits**
Additional health endpoints	A number of health endpoints could not be quantified due to insufficient information.	Not relevant	U
Slope of ERRs/DRRs	There are uncertainities in the evidence available to develop the ERR and DRR.	Not relevant	Could be either U or O
The latency period for cancer	In order to avoid underestimating the benefits from an OELV, an extremely conservative latency period of 10 years has been used for the estimation of future cancer cases.	Not relevant	O
Future trends	Exposed workforce and concentrations are assumed to remain unchanged.	O	O
Discount rate	The estimates in this report have all been modelled using a static discount rate. A declining discount rate would reduce both the costs and the benefits.	U	U
PPE in exposure data	Some of the input data have been corrected for PPE use. However, there is insufficient information to determine which data precisely have been corrected. Should PPE currently be worn, then both the costs and benefits would be overestimated.	O	O
'Positive bias' in reported data	It is possible that there has been some self-selection among companies that provided the data collected through consultation for this study, with worse-performing companies less likely to report their exposure concentrations.	U	U
Assessment period	The reference period of 60 years for this study was selected both to be consistent with previous Commission IAs but also to ensure that the long latency period for cancer does not mean that the benefits are not counted. The cumulative nature of cancer risk and the fact workers can develop sensory irritation every day mean that the impact of extending the assessment period would most likely to be significant.	U	U

1 Introduction

1.1 Background

The Carcinogens and Mutagens Directive (Directive 2004/37/EC), hereafter referred to as the CMD, aims to protect workers against health and safety risks from exposure to carcinogens or mutagens at work. To this end, it sets out the minimum requirements for protecting workers that are exposed to carcinogens and mutagens, including the so-called Binding Occupational Exposure Limit Values (OELVs).[1] For each OELV, Member States are required to establish a corresponding national limit value (OEL), from which they can only deviate to a lower but not to a higher value.

1.2 Objectives

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

- Methodological note;
- OEL/STEL deriving systems;
- Report for cadmium and its inorganic compounds;
- Report for beryllium and its inorganic compounds;
- Report for inorganic arsenic compounds including arsenic acid and its salts;
- Report for formaldehyde;
- Report for 4,4'-Methylene-bis(2-chloroaniline) (MOCA); and
- Report for Chromium (VI) in fumes from welding, plasma cutting and similar processes.

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 a view to support the European Commission in the preparation of an Impact Assessment report to accompany a potential proposal to amend Directive 2004/37/EC.

The general objectives with regard to these 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 Occupational Exposure Limit Value (OELV) and, where appropriate, a Short-Term Exposure Limits (STEL) and a skin notation. The specific objective of this report is to assess the impacts of introducing an OELV and/or a STEL for formaldehyde.

[1] See http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:c11137

1.3 Structure of the report

The report is organised as follows:

- Section 2 sets out the background (SCOEL/RAC, ACSH documents) and the scope of the assessment for formaldehyde;
- Section 3 sets out the baseline;
- Section 4 sets out the benefits of the relevant measures;
- Section 5 sets out the costs of the relevant measures;
- Section 6 summarises the market effects;
- Section 7 describes the environmental impacts;
- Section 8 describes the distribution of any impacts;
- Section 9 provides the conclusions; and
- Section 10 provides the limitations and sensitivity analysis.

The report is complemented with two annexes which summarise the consultation exercise and provide additional information not contained in the main report.

2 Background and Scope of the Assessment

This section comprises the following subsections:

- Section 2.1: Background
- Section 2.2: Summary of epidemiological and experimental data
- Section 2.3: Deriving an Exposure-Risk Relationship (carcinogenic effects) and a Dose-Response Relationship (non-carcinogenic effects)
- Section 2.4: Study scope
- Section 2.5: Reference OELVs

2.1 Background

2.1.1 SCOEL assessment

SCOEL (Scientific Committee on Occupational Exposure Limits) has derived a recommended Occupational Exposure Limit Value (OELV) of 0.3 ppm (0.37 mg/m^3) and a Short Term Exposure Limit (STEL) of 0.6 ppm (0.72 mg/m^3) for formaldehyde (SCOEL, 2016). SCOEL (SCOEL, 2016) has also considered that a skin notation for formaldehyde is not required due its exclusively local effects. Respiratory sensitisation from formaldehyde exposure has only been reported in single cases, so its designation as a respiratory sensitiser has been concluded by SCOEL not to be warranted.

For the protection of workers, SCOEL has considered two key effects relevant for worker protection and for deriving the recommended values for formaldehyde. These are:

- The potential for formaldehyde to produce respiratory irritation and chemosensory effects in humans and animals; and
- The local carcinogenicity[2] in studies where experimental animals have been subject to inhalation exposure.

In addition, skin-sensitising properties are relevant in the case of dermal exposure. Reproductive effects are not regarded as relevant for occupational exposure (inhalation and dermal contact).

SCOEL concludes that there is consistent evidence for the genotoxicity of formaldehyde in *in vitro* systems, laboratory animals and exposed humans. DNA-protein crosslinks have been reproducibly detected in the nasal mucosa of rats and monkeys exposed to formaldehyde. At higher concentrations of formaldehyde, genotoxicity [3] is greatly amplified by cell proliferation[4], resulting in a marked increase of malignant lesions in the nasal passages.

Tumour induction by formaldehyde is driven by sustained cytotoxicity[5] and (concomitant) cell proliferation with (secondary) genetic changes. Therefore, a threshold for formaldehyde can be

[2] Process of induction of malignant neoplasms, and thus cancer, by chemical, physical or biological agents. Source: IUPAC Glossary of Terms Used in Toxicology, 2nd Edition (2007), available at https://sis.nlm.nih.gov/enviro/iupacglossary/frontmatter.html

[3] Capable of causing a change to the structure of the genome. Source: IUPAC Glossary of Terms Used in Toxicology, 2nd Edition (2007), available at https://sis.nlm.nih.gov/enviro/iupacglossary/frontmatter.html

[4] Rapid increase in cell number. Source: IUPAC Glossary of Terms Used in Toxicology, 2nd Edition (2007), available at https://sis.nlm.nih.gov/enviro/iupacglossary/frontmatter.html

[5] Causing damage to cell structure or function. Source: IUPAC Glossary of Terms Used in Toxicology, 2nd Edition (2007), available at https://sis.nlm.nih.gov/enviro/iupacglossary/frontmatter.html

established for concentrations that do not lead to sustained cell proliferation and histopathological alterations. Since sensory irritation occurs at lower concentrations than cytotoxic effects, it is generally considered that the avoidance of sensory irritation will imply a safety margin to also avoid cytotoxic irritation-induced local cell proliferation as a first step in tumour-induction.

The recommended values have been derived by SCOEL from two studies at the lowest concentration investigated of 0.7 ppm (0.84 mg/m^3) in the literature. In these studies, between 0.3 ppm (0.37 mg/m^3) and peaks of 0.6 ppm (0.72 mg/m^3), there was a consistent NOAEL (No Observed Adverse Effect Level) so this has been taken as the basis for the recommended OELV and STEL value.

2.1.2 RAC assessment

RAC (Committee for Risk Assessment) have performed an assessment of formaldehyde for CLP classification purposes (Committee for Risk Assessment, 2012).

RAC concluded that formaldehyde should be classified as follows:

- Carcinogenic Category 1B (Carc. 1B);
- Mutagenic 2 Category 2 (Muta. 2);
- Acute Toxicity Category 3 (Acute Tox. 3);
- Skin Corrosion Category 1B (Skin Corr. 1B); and
- Skin Sensitiser Category 1 (Skin Sens. 1).

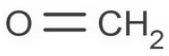
RAC also concluded in their assessment that the key effects by long-term inhalation in rodents are nasal squamous cell carcinoma (SCC) and benign tumours. Epidemiological studies indicated the key effect from workplace inhalation exposure to be nasopharyngeal cancer, for which RAC concluded that there is limited evidence in humans. No evidence of induction of tumours at distant sites by inhalation was found by RAC. Assessments by other institutions, such as the NRC (National Research Council), have concluded there is clear evidence for nasopharyngeal and sinonasal cancer and for myeloic anemia (NRC, 2014).

2.1.3 IARC assessment

IARC (International Agency for Research on Cancer) has concluded that there is sufficient evidence of the carcinogenicity of formaldehyde in humans. Formaldehyde causes leukaemia and cancer of the nasopharynx and there is sufficient evidence in experimental animals for the carcinogenicity of formaldehyde (IARC, 2012). A positive association between formaldehyde exposure and sinonasal cancer has also been observed. Formaldehyde has been classified as a group 1 carcinogen (carcinogenic to humans) by IARC.

2.2 Summary of epidemiological and experimental data

2.2.1 Identity and classification

Table 2-1: Substance Information	
Substance	Formaldehyde
Chemical formula	CH_2O
Structure	
Synonyms	Include methanal, formol and formic aldehyde
EC Number	200-01-8
CAS Number	50-00-0
Classification (ECHA, 2017)	Acute Tox. 3* (H301) ; Acute Tox. 3* (H311) ; Skin Corr. 1B (H314) ; Skin sens. 1 (H317); Acute tox. 3* (H331); Muta. 2 (H341); Carc. 1B (H350) (harmonised)
Unit classification	1 ppm = 1,2 mg/m³; 1 mg/m³ = 0,83 ppm
Sources: ChemID (2017): Formaldehyde. Available at : https://chem.nlm.nih.gov/chemidplus/rn/50-00-0 ECHA (2017): Formaldehyde Substance Information. Available at: https://echa.europa.eu/substance-information/-/substanceinfo/100.000.002	

2.2.2 General toxicity profile, critical endpoints and mode of action

Formaldehyde is a naturally occurring chemical which is also formed endogenously in mammals, including humans. In addition, common non-occupational exposures include combustion processes, which includes tobacco smoking, and emissions from building materials (IARC, 2012).

Formaldehyde can either be inhaled, ingested or absorbed through the skin. However, inhalation is considered to be the main route of exposure to exogenous (resulting from causes or derived from materials external to an organism) formaldehyde. Endogenous[6] formaldehyde is a normal intermediate in the one-carbon pool of the body and is present in measurable concentrations in all metabolically active cells and tissues (IARC, 2012). Formaldehyde dehydrogenase is the major detoxification pathway for formaldehyde, with no large interindividual variability observed (SCOEL, 2016).

Due to its high water solubility and high reactivity, exogenous formaldehyde shows intrinsic hazardous properties predominantly with respect to local effects at the exposure site, whereas directly induced systemic effects of inhalation at concentrations relevant for workplace exposure are considered unlikely.

The following key effects are considered as being relevant for the protection of workers and in particular the OEL derivation (SCOEL, 2016):

- Local carcinogenicity, as evident from inhalation studies with animals; and
- The respiratory irritation and chemosensory effects potential in humans and animals.

[6] Produced within or caused by factors within an organism. Source: IUPAC Glossary of Terms Used in Toxicology, 2nd Edition (2007), available at https://sis.nlm.nih.gov/enviro/iupacglossary/frontmatter.html

In addition, skin-sensitising properties are relevant in the case of dermal exposure. Reproductive effects are not regarded as relevant for occupational exposure (inhalation, dermal contact) (SCOEL, 2016).

There is consistent evidence for the genotoxicity of formaldehyde in in vitro systems, laboratory animals and exposed humans. DNA-protein crosslinks have been reproducibly detected in the nasal mucosa of rats and monkeys which have been exposed to formaldehyde. At higher concentrations of formaldehyde, genotoxicity is greatly amplified by cell proliferation, resulting in a marked increase of malignant lesions in the nasal passages (SCOEL, 2016).

In an EU (European Union) evaluation of cancer hazard, RAC concluded that the key effects by long-term inhalation in rodents are nasal squamous cell carcinoma (SCC) and benign tumours. Epidemiological studies indicated that the key effect for workplace inhalation exposure is nasopharyngeal cancer, for which RAC concluded that there is limited evidence in humans. According to RAC, no evidence of induction of tumours at distant sites was obtained by inhalation (RAC, 2012). Other institutions, like NRC (2014) concluded clear evidence for nasopharyngeal and sinonasal cancer and for myeloic anemia. IARC concluded that there is "sufficient evidence" that formaldehyde causes cancer of the nasopharynx and leukaemia in humans and that there is sufficient evidence in experimental animals for the carcinogenicity of formaldehyde.[7] Formaldehyde is assigned as a Carc. Cat. 1B in the EU, with animal data from nasopharyngeal cancer to be used for excess cancer risk quantification.

Tumour induction by formaldehyde is driven by sustained cytotoxicity and (concomitant) cell proliferation with (secondary) genetic changes. Therefore, a threshold for formaldehyde can be established for concentrations which do not lead to sustained cell proliferation and histopathological alterations (SCOEL, 2016). Since sensory irritation occurs at lower concentrations than cytotoxic effects, it is generally considered that the avoidance of sensory irritation will imply a safety margin to also avoid cytotoxic irritation-induced local cell proliferation as a first step in tumour-induction (SCOEL, 2016).

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

Several animal inhalation studies with elevated cancer incidence are available for example studies by Feron et al., 1988; Kamata et al., 1997; Monticello et al., 1996; and Woutersen et al., 1989). These studies were analysed in combination and provided the following dose response information which is presented in the following table (also presented by Nielsen et al.)

[7] However, "The Working Group was not in full agreement on the evaluation of formaldehyde causing leukaemia in humans, with a small majority viewing the evidence as sufficient of carcinogenicity and the minority viewing the evidence as limited" (IARC, 2012).

Table 2-2: Incidence of nasal squamous cell carcinoma (SCC) in nasal epithelia of rats after chronic formaldehyde inhalation (from AGS, 2015; Nielsen et al., 2013)	
Concentration	**Incidence of SCC (%)**
0 ppm (0 mg/m^3)	0/453(0)
0.3 ppm (0.37 mg/m^3)	0/32 (0)
0.7 ppm (0.84 mg/m^3)	0/90 (0)
2 ppm (2.5 mg/m^3)	0/364 (0)
6 ppm (7.2 mg/m^3)	3/325 (0.9)
10 ppm (12 mg/m^3)	20/99 (22)
14 ppm (16.8 mg/m^3)	103/232 (44)
15 ppm (18 mg/m^3)	120/278 (43)
Sources: AGS, Ausschuss für Gefahrstoffe (2015): Begründung zu Formaldehyd in TRGS 900. Fassung 23.2.2015. Ausgabe: Februar 2015. Stand: November 2014. Available at: https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/900/900-formaldehyd.pdf?__blob=publicationFile&v=2 Nielsen, G.D et al. (2013): Recent trend in risk assessment of formaldehyde exposures from indoor air *Archives of Toxicology*, 87, pp 73-98	

SCOEL (SCOEL, 2016) in their assessment, described a new recently-provided "bottom-up approach" for the assessment of low dose human cancer risk from exposure to chemicals that produce the same specific DNA adducts from endogenous and exogenous sources (SCOEL, 2016; Starr and Swenberg, 2013; Starr and Swenberg, 2016). This approach takes into account the background (endogenous) exposure consistent with the "additivity to background concept" and provides central and upper bound risk estimates that are linear at all doses. The endogenous and exogenous dG adducts of formaldehyde measured in Cynomolgus monkeys (Moeller et al., 2011) at 2 ppm (2.5 mg/m^3) after two six hour exposures were taken as a surrogate for humans for continuous life-time exposure. The build-up of adducts was estimated by kinetic modelling of the Swenberg *et al* (2013) rat data yielding an elimination half-life of 63 hours. Thereby, the authors arrived at an upper bound life time risk of $3.8x10^{-4}$ for continuous exposure at 1 ppm (1.2 mg/m^3) (a newer calculation based on more robust estimates of adduct formation gave a slightly smaller upper-bound risk of $2,7 \times 10^{-4}$). From these data, SCOEL calculated an upper-bound risk for workplace exposure (5 d/week, 8 h/d, 45 years) of 1.6×10^{-5} at 0.3 ppm (0.37 mg/m^3). The authors noted several reasons why the model should be considered conservative, for example all the background risks for NPC (Nasopharyngeal cancer) are only ascribed to dG adducts (and not also to the endogenous dA adducts not formed by exogenous FA) or linearity is assumed for all exposure levels without taking into consideration cytotoxicity or cell proliferation enhancing mutations. Using SCOEL's parameters for the exposure at the workplace and the data of Starr and Swenberg (2013), "bottom-up-approach" risks at 1 and 2 ppm (1.2 and 2.4 mg/m^3), the work life exposure can be calculated as 5.4×10^{-5} at 1 ppm (1.2 mg/m^3) and 1.1×10^{-4} at 2 ppm (2.4 mg/m^3), respectively.

The derivation of AGS (2015) is also based on mechanistic data on the mode of action of cytotoxic and genotoxic effects, considering concentration response curves for DNA-adduct levels, DNA-Protein-crosslinks (DPC) and induction of cell proliferation in nasal tissue, and also taking account sensory irritation in humans (Mueller *et al*, 2013).

In addition, many epidemiological studies are documented; however these are not used for the basis of the risk quantification. An overview of the respective studies is provided elsewhere, for example by IARC (2012), RAC (2012), and SCOEL (2016).

For latency, long term exposure (years) to formaldehyde may be needed for a carcinogenic outcome. SCOEL reports a latency of 20 years in one epidemiological study from Finland (SCOEL, 2016). However, no minimum exposure duration is given. For sinonasal cancer, in general, even long latency times are reported (43 years). The Hutchings & Rushton (2012) estimate (solid tumors peak latency: 36 years) appears to be at the upper end of this range. Some epidemiological studies on formaldehyde applied lower latency time assumptions in their risk estimates (e.g. 10 years). Animal data (rats) do not contradict these figures, but these are difficult to interpret. Formaldehyde is classified as a Carc. Cat. 1B (i.e. classification is not based on human data) and for other tumour sites, but sinonasal cancer (with different associated latency time) may be critical.

2.2.4 Non-cancer endpoints – toxicological and epidemiological key studies (from existing assessments)

Most OELs which are derived for formaldehyde are derived to protect from sensory irritation effects as a non-cancer toxicity endpoint. However, many of the assessments include considerations that the OEL should also protect from precursor effects, possibly leading to carcinogenicity at higher concentrations (see section 2.2.3). The most relevant studies on sensory irritation and/or potential cancer precursor effects, such as cell proliferation, used in those assessments were:

- Paustenbach et al. (1997), Bender (2002) and Arts et al. (2006) are major reviews covering an exceptionally broad database including human studies on sensory irritation (with altogether more than 400 volunteers), mostly in controlled human studies which take into account mechanistic data from animal experiments for cytotoxic and genotoxic effects of formaldehyde in target tissues (nasal tissues). The authors conclude that sensory irritation would be seldom observed at 0.5 ppm (0.62 mg/m^3) and that a limit of 0.3 ppm (0.37 mg/m^3) would prevent sensory irritation in nearly all occupational exposed individuals. These studies have been key assessments considered by SCOEL for deriving the formaldehyde OEL (SCOEL, 2016);
- Lang *et al* (2008): In this study, 21 volunteers (11 male and 10 female) were exposed to ten exposure conditions on ten consecutive working days, each for 4 hours, to formaldehyde concentrations of 0, 0.15, 0.3 and 0.5 ppm (0, 0.12, 0.37 and 0.6 mg/m^3) respectively. The authors concluded that eye irritation was the most sensitive parameter recorded, and that the no observed adverse effect level for objective eye irritation was 0.5 ppm (0.62 mg/m^3). This study was used for additional evidence from a recent study focusing on objective signs of irritation in the SCOEL assessment on formaldehyde (SCOEL, 2016);
- Mueller et al. (2013): This controlled study addressed the chemosensory effects of formaldehyde in so-called “hyposensitive” and “hypersensitive” persons. Exposure levels of 0.7 ppm (0.84 mg/m^3) for 4 h and 0.4 ppm (0.48 mg/m^3) for 4 h with peaks of 0.8 ppm (0.96 mg/m^3) for 15 minutes did not cause adverse effects related to irritation (NOAEC). No differences between hypo- and hypersensitive subjects were seen (Mueller et al. 2011). This study was used for supportive evidence in the SCOEL assessment on formaldehyde (SCOEL, 2016);
- Brüning et al. (2014) discussed the data on sensory irritation of formaldehyde and showed that respective effects occur below the tissue-irritating concentration. This study was used for supportive evidence in the SCOEL assessment on formaldehyde (SCOEL, 2016);
- Gelbke et al. (2014) showed data from animal experiments indicating that the non-carcinogenic effects with histological manifestation converge at 1 ppm (1.2 mg/m^3). This study was used as one of the key studies in the AGS-assessment on formaldehyde (AGS, 2014) and is also emphasized by SCOEL (2016);

- Casanova et al. (1989 and 1991) demonstrated a histopathological NOAEC for nasal effects of formaldehyde in rats and monkeys of 1 ppm (1.2 mg/m^3) and for regenerative cell proliferation in rats of 2 ppm (2.4 mg/m^3). This study was used for supportive evidence in the SCOEL assessment on formaldehyde; and
- In a study by Andersen and Molhave (1983), with human data, 19% of the exposed subjects reported eye irritation at an exposure concentration of 0.24 ppm (0.29 mg/m^3). It was estimated that 0.25 ppm (0.3 mg/m³) is a LOAEC at which sensory irritation may occur in a low but significant percentage of exposed workers. This study was used as a critical study in a DECOS/NEG-assessment on formaldehyde (DECOS, 2003). However, this study was regarded as not being sufficiently reliable by SCOEL (2016).

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

No biomonitoring values have been derived because of the exclusively local toxicity at the upper respiratory tract and the high endogenous formation. Genotoxic effects in mucous membrane cells are only expected at extreme exposure (AGS, 2015). Similarly, a biological limit value or biological guidance value was not proposed by SCOEL (SCOEL, 2016) or others.

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

The starting point to derive an exposure risk relationship (ERR, cancer effects) and a dose response relationship[8] (DRR, non-cancer effects) are the thresholds derived by SCOEL (2016). SCOEL concludes a threshold on 0.3 ppm (0.369 mg/m³) for non-cancer effects (sensory irritation) and assumes that this concentration also represents the threshold for carcinogenicity ("Carcinogen group C; genotoxic carcinogen with a mode-of- action based threshold).

A short term exposure limit (STEL) of twice the OEL (i.e., 0.6 ppm, 0.738 mg/m³) is assigned by SCOEL, which will be adopted for this impact assessment. SCOEL also assigned a notation for (dermal) sensitisation to formaldehyde.

2.3.1 Discussion

From the analysis of recently established OELs for formaldehyde, there is no large discrepancy in potency estimates for cancer and non-cancer effects and the assumed mode of action. Some limited uncertainty on the cancer risk potency is introduced by new epidemiological studies (see section 3.13 for a further discussion).

2.3.2 Carcinogenic effects

Approach

No excess risk quantification is available from ECHA/RAC.

[8] Association between dose and the incidence of a defined biological effect in an exposed population usually expressed as percentage. Source: IUPAC Glossary of Terms Used in Toxicology, 2nd Edition (2007), available at https://sis.nlm.nih.gov/enviro/iupacglossary/frontmatter.html

SCOEL (2016) described a new recently-provided "bottom-up approach" for the assessment of low dose human cancer risk developed by Starr and Swenberg (Starr and Swenberg, 2013). This approach takes into account that the background (endogenous) exposure is consistent with the "additivity to background concept" and provides the upper bound risk estimates. Using the risk estimate for lifetime exposure presented in the publication of Starr and Swenberg (2013), SCOEL calculated an upper-bound risk for nasopharyngeal cancer at workplace exposure (5 d/week, 8 h/d, 45 years) of 1.6 x 10^{-5} at 0.3 ppm (0.37 mg/m³, corresponding to 5.4 x 10^{-5}/ppm). According to Starr and Swenberg, this "bottom-up approach" is considered valid for airborne concentrations of formaldehyde up to and including 2 ppm (2.5 mg/m³).

At concentrations exceeding 2 ppm up to 6 ppm (2.5 mg/m³ - 7.25 mg/m³), a linear concentration-risk relationship of 1,67 x 10^{-3}/ppm will be used, based on the data presented by AGS (2015). The AGS approach is based on a 1 % tumour incidence at 6 ppm formaldehyde in rats, taking additionally into account the sublinear exposure-tumour-relationship (AGS, 2015). Hence, the risk estimates at concentrations exceeding 2 ppm (2.5 mg/m³) formaldehyde is based on the incidence of nasal tumours in rats. From a number of data from mechanistic studies and from modelling of these data, it can be concluded that rats are more sensitive to the toxic and carcinogenic effects of formaldehyde than monkeys and, most likely, humans. However, this data has not been integrated in risk estimations at formaldehyde concentrations above 2 ppm (2.5 mg/m³), and the available quantitative risk estimations for concentrations above 2 ppm (2.5 mg/m³) is based on rat data (AGS, 2015).

Concentrations exceeding a TWA (Time Weighted Average) of 6 ppm (7.2 mg/m³) formaldehyde are unlikely to occur at workplaces. No quantification of tumour risk at concentrations exceeding 6 ppm has been reported by AGS (2015) and others. However, a risk estimate may be conducted by analogy to the approach of AGS (2015), using the pooled incidence of tumours (squamous cell carcinoma) in rat nasal tissue of 22/103 or about 21 % at 9.93 ppm (11.92 mg/m³) (AGS, 2015; Subramaniam et al., 2007). From this data, linear extrapolation between 6 and 10 ppm (7.25-12 mg/m³) leads to an increase of 5.3 x 10^{-2}/ppm with in this concentration range.

In summary, the following ERR is proposed for the estimation of risk for nasopharyngeal cancers in humans at workplace exposure:

Table 2-3: Proposed ERR for the estimation of risk for nasopharyngeal cancers in humans at workplace exposure

TWA long term exposure	Excess cancer risk nasopharyngeal cancer in exposed workers
0.3 ppm (0.37 mg/m³)	No elevated excess risk; $\mathbf{y_{(0.3\ ppm)}=0}$
> 0.3 ppm – 2 ppm; (> 0.37 mg/m³ - 2.4 mg/m³)	5.4 x 10^{-5}/ppm : **$y= 0.000054x_{ppm} \times 0.0000162$** 6.5 x 10^{-5}/mg/m³ **$y= 0.000065x_{mg/m3}-0.0000195$**
> 0.3 ppm – 2ppm (> 0.37 mg/m³ - 2.4 mg/m³)	1.67 x 10^{-3}/ppm; **$y= 0.00167x_{ppm} – 0.0032$** 2 x 10^{-3}/ mg/m³ **$y= 0.002x_{mg/m3} – 0.00389$**
> 2 ppm – 6 ppm; > 2.4 mg/m³ - 7.2 mg/m³)	5.3 x 10^{-2}/ppm; **$y= 0.053x_{ppm} – 0.31$** 6,4 x 10^{-2}/mg/m³ **$y= 0.064x_{mg/m3} – 0.376$**
> 6 ppm – 10 ppm; > 7.2 mg/m³ - 12 mg/m³	5.4 x 10^{-5}/ppm; **$y= 0.000054x_{ppm} – 0.0000162$** 6,5 x 10^{-5}/ mg/m³ **$y= 0.000065x_{mg/m3} – 0.0000195$**

Source: Derived by the study team.

A graphical presentation of this ERR is shown in the following figure in combination with the DRR for non-cancer effects.

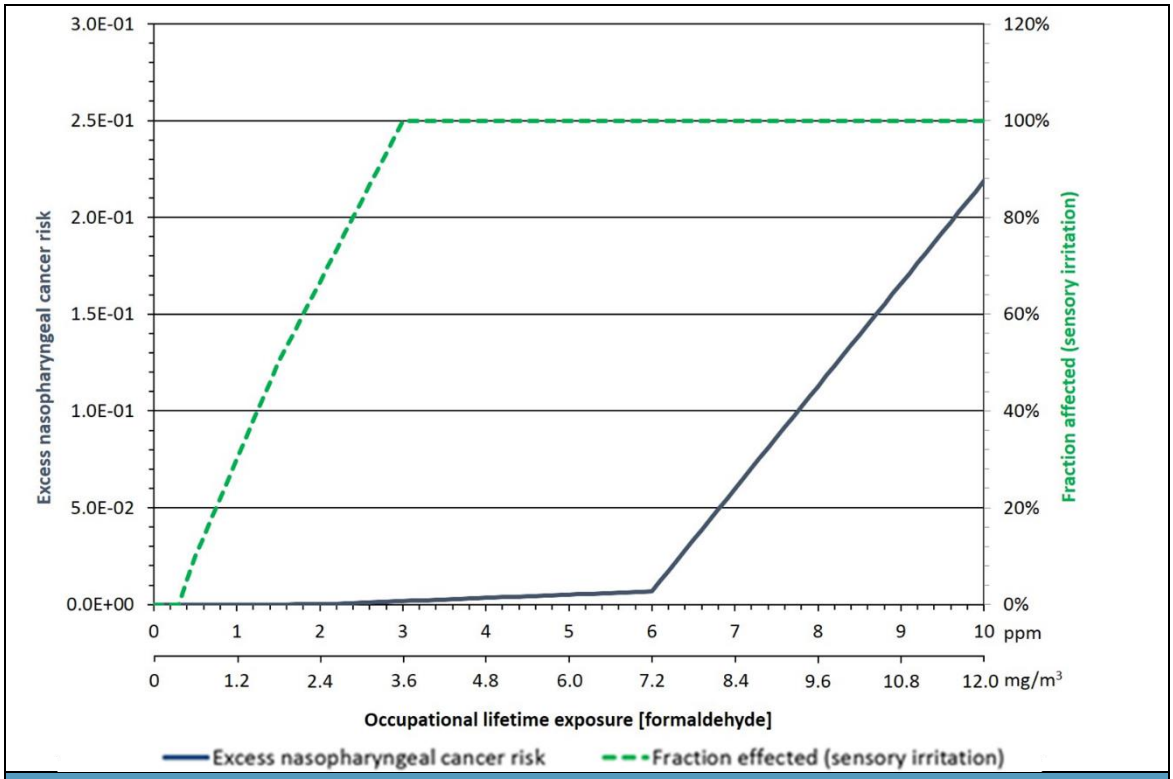


Figure 2-1: Exposure Risk Relationship (ERR) for nasopharyngeal cancer risk (left y-axis) and Dose Response Relationship (DRR) for non-cancer effects (right y-axis) from occupational exposure to formaldehyde
Source: Derived by the study team

Discussion

In order to apply an existing excess risk slope data for exposures slightly above 0.3 ppm (0.37 mg/m^3) and assuming a "practical threshold" at 0.3 ppm (0.37 mg/m^3), the derived ERR is not a continuous function but shows a saltus with no elevated risk at 0.3 ppm (0.37 mg/m^3) and a very low increased risk minimally above 0.3 ppm (e.g., 1.67 x 10^{-5} at 0.31 ppm, 0.37 mg/m^3). This mathematical definition has no practical implications and is consistent with a "practical threshold", which essentially would be identical to a not clearly quantified concentration, but is very low risk at exposures close to (above) 0.3 ppm (0.37 mg/m^3).

The cancer risk up to 2 ppm (2.5 mg/m^3) is calculated from human data as suggested by SCOEL and the excess risk quantification is directly adapted from SCOEL. However, we are aware from the classification of formaldehyde as a Carc. Cat. 1B carcinogen that there is some relevant uncertainty on the use of human data for a substance where the evidence used for classification is animal data.

There are some more recent epidemiological updated data from Starr and Swenberg (2016) with a slightly different associated excess risk. This update has not yet been discussed by SCOEL in their analysis and is therefore not considered in this assessment. However, differences in resulting potency would be very small and contribute only marginally to overall uncertainty.

The ERR as provided from epidemiological data is only regarded to be valid up to 6 ppm (7.2 mg/m³). Above that level, no qualified ERR could be established from the epidemiological data; therefore, the slope for carcinogenicity as provided from animal experiments in higher concentrations has been used, which contributes to the uncertainties at such high exposures.

2.3.3 Noncarcinogenic effects

Approach

To our knowledge, no DRR has been derived by the regulatory committees for an adequate range of exposures.

The OEL quantification by SCOEL (2016) has been selected as a starting point. Thus, 0.3 ppm (0.369 mg/m³) represents a NOAEC for sensory irritation in humans. SCOEL also further reports that a concentration-effect curve was constructed based on 17 volunteer studies on eye irritation (Paustenbach et al., 1997) showing that at 0.5 - 1 ppm (0.6 - 1.2 mg/m³), exposure for up to 6 hours may produce eye irritation in 5-25% of the exposed persons. However, responses below 20% were often not considered to be attributable to formaldehyde alone. Significant increases in eye irritation are reported at concentrations of ≥ 1 ppm (≥ 1.2 mg/m³).

Table 2-4: Incidences of sensory irritation in exposed workers

TWA long term exposure concentration	Incidence of "sensory irritation" in exposed workers
x≤ 0.3 ppm; ≤0.367mg/m³	0 % ; **y= 0**
x=[0.3-0.5 ppm]; [0.37-0.6 mg/m³] e.g., x =0.5 ppm	**$y= 0.5x_{ppm}-0.15$; $y= 0.417x_{mg/m3} - 0.15$** $y_{x=0.5ppm}$ = 0.1 (=10%)
x=[0.5-1.5 ppm]; [0.6-1.8 mg/m³] e.g., x =1 ppm	**$y= 0.4x_{ppm}-0.1$; $y= 0.33x_{mg/m3} - 0.1$** e.g., $y_{x=1ppm}$= 0.3 (= 30%)
x=[1.5 – 3 ppm]; [1.8-3.6 mg/m³] e.g., x =2 ppm	**$y= 0.333x_{ppm}$; $y= 0.278x_{mg/m3}$** e.g., $y_{x=2ppm}$= 0.67 (= 67%)
X≥ 3 ppm; ≥3.6 mg/m³	100 %; **y=1**
Source: Derived by the study team.	

Taking into account the data reported by SCOEL, including the evaluation of Paustenbach et al. (1997), 0.5 ppm (0.6 mg/m³) will be considered as the LOAEC for further evaluations. The incidence of 5-25% reported by Paustenbach et al. (1997) is within the range of an assumed 10% incidence at the LOAEC.

There are is a few qualified data available to estimate a slope for dose response of sensory irritation (affected fraction) above 0.5 ppm, 0.6 mg/m³ (LOAEC). However, more severe tissue effects will also occur at concentrations at or above 1 ppm. These cannot be explicitly linked to a defined fraction of exposed persons with sensory irritation. We have therefore selected a default factor of 3 (increase in concentration from 0.5 ppm to 1.5 ppm (0.6 - 1.8 mg/m³)), to be associated with an increase from a rather low fraction (10% at the LOAEC) to an elevated fraction (50% at 1.5 ppm; 1.8 mg/m³). Similarly, the increase of the DRR at exposure levels above 1.5 ppm (1.8 mg/m³) is estimated by a default procedure (factor 2 from 50% to 100% incidence) because of insufficient substance specific data for sensory irritation at high exposure concentrations. Thus, the incidences in the below table are considered for sensory irritation in humans by occupational formaldehyde exposure. A graphical presentation of this DRR is shown in Figure 2-1 in combination with the ERR for cancer effects.

Discussion

The critical non-cancer endpoint at exposure levels above 0.3 ppm (0.37 mg/m³) is sensory irritation.

This endpoint was therefore considered when the DRR was derived. However, at higher exposure concentrations, the calculation of a DRR entails more uncertainties:

- Sensory irritation is the "first sign" of a local effect (associated with, e.g., eye irritation, rhinitis, upper respiratory tract irritation, headaches etc.), which will then increase to more severe tissue effects (e.g., local inflammation) at higher concentrations, where observations would not be linked to the initial irritating effect. Because of this, no adequate DRR is available at high concentrations for sensory irritation;
- Above 0.3 ppm (0.37 mg/m^3), other relevant toxic effects beyond sensory irritation (including an increasing probability of skin sensitisation) will occur, each with a different slope. Gelbke et al. (2014) found that for histopathological lesions, a NOAEC of 1 ppm (1.2 mg/m^3) may be defined. Thus, other histopathological effects have to be considered above 1 ppm (1.2 mg/m^3). RAC concluded that at 2 ppm (2.4 mg/m^3), formaldehyde represent a LOAEC for polypoid adenomas, histopathological lesions and cell proliferation (RAC, 2012). Therefore, it would not be feasible to provide an adequate overall DRR linked to the critical toxicological endpoints, which are changing over the different exposure levels; and

Therefore, in order to provide a pragmatic approach and because of the lack of appropriate data, default assumptions were applied as reported above to approximate an overall slope for "sensory irritation or other respiratory effects" with no possibility for a more exact discrimination.

Short term limit value (STEL)

The STEL of 0.6 ppm (0.738 mg/m^3), that is derived by SCOEL (2016) is based on observations in chamber studies: Exposures with 4 superimposed peaks are the most relevant for the derivation of an OEL with STEL were 0.3 ppm (037mg/m^3), plus peaks of 0.6 ppm (0.738 mg/m^3) and 0.5 ppm (0.6 mg/m^3), plus peaks of 1 ppm (Lang et al., 2008), and in a second study (Mueller et al., 2013) 0.3 ppm (0.37 mg/m^3) plus peaks of 0.6 ppm (0.738 mg/m^3) and 0.4 ppm (0.48 mg/m^3) plus peaks of 0.8 ppm (0.96 mg/m^3). Objective signs of irritation were only observed at 0.5 ppm plus peaks of 1 ppm. As 0.3 ppm (0.37 mg/m^3), plus peaks of 0.6 ppm (0.738 mg/m^3) was a consistent NOAEC in both of these investigations this exposure regime is taken forward for derivation of the OEL, TWA with STEL.

From this starting point for the STEL, there are insufficient criteria to develop a dose response relationship with effects at other selected STELs.

A STEL of 0.6 ppm (0.738 mg/m³) is confirmed by other assessments, for example AGS (2015).

Biomonitoring values

No biomonitoring values have been derived because of the exclusively local toxicity at the upper respiratory tract.

2.4 Study scope

The scope of this assessment concerns the impacts of an OELV and STEL for formaldehyde. For both, five options for formaldehyde are considered:

- The lowest technically feasible concentration;
- The lowest economically viable concentration;
- The SCOEL recommended OELV of 0.3ppm (0.369 mg/m^3) and the recommended STEL of 0.6 ppm (0.73 mg/m^3);

- The lowest current OELV in EU member states which is 0.15 mg/m^3 (0.12 ppm) and
- The mode of the national OELs in EU member states which is 0.6 mg/m^3 (0.49 ppm).

2.5 Reference OELVs/STELs

The reference points under consideration are:

- The SCOEL recommended OELV of 0.3 ppm (0.37 mg/m^3) and a recommended STEL of 0.6 ppm (0.73 mg/m^3);
- The lowest current OELV in EU member states is 0.12 ppm (0.15 mg/m^3) and the lowest STEL is 0.3 ppm (0.37 mg/m^3); and
- The mode of the national OEL in EU member states is 0.5 ppm (0.6 mg/m^3) and the mode of the STELs is 1 ppm (1.2 mg/m^3).

3 The Baseline Scenario

3.1 Introduction

This section comprises the following subsections:

- Section 3.2: Existing national limits
- Section 3.3: Relevant sectors, uses, and operations
- Section 3.4: Exposed workforce
- Section 3.5: Exposure concentrations
- Section 3.6: Current Risk Management Measures (RMMs)
- Section 3.7: Voluntary industry initiatives
- Section 3.8: Best practice
- Section 3.9: Standard monitoring methods/tools
- Section 3.10: Relevance of REACH authorisations or restrictions
- Section 3.11: Market analysis
- Section 3.12: Alternatives
- Section 3.13: Epidemiological and experimental data
- Section 3.14: Current and future burden of disease

3.2 Existing national limits

3.2.1 Occupational exposure limits

Table 3-1 provides an overview on the OELs and STELs for formaldehyde in the EU-28 member states and for a number of non-EU countries. As can be seen from the table, OELs for formaldehyde vary from 0.12 ppm (0.15 mg/m³) to 2.1 ppm (2.5 mg/m³), with most in the range of 0.3 ppm (0.37 mg/m³) to 0.5 ppm (0.6 mg/m³). The OELs, where the background on how the OEL has been set is clear, were based on human observations (controlled studies and epidemiology). For many of the assessments, a notation for (dermal) sensitisation for formaldehyde has been included.

The current existing OELs have been derived based on non-carcinogenic effects; however, some of these effects are considered to be precursor effects for carcinogenicity, for example increasing cell proliferation. For many of the OELs, it is stated in the background documents to the setting of the OEL that there is no elevated risk for carcinogenicity, if the OEL based on non-carcinogenic effects is met.

In Germany, the OEL specifically addresses excess cancer risk above the assumed threshold of 0.3 ppm (0.37 mg/m^3) and a respective ERR is derived (AGS, 2014; see Section 2.4.6). SCOEL (2016) documents a cancer risk estimate by Starr and Swenberg (2013) and this data is used to compare and validate the OEL; the data was derived from non-cancer effects.

In many of the countries, information on how the OEL was set is not available. The majority of the OEL values are however close to or identical to the recommended SCOEL value of 0.3 ppm (0.37 mg/m³). For an OEL up to 0.6 ppm (0.72 mg/m^3), eleven EU-countries have adopted very similar values (Austria, Denmark, Estonia, Finland, France, Germany, Hungary, Latvia, Lithuania, Poland, and Sweden; in addition to South Korea outside the EU). No OELs for formaldehyde were retrieved for 14 EU-countries (Belgium, Bulgaria, Croatia, Cyprus, Greece, Italy, Luxembourg, Malta, Portugal, Romania, Slovakia, Slovenia, and Spain).

There are some deviations from the widely agreed OEL of 0.3-0.5 ppm (0.37-0.6 mg/m^3), both lower and higher. These are as follows:

- The United Kingdom propose the highest OEL of 2 ppm (2.5 mg/m^3). The background for this assessment is not available;
- The Netherlands (DECOS, 2003) derived a lower OEL of 0.12 ppm (0.15 mg/m^3). This report also refers to sensory irritation as a critical effect, with the value on based on a study by Anderson (Anderson and Molhave, 1983) with a LOAEC [9]of 0.21 ppm (0.25 mg/m^3) and an applied factor of 2 to estimate the NOAEC [10]; and
- In non-EU countries, there are a few deviations from the OEL suggested by SCOEL. In Japan a similar value as in the Netherlands was derived. In the US, the NIOSH (National Institute for Occupational Safety and Health) derived a lower OEL of 0.016 ppm (0.02 mg/m^3), whereas the US-OSHA (US Occupational Health and Safety Administration) established a TLV (Threshold Limit Value) of 0.75 ppm (0.9 mg/m^3), about a factor 2 higher than SCOEL. A higher OEL has also been proposed in Australia.

Overall, there appear to be minor discrepancies between the international assessments on non-cancer effect potency of formaldehyde, and regarding the eight-hour TWA.

3.2.2 STELs

The range of short term exposure limit values (STELs) varies from 0.3 ppm (0.37 mg/m^3) to 2.5 ppm (3 mg/m^3). A STEL of twice the OEL (i.e., 0.6 ppm, 0.738 mg/m^3) has been assigned by SCOEL. Similarly, the STEL for local effects is often higher by a factor of 1 or 2 compared to the OEL. However, the background to the respective STELs adopted by the various national assessments is rarely known. Some of the OELs are provided as ceiling values.

STELs for formaldehyde are in use in many member states (table overleaf) and are also used by industry (see section 3.5) for exposure. For the calculation of the baseline, the STEL has not been considered as no formula could be deduced taking into account the STEL.

The STEL that is derived by SCOEL (0.6 ppm; 0.738 mg/m^3) is based on observations in chamber studies. Exposures with 4 superimposed peaks being most relevant for derivation of an OEL with STEL were 0.3 ppm (0.37 mg/m^3), plus peaks of 0.6 ppm (0.738 mg/m^3) and 0.5 ppm (0.6 mg/m^3), plus peaks of 1 ppm (Lang et al., 2008), and in a second study (Mueller et al., 2013) 0.3 ppm (0.37 mg/m^3) plus peaks of 0.6 ppm (0.738 mg/m^3) and 0.4 ppm (0.48 mg/m^3) plus peaks of 0.8 ppm (0.96 mg/m^3). Objective signs of irritation were only observed at 0.5 ppm plus peaks of 1 ppm. As 0.3 ppm (0.37 mg/m^3) plus peaks of 0.6 ppm (0.738 mg/m^3) was a consistent NOAEC in both of these investigations this exposure regime is taken forward for derivation of the OEL, TWA with STEL. Using this as a study point, there is insufficient criteria for taking the STEL into account for the calculation of the baseline.

[9] Lowest concentration or amount of a substance (dose), found by experiment or observation, which causes an adverse effect on morphology, functional capacity, growth, development, or life span of a target organism distinguishable from normal (control) organisms of the same species and strain under defined conditions of exposure. IUPAC Glossary of Terms Used in Toxicology, 2nd Edition (2007), available at https://sis.nlm.nih.gov/enviro/iupacglossary/frontmatter.html

[10] Greatest concentration or amount of a substance, found by experiment or observation, which causes no detectable adverse alteration of morphology, functional capacity, growth, development, or life span of the *target* organism under defined conditions of exposure. IUPAC Glossary of Terms Used in Toxicology, 2nd Edition (2007), available at https://sis.nlm.nih.gov/enviro/iupacglossary/frontmatter.html

3.2.3 Biomonitoring values

No biomonitoring values have been derived by SCOEL (2016) or others because of exclusively local toxicity at the upper respiratory tract and the high endogenous formation.

Table 3-1: OELs and STELs in EU Member States and selected non-EU countries for Formaldehyde						
Country	**Value [mg/m³ (ppm)]**	**Specification of value (year)**	**OEL definition**	**Study details**	**STEL [mg/m³ (ppm)]**	**Specification of STEL**
Austria[1, 7, 8]	0.37 (0.3)	-SKIN (2017)	HB	Adopted: SCOEL assessment	0.74 (0.6)	-15 min, SKIN
Belgium[1]	-	(2014)		Not known or not reported	0.38 (0.3)	-momentary, 15 min
Bulgaria	1.0 (0.83)		SE/T		2.0 (1.7)	
Croatia	2.5 (2.0)		SE/T		2.5 (2.0)	
Cyprus	3.0 (2.0)	-SKIN	SE/T		-	n.a.
Czech Republic	0.5 (0.42)	-SKIN	HB		1.0 (0.8)	-ceiling, -SKIN
Denmark[1, 13]	0.4 (0.3)	(2012)	SE/T		0.4 (0.3)	-ceiling
Estonia[1]	0.6 (0.5)		SE/T		1.2 (1.0)	-ceiling, 15 min
Finland[1,15]	0.37 (0.3) (2016)		SE/T		1.2 (1.0)	-ceiling, 15 min
France[1, 12, §§]	0.6 (0.5) [0.35 (0.3) [12]] (2017)		Not known HB	Lang et al. (2008) Endpoint: sensory irritation Species: human	1.2 (1.0) [0.70 (0.6)]	- Mueller et al. (2013)
Germany[1, 11]	0.37 (0.3) (2015 AGS)		HB	Mueller et al. (2013) Species: human Endpoint: sensory irritation; Gelbke et al. (2014)	0.74 (0.6)	-15 min
Greece	2.5 (2.0)		SE/T	Not known or not reported	2.5 (2.0)	
Hungary[1]	0.6 (0.5) (2000)	-SKIN	HB		0.6 (0.5)	-15 min, SKIN
Ireland[1, 14]	0.24 (0.2) (2016)	+	HB		0.5 (0.4))	-15 min
Italy	-	-	n.a.		-	n.a.
Latvia[1]	0.5 (0.42) (n.r.)		SE/T		-	n.a.
Lithuania[1]	0.6 (0.5)		SE/T		1.2 (1.0)	-ceiling
Luxembourg	-		n.a.		-	n.a.

Table 3-1: OELs and STELs in EU Member States and selected non-EU countries for Formaldehyde						
Country	**Value [mg/m³ (ppm)]**	**Specification of value (year)**	**OEL definition**	**Study details**	**STEL [mg/m³ (ppm)]**	**Specification of STEL**
Malta	-		n.a.		-	n.a.
Netherlands [1]	0.15 (0.12) (2007)		HB	Endpoint: sensory irritation Species: human Paustenbach et al. (1997); Andersen and Molhave (1983), Wilhelmsson and Holmstrom (1992)	0.5 (0.42)	-15 min
Poland[1]	0.5 (0.42) [0.37 (0.3)] (2008)	-SKIN -intended change˜	HB	Not known or not reported	1.0 (0.8) 0.74 (0.6)	-15 min -intended change˜
Portugal[19]	0.37 (0.3)		HB		-	n.a.
Romania	1.2 (1.0)		Not known		3.0 (2.0)	
Slovakia	0.37 (0.3)	-SKIN	HB		0.74 (0.6)	-15 min, SKIN
Slovenia	0.62 (0.5)	-SKIN	SE/T		0.62 (0.5)	-SKIN
Spain[1, 17]	- (2010)		n.a.	Endpoint: sensitisation	0.37 (0.3)	
Sweden[1, 16]	0.37 (0.3) (2011)	-SKIN	SE/T	Endpoint: irritation of mucous membranes, genotoxicity Species: human	0.74 (0.6)	-15 min, SKIN
United Kingdom[1, 10]	2.5 (2.0)	-SKIN	SE/T	Unknown or not reported	2.5 (2.0)	-15 min, SKIN
SCOEL[1]	0.369 (0.3 ppm) (2016)		HB	Endpoint: sensory irritation Species: human Mueller et al. (2013) ; Lang et al. (2008); (Brüning et al., 2014)	0.738 (0.6)	-15 min
Selected Non-EU countries						
Australia[1]	1.2 (1.0) (2011)		Not known	Not known or not reported	2.5 (2.0)	
Brazil	2.3 (1.6)	-48 hours/week	Not known		-	n.a.

Table 3-1: OELs and STELs in EU Member States and selected non-EU countries for Formaldehyde						
Country	**Value [mg/m³ (ppm)]**	**Specification of value (year)**	**OEL definition**	**Study details**	**STEL [mg/m³ (ppm)]**	**Specification of STEL**
Canada, Ontario[1, 9]	Pending (2015, 2015, 2016)		Not known	Based on ACGIH[9]	1.2 (1.0) 1.8 (1.5)	-STEL -ceiling
Canada, Quebec	- (2010)		Not known	Not known or not reported	-[+]	n.a.
China[1]	- (n.r.)		SE/T		0.5 (0.4)	-ceiling, 15 min
India	1.5 (1.0)		Not known		3.0 (2.0)	
Japan[1]	0.12 (0.1 (2015))		HB		0.24 (0.2)	-ceiling
South Korea[1]	0.75 (0.5) (n.r.)		SE/T		1.5 (1.0)	
USA; ACGIH	0.12 (0.1)[4] (2017)		HB	Endpoint: sensory irri-tation, Species: human, Lang et al. (2008); Anderson and Molhave (1983)	0.37 (0.3)[5]	-ceiling, 15 min[5]
USA, OSHA[1]	0.9 (0.75) (2006)		SE/T	Unknown or not reported	2.4 (2.0)	
USA, NIOSH[$, 1, 18]	0.02 (0.016) (1988)		SE/T	carcinogenicity; study not known	0.12 (0.1)	-ceiling, 15 min

+ Contradictory data from questionnaire responses or GESTIS.
- not established/assigned
˜ Intended change not implemented, yet.
§ Unit transformation according to specific country rounding or for formaldehyde according to 1 ppm = 1.2 mg/m³; 1 mg/m³ = 0.83 ppm.
SKIN: Skin notation assigned.
$ "For NIOSH recommended exposure limits (RELs), "TWA" indicates a time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek. ";
§§ Limit values are recognised indicative values according to decree modified on 30 June 2004 – thus not legally binding.
n.a. = not applicable
SE/T = influenced by socio-economic and/or technical considerations; HB = health or risk-based

References:
Questionnaire information (this project) or GESTIS, IFA (2017), or country specific lists of OEL from web-search, if not stated otherwise (references 1-4 or 5-19, below).

1: SCOEL (2016), Recommendation from the Scientific Committee on Occupational Exposure Limits for Formaldehyde
2: ECHA (2011) CLH report Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No

Table 3-1: OELs and STELs in EU Member States and selected non-EU countries for Formaldehyde						
Country	Value [mg/m³ (ppm)]	Specification of value (year)	OEL definition	Study details	STEL [mg/m³ (ppm)]	Specification of STEL
1272/2008 (CLP Regulation), Annex VI, Part 2 Substance Name: FORMALDEHYDE 3: ECHA (2012) Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of Formaldehyde 4: IFA, 2017, Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung. GESTIS - Internationale Grenzwerte für chemische Substanzen. 5: ACGIH (2017), American Conference of Governmental Industrial Hygienists. Formaldehyde. 6: The Social and Economic Council of the Netherlands (SER). OEL database. Available at: https://www.ser.nl/en/oel_database.aspx (Accessed Nov. 2017) and HCN (Health Council of the Netherlands: Dutch Expert Committee on Occupational Standards). Formaldehyde; Health-based recommended occupational exposure limit. Available at : https://www.gezondheidsraad.nl/sites/default/files/0302oshr_0.pdf 7: Bundesgesetzblatt für die Republik Österreich, Ausgegeben am 24. Oktober 2017 Teil II. 288. Verordnung: Änderung der Grenzwerteverordnung 2011. Available at: https://www.ris.bka.gv.at/Dokumente/BgblAuth/BGBLA_2017_II_288/BGBLA_2017_II_288.pdf (Accessed 8.11.2017) 8: Formaldehyd: Änderung der Grenzwerteverordnung 25.10.2017). Herausgeber: Bundesarbeitskammer und Österreichischer Gewerkschaftsbund. Available at: http://www.gesundearbeit.at/cms/V02/V02_0.a/1508479599230/home/formaldehyd-aenderung-der-grenzwerteverordnung (accessed 8.11.2017) 9: Ontario Ministry of Labour: 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 8.11.2017) 10: HSE EH40/2005 Workplace exposure limits. March 2013. Available at : http://www.hse.gov.uk/pUbns/priced/eh40.pdf 11: AGS (2015): Begründung zu Formaldehyd. Available at : https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/900/900-formaldehyd.pdf?__blob=publicationFile&v=2 12: ANSES (2017) Collective Expert Appraisal: Summary and Conclusions. Formaldehyde. Version for public consultation. 13: Beskæftigelsesministeriet (2012). Available at: https://www.retsinformation.dk/pdfPrint.aspx?id=143596 14: HSA (2016) Code of Practice for the Chemical Agents Regulations. Published by the Health and Safety Authority, Dublin, Ireland. Available at: http://www.hsa.ie/eng/Publications_and_Forms/Publications/Chemical_and_Hazardous_Substances/Chemical_Agents_COP_2016.pdf HTP-ARVOT (2016) Haitallisiksi tunnetut pitoisuudet. Available at: http://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/79109/08_2016_HTP-arvot_suomi_22122016_netti_kansilla.pdf?sequence=1&isAllowed=y 16: Arbetsmiljöverket (2015) Hygieniska gränsvärden. Available at: https://www.av.se/globalassets/filer/publikationer/foreskrifter/hygieniska-gransvarden-afs-2015-7.pdf 17: INSHT (2017) Instituto Nacional de Seguridad e Higiene en el Trabajo (INSHT). Límites de exposición profesional para agentes químicos en España. 2017. Available at: http://www.insht.es/InshtWeb/Contenidos/Documentacion/LEP%20_VALORES%20LIMITE/Valores%20limite/LEP%202017.pdf 18: NIOSH (1988) Occupational Safety and Health Guideline for Formaldehyde. Available at : https://www.cdc.gov/niosh/docs/81-123/pdfs/0293.pdf 19: Portuguese Rule NP 1796:2014 Segurança e Saúde do Trabalho: Valores-Limite e Índices Biológicos de Exposição Profissional a Agentes Químicos.						

3.3 Relevant sectors, uses, and operations

3.3.1 Overview

Formaldehyde is used in a wide variety of sectors, with these identified below. Operations where exposure can occur to formaldehyde on these sectors are also discussed, with more information on exposure presented in section 3.5. Furthermore, formaldehyde is also present in the environment as a result of natural processes, specifically the photochemical oxidation [11] and incomplete combustion of hydrocarbons.

3.3.2 Manufacture of formaldehyde

Formaldehyde is technically produced as an aqueous solution by oxidative dehydrogenation of methanol with air via either a silver (for one half) or metal oxide (the other half) catalyst process (TNO Triskelion B.V. and RPA, 2013). The process is illustrated in Figure 3-1. The silver catalyst route can be performed in one of two ways:

- The partial oxidation and dehydrogenation in air in the presence of silver crystals, excess methanol and steam in a temperature range of 680- 720 °C at atmospheric pressure; or
- The partial oxidation and dehydrogenation in air in the presence of silver crystals or silver gauze, excess methanol and steam at a temperature of 600-650 °C; followed by distillation of the product and recovery and recycling of the unreacted methanol.

For the metal-oxide route, methanol is oxidised with excess air with a modified iron molybdenum oxide catalyst at a temperature of 250-400 °C and at atmospheric pressure.

Formaldehyde at room temperature is a volatile gas with a high vapour pressure and is unstable. Formaldehyde is dissolved in water to produce methanediol. Formaldehyde aqueous solutions are known as formalin (in 2013, over 7 million tonnes were produced in the EU) and methanol can be added to the solution to prevent polymerisation. Formaldehyde is also used as a monomer in the synthesis of paraformaldehyde (polymer) and is also available as a solid crystal (trioxane).

[11] Reaction of a substance with oxygen under the influence of ultraviolet, visible, or infrared light. IUPAC Glossary of Terms Used in Toxicology, 2nd Edition (2007), available at https://sis.nlm.nih.gov/enviro/iupacglossary/frontmatter.html

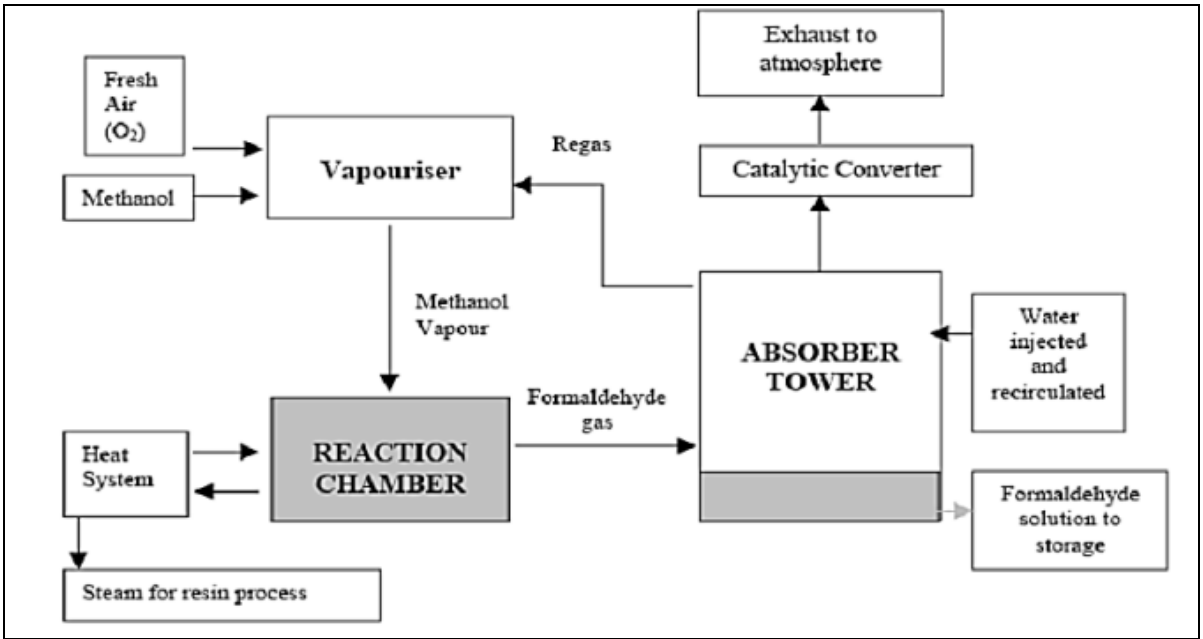


Figure 3-1: Formaldehyde manufacturing process.
Source: Merchant Research & Consulting (2012): Formaldehyde: 2012 World Market Outlook and Forecast up to 2017

The European Union is the second largest producer of formaldehyde after Asia and, in 2015, produced over 8.6 million tonnes of 37% formaldehyde and 3.2 million tonnes of 100% formaldehyde.[12] Within Europe, Germany has the highest formaldehyde manufacturing capacity, followed by Italy with formaldehyde capacity for each member state described in the below table based on the year 2009.

Table 3-2: EU 100% Formaldehyde Production & Capacity, 2009

Country	Capacity (thousand tonnes/year)
Germany	2,765
Italy	1400
Spain	930
Netherlands	696
UK	695
Belgium	638
Sweden	500
Poland	470
Portugal	318
Austria	282
Finland	165
Lithuania	120
Hungary	120
Bulgaria	110
Czech Republic	108
Denmark	80
Ireland	65
France	65
Greece	22

[12] Estimates from Formacare based on the IHS/CEH report on formaldehyde (2015)

Table 3-2: EU 100% Formaldehyde Production & Capacity, 2009	
Country	**Capacity (thousand tonnes/year)**
Source: Formacare (2014): The EU Formaldehyde Market. Available at: http://www.formacare.org/about-formaldehyde/eu-market/	

The number of formaldehyde manufacturers located in each member state is as follows:[13]

- Austria, Bulgaria, Czech Republic, Denmark, France, Greece, Hungary, Ireland and Lithuania: 1 formaldehyde manufacturer in each of these member states;
- Finland, Portugal, Slovakia, Slovenia and Sweden: 2 formaldehyde manufacturers in each of these member states;
- Belgium, Netherlands, Poland and Romania: 4 formaldehyde manufacturers in each of these member states;
- United Kingdom: 5 formaldehyde manufacturers;
- Spain: 6 formaldehyde manufacturers;
- Italy: 8 formaldehyde manufacturers; and
- Germany: 12 formaldehyde manufacturers.

3.3.3 Overview of uses

As discussed in Section 3.3.2, in its pure monomeric form, formaldehyde is somewhat unstable and, as such, it is usually converted into a variety of forms for consumer or commercial use, for example into formaldehyde-based resins and polymeric materials, such as polyurethane (RPA, 2006).

Formaldehyde is used in a wide variety of sectors. According to the ECHA substance information portal, formaldehyde is used in: adhesives and sealants; coating products; polymers; biocides; laboratory chemicals; polishes and waxes; fuels; washing and cleaning products; cosmetics and personal care products. Formaldehyde is also used in the manufacturing of leather and fur, pulp, paper and paper products, textile and wood and wood products and is used in building and construction work (ECHA, 2017a).

Formaldehyde is used for tissue preservation in embalming fluids and as a disinfectant in pathology departments and autopsy rooms, usually in the form of formalin (i.e. mixture of formaldehyde, water, and methyl alcohol). Formaldehyde can also be used in the form of a polymerized solid - paraformaldehyde, which tends to be favoured in industrial applications in plants that are located at long distances from formaldehyde manufacturing plants due to its lighter weight and lower shipping costs (IARC, 2012).

The breakdown of formaldehyde use in the EU is as follows from information supplied by Formacare:

- 41% is used in urea formaldehyde (UF);
- 9% is used in phenolic resins;
- 7% is used for melamine formaldehyde (MF);
- 11% is used in polyols;
- 8% is used for methylene dianiline (MDA);
- 7% is used in polyacetal resins (POM); and
- 17% for other uses.

[13] Consultation correspondence from Formacare

The most relevant sectors/uses of formaldehyde from literature review and consultation are discussed in the following sectors.

Agriculture, Forestry and Fishing (NACE Code A)

Formaldehyde is used in slow release fertilisers and in urea treated with formaldehyde as a stabiliser in fertiliser manufacturing. Further information about this use is discussed in the manufacturing of chemicals and chemical products section.

Formaldehyde has been identified as being used in fish farms which are stocked with brown and rainbow trout. It used in the form of formalin with a concentration of 200 ppm and is mainly used in ponds on an infrequent basis dependent on weather conditions (<10 times per year from consultation). It is used to treat fungal infection and growth in ponds stocked with brown and rainbow trout and may be used to some extent in all trout fish farms in Ireland. From consultation, a limited number of people are involved in the formaldehyde treatment.

Manufacturing of food products (NACE Code C10)

Formaldehyde is used in the manufacturing of food products as a bacteriostatic agent, for example in foods such as cheese, in the preservation of dried foods, for disinfecting containers, in the preservation of fish and certain oils and foods, and in the modification of starch for cold swelling (OECD, 2017).

Formaldehyde is also used in sugar beet processing, where it is used as a biocidal agent in saccharose extraction from beetroots (ANSES, 2016).

Manufacture of textiles (NACE Code C13)

In the manufacture of textiles, formaldehyde based resins are used. These resins are used to bind dyes and pigments to fabrics and also to prevent colours from running when clothes are washed. Urea formaldehyde (UF) and melamine formaldehyde (MF) resins can also be used in textile manufacturing for making clothes stain and wrinkle resistance (Formacare, 2014a).

Operations where exposure could occur are during the manufacturing process, which includes spraying, processing, mixing/blending, assembly, dipping/pouring and cutting/sanding. This is further discussed in Section 3.5.

Manufacture of leather and related products (NACE Code C15)

In the REACH dossier, the use of formaldehyde in leather tanning is listed (ECHA, 2017b). Operations where exposure could occur are during the manufacturing process which includes spraying, processing, mixing/blending, assembly, dipping/pouring and cutting/sanding. This is discussed in more detail in Section 3.5.

Manufacture of wood and products of wood and cork; except furniture (NACE Code C16)

The majority of formaldehyde produced in the EU is used to manufacture resins. The primary use is in the production of urea-formaldehyde resins (50% of EU consumption), melamine formaldehyde resins (10% of EU consumption) and phenol formaldehyde resins (12% of EU consumption). Polyacetyl resins (POM) account for 8% of the EU formaldehyde market and is a growing market as POMs are self-lubricating thermoplastics for metal components and are used in a variety of sectors such as gears, housings and bearings.

The primary use of formaldehyde based resins is in the manufacture of wood based panels (TNO Triskelion B.V. and RPA, 2013). In particular, urea-formaldehyde (UF) resin and phenol formaldehyde (PF) resins are used in the manufacture of wood and products of wood and cork. The primary application of the resins is as a "glue resin" in wood panels and wooden plates.

For these uses, emission standards are in place in the EU to limit formaldehyde exposure. Two standards exist for wood-based products: emission class E1 and emission class E2. In E1 boards, formaldehyde emissions are less than 0.1 ppm; and for E2 boards formaldehyde emissions are between 0.1 and 0.3 ppm (Health and Safety Executive, undated).

Emission class E1 is the class that applies to panel production (ANSES, 2016). Operations where exposure could occur are during panel production (which includes loading/unloading; process operations; line operations; sorting/packing; testing; weighing; mixing and filling) and also during *in situ* use for downstream users. This is discussed in more detail in Section 3.5.

Manufacture of paper and paper products (NACE Code C17)

Formaldehyde is used in the manufacture of paper and paper products. Urea formaldehyde resin is used for producing printer paper, kraft paper, packaging paper, hygienic paper and also paper that requires special security features such as bank notes and passports (ANSES, 2016).

Manufacture of chemicals and chemical products (NACE Code C20)

Formaldehyde manufacturing is discussed in Section 3.3.2 and the manufacture of resins is discussed in the manufacture of wood products (see above). Formaldehyde is also used in the manufacturing of the following chemical products:

- Fertilisers (NACE Code C20.1): In slow release fertilisers, formaldehyde is used in the preparation of the polymer nutrient but is not present in the final product (consultation with Fertilizer Europe). In urea, formaldehyde is added as a stabiliser which improves the physical characteristics of the granules and also avoids caking phenomenon further down the supply chain (from consultation). Exposure could occur during fertiliser production (during cleaning/maintenance, sampling and general operation) and in some cases, where formaldehyde is used as a stabiliser as this may be partially sprayed over the final product;
- Methylene dianiline (MDA) and diphenylmethane diisocyanate (MDI), where its use is as an intermediate. MDA is used in the manufacture of MDI which is used in insulation foams, paints and coatings, adhesives for wood panels, automotive seats, bedding and mattresses (8% of formaldehyde in the EU is used for this purpose);
- Paints, varnishes and similar coatings, printing inks and mastics (NACE Code C20.3): Urea formaldehyde resins, melamine formaldehyde resins and phenol formaldehyde resins) are used as binding agents. The applications of adhesives and coatings is also listed as a use for professional workers in the REACH registration dossier (ECHA, 2017b);
- Soaps and detergents, cleaning and polishing preparations, perfumes and toilet preparations (NACE Code C20.4): Formaldehyde can be used for preservation applications, household cleaning agents and in nail hardeners amongst others and is present in low concentrations (Denmark Environmental Protection Agency, 2014 and Boyer, 2013); and
- Explosives (NACE Code C20.51): Formaldehyde can also be used in the manufacture of explosives such as RDX. In this application, formaldehyde is reacted with ammonia to produce hexamine (which can then be used in explosives) (Maxwell, 2004).

Exposure to formaldehyde during manufacturing of chemicals and chemical products can occur during process control and sampling, cleaning/service/repairs and filter changing amongst others.

Manufacture of basic pharmaceutical products and pharmaceutical preparations (NACE Code C21)

In the pharmaceutical sector, formaldehyde is used in the manufacture of gelatin capsules. It is also used as an inactivating agent in vaccines (Pina and Sousa, 2002), where it is used to inactivate toxins from bacteria and viruses. There may be traces of formaldehyde in the final vaccine, however, this is broken down in water (and most of the vaccine is water - Oxford Vaccine Group, 2015).

Manufacture of rubber and plastic products (NACE Code C22)

Formaldehyde has been identified as being used in the manufacture of rubber and plastic products in the ANSES (2016) risk management option analysis with hexamine (formaldehyde is used as a starting material) used as a rubber accelerator (ANSES, 2016). In the study by Clerc *et al*, exposure to formaldehyde has been observed in France and Germany in the manufacture of rubber and plastic products (Clerc *et al*, 2015). Phenol formaldehyde and urea formaldehyde resins are also used in plastic fuse boxes, knobs and switches (British Plastics Federation, 2015).

Operations where formaldehyde exposure in this sector could occur include in weighing and loading; mixing; shaping; vulcanisation/curing; and finishing.

Manufacture of fabricated metals, except machinery and equipment (NACE Code C25)

Formaldehyde can be used as a preservative in metal remover fluids, anticorrosive agents and metalworking agents; these products may also release formaldehyde. The use of formaldehyde releasers for metal working fluids is covered in PT 13 of the biocidal products regulation (RIVM, 2015). Exposure can occur during metal finishing and plating. Exposure can also occur in foundries, as when sand is hardened, formaldehyde based resins are used (consultation with Ferro-Preis d.o.o.).

Manufacture of electrical equipment (NACE Code C27)

Polyoxymethylene (also called Polyacetal) resins are formaldehyde polymers which are used in powder injection moulding technology (Antoun et al, 2013). POM resins are also used in the manufacture of electrical and electronic appliance parts (moulding).

Manufacture of machinery and equipment (NACE Code C28)

Phenol formaldehyde resin is used in the production of abrasive wheels.

Manufacture of motor vehicles, trailers and semi-trailers (NACE Code C29)

Formaldehyde based resins are used in many automotive applications and these are described in the below table.

Table 3-3: Formaldehyde resins used in automotive applications		
Formaldehyde resin	**Properties for application**	**Application**
Phenol formaldehyde	High moisture resistance, high chemical resistance, and high thermal resistance	Engine parts, transmission parts, brake parts, brake pads, clutches, and decorative laminates
Melamine formaldehyde	Withstand high temperatures, fast curing, and excellent chemical resistance	Surface coatings and decorative laminates
Polyoxymethylene	Gasoline resistance and lubricant properties (main use in the manufacture of fuel pumps)	Automatic transmission parts, car heater plates, gear selectors, steering column shear pin parts, suspension links, tyre valve stems, electrical switch parts, light sockets, fuel system components, fan parts, car ventilation grille, truck release levers, door handles, door catches, window cranks, control switches and instrument knobs, gear selectors, plastic component of seat belt systems, and locks, hooks, fasteners, clips and mirrors
Source: Formacare (2014): Formaldehyde in Automotive Applications. Available at: http://www.formacare.org/automotive/		

Methylene bis (dephenyl di-isocyanate) (MDI), 1,4-Butanediol (BDO) and Pentaerythritol (Penta), in which formaldehyde is used as a starting material, are also used in automotive applications (Formacare, 2014b).

Manufacture of air and spacecraft and related machinery (NACE Code C30.3)

According to Formacare, formaldehyde based resins are used in the following aircraft applications (Formacare, 2014c):

- Phenol formaldehyde resins are used in the panelling of aircraft interiors;
- Polyoxymethylene is used in the manufacture of seatbelt plastic components;
- Hexamine is used as an accelerator in rubber tyres;
- Pentaerythritol is used as a lubricant for turbines; and
- MDI is used in aircraft seats.

Manufacture of furniture (NACE Code C31)

Urea formaldehyde and phenol formaldehyde resins are used as "glue resins" in furniture manufacturing, which is further discussed in the "Manufacture of wood and products of wood and cork; except furniture" section above.

Construction of buildings (NACE Code F41)

Formaldehyde based foams (urea-formaldehyde and phenol formaldehyde) are used as building materials, insulator materials, and can also be used as an adhesive in mineral wools which have applications as thermal insulators. ECHA lists the use of formaldehyde in outdoor use in long life materials with low release rates such as building materials and in indoor use in long life materials with low release rates such as construction materials (ECHA, 2017a).

Professional, Scientific and Technical Activities: Scientific research and development (NACE Code M72)

Formaldehyde is used in the electrophoresis (method to separate charged molecules by size) of RNA (ThermoFisher Scientific, undated and Bryant, 1998). In the formaldehyde gel used, formamide (30-60 wt. %) and formaldehyde (10-30 wt. %) is used (ThermoFisher Scientific, 2013). ANSES (2016) also reports that formaldehyde is used as a laboratory reagent in control laboratories (ANSES, 2016).

Formaldehyde is also used in the synthesis of chelating agents and pyridines and is used for health research which is further discussed in the higher education sector.

Professional, Scientific and Technical Activities: Veterinary activities (NACE Code M75)

Formaldehyde is used as a veterinary biocidal agent in the poultry sector and is used as a fumigant due to its capability to destroy microorganisms on eggs, egg cases, chick boxes and hatchery equipment; it is also used as a disinfectant for poultry houses (Association of Poultry Processors and Poultry Trade in the EU Countries, 2015). In a submission to an ECHA consultation regarding formaldehyde as a potential candidate for substitution under the BPR regulation, the British Poultry Council stated that formaldehyde is used in the poultry industry for the following reasons (British Poultry Council, 2015):

- Formaldehyde is used in hatcheries to stop bacterial contamination in fluff and hatching eggs;
- It can be useful for controlling zoonooses in hatcheries;
- Formaldehyde vapour is easily generated from formalin or paraformaldehyde for use as a disinfectant;
- Formaldehyde is efficient for treating buildings;
- There is more penetration power down the pores of eggshells (gas-phase disinfectant) undergoing fumigation and this process does not damage the eggs or embryos; and
- The use of formaldehyde decreases chick mortality.

Formaldehyde is also used as a disinfectant in greenhouses between crop cycles and in foot baths for treating mortellaro disease in dairy cows (LTO Netherlands, undated). The use of formaldehyde in fish farms is discussed in the agricultural uses section.

Education (NACE Code P85- P85.4. Higher Education)

Formaldehyde is used as a used as a preservative for specimen and tissue samples which is discussed in more detail in the following section. Formaldehyde is used in the following activities (from consultation):

- Preparation of fixation solutions (3-4% formaldehyde);
- Fixation of human bodies;
- Storage (preservation of bodies); and
- Teaching for student courses, for example dissection activities.

Human health and social work activities: Human health activities (NACE Code Q86)

Formaldehyde is used for the following applications in the healthcare sector:

- **Health services**: Cleaning medical equipment, surfaces and environments; used to fix and maintain specimens and tissue samples; used as a tissue preservative (typically 10% concentration) and as an embalming agent;
- **Dentistry**: Antiseptics and disinfectants, e.g. composite resins replacing amalgam and root canal fillings; and
- **Schools and universities**: Used as a preservative for specimen and tissue samples.

Operations where formaldehyde exposure could occur include in operating rooms and pathology laboratories and for the uses listed above.

Funeral and related activities (NACE S96.03)

Formaldehyde is used for embalming in funeral homes. From consultation, formaldehyde is used as it cross-links to protein to stop bacteria nourishment. Exposure could occur during the embalming process.

Other Biocidal Uses

Formaldehyde is also reportedly used in the hot water treatment of flower bulbs to destroy nematodes in a submission from the Royal General Bulb Growers Association; as hot water treatment can lead to basal rot and Legionella Pneumophila, formaldehyde (0.5% solution of formalin) is added to the bath (Royal General Bulb Growers Association, undated) to prevent this from occurring.

3.3.4 Summary of sectors and uses

A summary of the relevant sectors and uses in which occupational exposure to formaldehyde could occur are summarised in the following table. The sectors that are important in terms of the highest potential exposure concentrations (further information is discussed in section 3.5) are:

- Professional, Scientific and Technical Activities: Veterinary activities;
- Education (NACE Code P85.4);
- Human health activities (NACE Code Q86); and
- Funeral and related services (NACE Code S96.0.3)

For many uses, these are not covered under REACH such as in the manufacture of resins and use in hospitals and other biocide activities; this is further discussed in section 3.10.

Table 3-4: Formaldehyde exposure sectors		
Sector	**Form**	**Applications**
Agriculture, Forestry and Fishing (NACE Code A)	Urea-formaldehyde (UF) resin Melamine formaldehyde (MF) resin Biocide	Used as a preservative and biocide in: Pesticides, fungicides, herbicides, etc.
Manufacturing of food products (NACE Code C10)		Used in the manufacturer of sugar (saccharose extraction from beetroots); as a preservative agent for food additives; as a synthetic reactive substance for food contact materials and as a surface cleaning agent
Manufacture of textiles (NACE Code C13)	Urea-formaldehyde (UF) resin Melamine formaldehyde (MF) resin Phenol formaldehyde (PF) resin	Used as a crease-proof (or anti-wrinkle) agent for: clothes and household linen products, curtains, carpets, fabric softeners, textile processing (dyes) and finishing (permanent press); used as an antimicrobial in medical textiles and also used in textile processing (formaldehyde-based resins)
Manufacture of leather and related products (NACE Code C15)	Urea-formaldehyde (UF) resin	Used in tanneries Used as a preservative for preventing hides from decomposing
Manufacture of wood and products of wood and cork; except furniture (NACE Code C16)	Urea-formaldehyde (UF) resin Phenol formaldehyde (PF) resin	Used as a “glue resin” in wood panels and wooden plates
Manufacture of paper and paper products (NACE Code C17)	Urea-formaldehyde (UF) resin	Used in towel products, kitchen rolls, napkins, sack papers, labels, currency, maps and filter papers

Table 3-4: Formaldehyde exposure sectors		
Sector	**Form**	**Applications**
Manufacture of chemicals and chemical products (NACE Code C20: C20.1, 20.2 and 20.4))	Formaldehyde, 37% solution, 49%, 50-55%	Production of formaldehyde; used in fertiliser synthesis; used as a starting material in the production of polyacetal resins (polyoxymethylene- POM) and paraformaldehyde; used as a starting material in the production of condensed resins: Urea-formaldehyde (UF); melamine-formaldehyde resins; phenol-formaldehyde resins; used as an intermediate in the synthesis of methylene dianiline (MDA), diphenylmethane diisocyanate (MDI), hexamethylenetetramine; used in HTMA which is used as a curing agent, rubber accelerator and in the manufacture of explosives, trimethylol propane, neopentylglycol, pentaerythritol, butanediol (BDO) and acetylenic agents Used in adhesives and used in biocidal applications
Manufacture of paints, varnishes and similar coatings, printing inks and mastics (NACE Code C20.3)	Urea-formaldehyde (UF) resin Melamine formaldehyde (MF) resin Phenol formaldehyde (PF) resin	Used as a binding agent in: paints, polishes, varnishes, lacquers, wax for furniture and floors, furniture polish, shoe shine, printing inks, external coating for cars and in external coatings for building claddings and for white goods etc.
Manufacture of soaps and detergents, cleaning and polishing preparations, perfumes and toilet preparations (NACE Code C20.4)	Preservatives Nail hardening agents Disinfectants	Used in the preservation of cosmetic products and raw materials against microbial contamination; use in certain cosmetic treatments, such as hardening of fingernails; and plant and equipment hygiene. Used in shower gels, shampoos, deodorants, nail hardeners, etc.
Manufacture of explosives (NACE Code C20.51)	Urea-formaldehyde (UF) resin Melamine formaldehyde (MF) resin	Used in the form of foam resin and other in: Household cleaning products, carpet cleaning agents, car cleaning agents, swimming pool cleaning products, etc. Used as an antimicrobial preservative in household and industrial products; and used to clean surfaces and equipment Used in the manufacture of explosives such as RDX
Manufacture of basic pharmaceutical products and pharmaceutical preparations (NACE Code C21)	Polyacetal (POM) resin	Used as an inactivating agent in vaccines: e.g. human vaccines and medicines; and used in the manufacture of gelatin capsules

Table 3-4: Formaldehyde exposure sectors		
Sector	**Form**	**Applications**
Manufacture of rubber and plastic products (NACE Code C22)		Used in tyre and rubber manufacturing
Manufacture of fabricated metals, except machinery and equipment (NACE Code C25)	Preservatives Formaldehyde resins	Uses as metal remover fluids, as anti-corrosive agent, as an oxidising and reducing agent, used in electroless plating, used in coatings and used to harden sand in foundries. Metalworking fluids can also be formaldehyde releasing agents, such as triazine; used in paints and coatings to extend shelf life
Manufacture of electrical equipment (NACE Code C27)	Polyacetal (POM) resin	Electrical/electronic appliances parts
Manufacture of machinery and equipment n.e.c. (NACE Code C28)	Phenol formaldehyde resin	Production of abrasive wheels
Manufacture of motor vehicles, trailers and semi-trailers (NACE Code C29)	Polyacetal (POM) resin Phenol formaldehyde (PF) resin	Used for safety belt components, fuel system components and engine components
Manufacture of furniture (NACE Code C31)	Urea-formaldehyde (UF) resin Phenol formaldehyde (PF) resin	Used as a “glue resin” in the furniture manufacturing industry
Water collection, treatment and supply (NACE Code E36)		Used in water control (laboratories) and water purification
Waste collection, treatment and disposal activities; materials recovery (NACE Code E38)		Precious metals recycling
Construction of buildings (NACE Code F41)	UF foam; PF foam	Used in building and insulating materials; and used as an adhesive in mineral wools that are used as thermal insulators
Professional, Scientific and Technical Activities: Photographic activities (NACE Code M74.2)	Stabilising agents in photographic colour processing Hardener/crosslinking agents Binding agent	Photographic materials (plates and papers) and processes
Professional, Scientific and Technical Activities: Scientific research and development (NACE Code M72)		Used as a laboratory reagent; used in electrophoresis of RNA; and used in the synthesis of chelating agents and pyridines
Professional, Scientific and Technical Activities: Veterinary activities (NACE Code M75)	Antiseptic, antimicrobial food additive, disinfectant	Used in animal feed, fish vaccines, etc.
Education (NACE Code P85.4):		**Schools and universities**: Used as a preservative for specimen and tissue samples; used for fixation; and used in teaching courses

Table 3-4: Formaldehyde exposure sectors		
Sector	**Form**	**Applications**
Human health and social work activities: Human health activities (NACE Code Q86)		**Health services**: Used for cleaning medical equipment, surfaces and environments; used to maintain specimens and tissue samples; and is also used as a tissue preservative (typically 10% concentration **Dentistry**: Used for antiseptic and disinfectants e.g. composite resins replacing amalgam and root canal fillings
Funeral and related activities (NACE Code S96.0.3)	Formalin	Used as an embalming agent
Sources: ANSES (2016): Analysis of the most appropriate risk management option (RMOA) - formaldehyde. Available at http://www.consultations-publiques.developpement-durable.gouv.fr/IMG/pdf/RMOA_Formaldehyde_040716.pdf Consultation Responses Formacare (2014): About formaldehyde. Available at: http://www.formacare.org/about-formaldehyde/ IPCS (1991): Formaldehyde Health and Safety Guide. Available at: http://www.inchem.org/documents/hsg/hsg/hsg057.htm#SectionNumber:1.5 RPA (2006): Comparative Assessment of Alternatives in Formaldehyde in Consumer and Non-Consumer Products and Applications. Report for AFSSET		

3.4 Exposed workforce

3.4.1 Total number of exposed workers

This section first summarises the estimates at the EU-28 level of exposed workers and then provides a breakdown by sector. It is of note that there are differences in the estimates between different sources.

The starting point for estimating the occupationally exposed population to formaldehyde is the CAREX (CARcinogen EXposure) database, with further estimates being available from SUMER (Medical Monitoring Survey of Professional Risks, France in 2003 and 2010), FinJem (Finnish Job-Exposure Matrix, Finland, reproduced in Santonen, 2013), Regex (Registry of Subjects Occupationally Exposed to Carcinogens, Czech Republic in 2009-16), and Siew *et al* (2012). These estimates are summarised below.

Table 3-5: Published data – workforce exposed to formaldehyde					
Study	**Country**	**Year/period**	**No. of exposed workers**	**% of exposed workforce**	**Notes**
Carex	EU15	1990-1993 (mean)	971,402		
	France	1990-1993 (mean)	307,025		
	Finland	1990-1993 (mean)	10,530		
	Czech Republic	1997	43,669		
	UK	1990-1993 (mean)	93,807		

Table 3-5: Published data – workforce exposed to formaldehyde					
Study	**Country**	**Year/period**	**No. of exposed workers**	**% of exposed workforce**	**Notes**
SUMER	France	2003	153,600 (66,800 men and 86,800 women)	0.9% (0.7% men and 1.2% women)	
		2010	139,400 (66,100 men and 73,300 women)	0.6% (0.6% men and 0.7% women)	
FinJem	Finland	2006	10,700		Woodworking & furniture industry, foundries
Siew et al (2012)	Global	Not specified		1%	
Regex	Czech Republic	2009-2016	173		

In addition, the total numbers of potentially exposed workers, as well as figures by sector, were estimated based on data obtained through consultation and for some sectors by estimating the share of exposed workers based on the extent of formaldehyde application within the relevant sectors. The results are presented in more detail in the Section 3.4.2.

In order to be able to compare the results from different sources, the published data have been extrapolated to the EU28 and the year 2015 based on the number of persons employed in each country and based on the changing trends in employment during the time period concerned. According to Eurostat, the total number of people in employment or self-employment in the EU-28 was 220 million in 2015. Applying the estimates of the proportion of the exposed workforce in the table above suggests an occupationally exposed population between 1.3 million and 2.2 million. A comparison of the number of workers exposed to formaldehyde identified through different sources is presented in the following table.

Table 3-6: Comparison of the number of workers exposed to formaldehyde identified through different sources	
Source of data	**Number of exposed workers in the EU28 in 2015**
Consultation/share of workforce using Eurostat data	0.99 million
Carex database*	1.4 million
FinJem database*	0.99 million
Sumer	1.6 million
Siew et al	2.2 million
*data have been extrapolated based on employment shares	

The lowest estimate is 990,000 which were obtained through consultation and the estimation of workers using Eurostat data. This corresponds with another estimate which relies on extrapolation to the EU-28 of the FinJem data (the Regex data for the Czech Republic are considered to be an outlier). The highest estimate can be derived on the basis of applying the 1% estimate in Siew *et al* (2012) to the total EU workforce which yields an estimate of 2.2 million. All other estimates and extrapolations (CAREX, SUMER) fall between these two values.

CAREX data, Siew *et al* and SUMER data are considered to be overestimates of the current occupationally exposed population. The figure of 0.99 million of exposed workers estimated based on consultation/Eurostat data will be used as a base estimate for the calculation of the current and future burden of disease in Section 3.14.

Rate of change

Comparing the number of workers exposed in France in 2003 and 2010 (SUMER) suggests an annual rate of decline of around 3%; this is fully accounted for by a decline in the number of exposed women. A similar comparison for Finland (1993 CAREX vs 2006 FinJem) suggests no decline in the number of workers exposed to formaldehyde.[14] It is of note though that one might expect a more pronounced impact than suggested by these findings due to the harmonised classification of formaldehyde in 2014 as a Carc. 1B. Thus, there is some uncertainty as to whether or not these rates are too low.

3.4.2 Breakdown by MS and sector

Breakdowns by sector and by Member State (MS) of the data presented above are given in Table 3-7 and 3-8 below.

[14] Finnish ASA has data on the numbers of workers exposed but these have increased over time, probably as a result of improved notification rather than an increase in the number of workers. See http://annhyg.oxfordjournals.org/content/51/5/463.full.pdf

Table 3-7: Breakdown of exposed workers by sector					
Sector (NACE rev. 2)	**Use/Process**	**Details about formaldehyde application**	**Estimated share of workers exposed in the sector**	**Exposed workforce in EU28**	**%Share of total workers exposed**
A	Used in slow release fertilisers Stabilizer	Formaldehyde is not present in the final product and is used for a limited number of applications. Exposure could occur during fertiliser production, cleaning/maintenance, sampling and general operations	0.5%	**47,550**	**4.0%**
	Used to treat fungal infection and growth in ponds stocked with brown and rainbow trout	Limited number of people (1-2 per fish farm) are involved in formaldehyde treatment; used less than ten times a year	2%	**780**	**0.1%**
C10	Bacteriostatic agent in some foods such as cheese and preservation of preservation of dried foods and for disinfecting containers and in sugar beet processing	Formaldehyde has does not have a wide range of applications in this sector. Share of workforce exposed is not known, however based on the number of applications is assumed to be low	1%	**40,769**	**3.4%**
C13	Formaldehyde resins are used in binding dyes and pigments to fabrics; used in textile manufacturing for making clothes stain and wrinkle resistance	Operations where exposure could occur are during the manufacturing process which includes spraying, processing, mixing/blending, assembly, dipping/pouring and cutting/sanding	5%	**30,097**	**5.0%**
C15	Leather tanning	Exposure could occur during the manufacturing process which includes spraying, processing, mixing/blending, assembly, dipping/pouring and cutting/sanding	2%	**7,523**	**0.6%**
C16	The primary use of formaldehyde resins is in the manufacture of wood based panels	Exposure could occur during panel production (which includes loading/unloading; process operations; line operations; sorting/packing; testing; weighing; mixing and filling)	1%	**5,053**	**0.4%**
C17	Urea formaldehyde resin is used for producing printer paper, kraft paper, packaging paper, hygienic paper and paper that requires special security features such as bank notes and passports	Formaldehyde is used in a wide range of applications. It is assumed that half of the companies active in this sector expose their workers to formaldehyde	10%	**61,802**	**5.2%**
C20	Formaldehyde manufacturing		0.2%	**2,750**	**0.2%**

Table 3-7: Breakdown of exposed workers by sector					
Sector (NACE rev. 2)	**Use/Process**	**Details about formaldehyde application**	**Estimated share of workers exposed in the sector**	**Exposed workforce in EU28**	**%Share of total workers exposed**
	Manufacture of resins	Formacare report that employees at formaldehyde and formaldehyde-based resin manufacturing plants such as operators, maintenance people as well administrative personnel are directly involved in the production of formaldehyde and intermediate use of formaldehyde			
	Manufacture of paints, varnishes and similar coatings, printing inks and mastics	Formaldehyde-based resins are used as binding agents	2%	**11,529**	**1.0%**
	Manufacture of soaps and detergents, cleaning and polishing preparations, perfumes and toilet preparations	Used for preservation applications, household cleaning agents and in nail hardeners amongst others			
	Manufacture of explosives	Formaldehyde is reacted with ammonia to produce hexamine			
C21	Manufacture of gelatin capsules and is also used as an inactivating agent in vaccines		2%	**11,273**	**0.9%**
C22	Hexamine (formaldehyde is used as a starting material) is used as a rubber accelerator; Phenol formaldehyde and Urea formaldehyde resins are used in fuse boxes, knobs and switches		0.5%	**8,320**	**0.7%**
C25	Preservative in use in metal remover fluids, anticorrosive agents and metalworking agents	Exposure could occur during metal finishing and plating	<0.1%	**4,325**	**15.2%**
C27	POM resins are used in the manufacture of electrical and electronic appliance parts (moulding).		5%	**73,456**	**6.1%**
C28	Phenol formaldehyde resin is used in the production of abrasive wheels.		0.1%	**2,944**	**0.2%**
C29	Used in many automotive applications		5%	**122,002**	**10.2%**
C30.3	Used in many aircraft applications		5%	**18,911**	**1.6%**
C31	Urea formaldehyde and Phenol formaldehyde resins are used as "glue resins" in furniture manufacturing		20%	**199,868**	**16.7%**

Table 3-7: Breakdown of exposed workers by sector					
Sector (NACE rev. 2)	**Use/Process**	**Details about formaldehyde application**	**Estimated share of workers exposed in the sector**	**Exposed workforce in EU28**	**%Share of total workers exposed**
E36	Used in water control (laboratories) and water purification	Based on the Italian SIREP database, only a small number of workers (50) were exposed in these two sectors in Italy between 1996 and 2014	0.5%	**1,940**	**0.2%**
E38	Precious metals recycling		0.5%	**4,617**	**0.4%**
F41	Formaldehyde based foams (urea-formaldehyde and phenol formaldehyde) are used as building materials, insulator materials		2%	**62,598**	**5.2%**
M72	Formaldehyde is used in the electrophoresis (method to separate mixtures by size) of RNA		0.5%	**3,053**	**0.3%**
M74.2	Photographic materials (plates and papers) and processes		10%	**15,901**	**1.3%**
M75	Formaldehyde is used as a veterinary biocidal agent in poultry sector		2%	**4,898**	**0.4%**
P85.4	Formaldehyde is used as a used as a preservative for specimen and tissue samples		2%	**27,344**	**2.3%**
Q86	Health services, dentistry, schools and universities	Operations where formaldehyde exposure could occur include in operating rooms and pathology laboratories	1%	**214,906**	**17.9%**
S96.0.3	Exposure could occur during the embalming activity		n/a	**4,000**	**0.3%**

Sources: Eurostat Structural Business Statistics database; Labour Force Survey, consultation responses and data derived by the study team

Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities

Table 3-8: Breakdown of potentially exposed workers to formaldehyde by MS																								
MS	A	C10	C13	C15	C16	C17	C20	C21	C22	C25	C27	C28	C29	C30.3	C31	E36	E38	F41	M72	M74.2	M75	P85.4	Q86	S96.03	TOTALS by MS
AT	557	748	432	37	107	1,014	217	283	148	88	1,463	80	1,563	57	3,334	8	75	1,246	48	364	105	1,218	3,818	n/a	**17,010**
BE	285	851	867	13	68	1,344	548	479	113	64	984	31	1,478	279	3,042	37	63	1,625	57	348	94	572	5,820	n/a	**19,060**
BG	1,607	822	623	316	133	1,481	174	169	144	67	1,648	32	1,051	1	6,220	85	74	1,137	17	141	26	474	1,448	n/a	**17,889**
CY	85	109	22	1	7	47	8	30	4	4	19	0	7	0	139	2	n/a	161	0	38	5	58	158	n/a	**903**
CZ	537	1,016	1,304	111	245	2,679	369	188	433	222	7,203	128	7,956	436	6,968	92	163	1,986	55	325	76	330	3,167	n/a	**35,990**
DE	2,631	7,895	3,893	145	466	9,013	4,114	2,571	2,116	1,031	16,018	1,111	42,541	3,757	17,623	175	738	5,837	871	2,432	983	7,924	45,798	n/a	**179,686**
DK	292	559	187	3	50	564	202	657	80	48	682	69	242	30	2,045	5	46	544	72	202	59	742	4,530	n/a	**11,908**
EE	110	138	224	29	168	241	31	6	20	15	493	4	165	0	2,676	6	10	288	5	37	7	96	335	n/a	**5,105**
EL	2,385	962	373	34	19	662	135	176	56	34	291	10	75	73	1,720	46	29	875	117	459	51	304	1,675	n/a	**10,562**
ES	4,250	3,163	1,991	695	273	4,862	1,033	782	451	262	3,838	99	7,148	1,111	12,625	217	531	8,576	220	1,573	408	3,140	13,454	n/a	**70,704**
FI	299	365	133	21	112	2,110	160	91	65	30	918	49	362	67	1,389	9	30	1,420	25	167	49	298	3,759	n/a	**11,926**
FR	3,736	5,111	1,945	475	387	7,485	1,838	1,777	732	365	6,746	179	11,166	5,546	10,887	189	527	3,434	279	1,898	477	2,184	34,749	n/a	**102,110**
HR	885	540	235	235	134	640	75	97	55	98	831	11	141	38	2,849	43	63	720	13	106	46	322	975	n/a	**9,154**
HU	2,181	933	714	346	184	2,732	186	349	242	90	4,134	62	4,428	26	6,882	111	101	1,121	74	274	50	420	2,582	n/a	**28,220**
IE	843	452	98	2	19	249	95	323	39	17	164	11	148	n/a	689	3	34	551	23	218	76	184	2,325	n/a	**6,563**
IT	4,176	3,914	6,099	1,938	379	6,557	1,308	1,151	854	586	7,494	452	8,010	1,596	24,634	155	695	6,402	123	1,847	306	180	15,095	n/a	**93,950**
LT	728	400	453	19	162	549	68	13	44	17	333	6	221	5	7,149	28	34	907	7	179	19	262	824	n/a	**12,427**
LV	411	216	148	3	94	90	35	41	15	13	94	4	92	4	890	9	20	465	4	65	17	136	493	n/a	**3,356**
LX	20	51	n/a	0	4	n/a	13	n/a	n/a	4	29	4	n/a	0	36	1	5	245	n/a	12	6	16	226	n/a	**672**
MT	27	29	n/a	0	2	n/a	4	23	n/a	2	34	n/a	n/a	0	319	n/a	3	75	0	n/a	2	32	164	n/a	**715**
NL	803	1,219	607	16	40	1,027	542	255	155	106	642	81	1,015	192	2,763	27	109	2,572	188	1,319	198	1,252	11,455	n/a	**26,583**
PL	9,616	3,927	2,690	386	665	6,246	969	460	951	359	5,954	126	8,915	799	37,550	160	308	5,318	54	1,146	272	1,948	8,349	n/a	**97,168**
PT	1,621	923	2,133	1,116	222	1,493	150	126	125	94	1,471	22	1,672	43	8,786	68	73	2,744	28	327	94	646	3,780	n/a	**27,759**
RO	7,772	1,619	1,608	1,178	448	1,794	301	185	286	107	2,933	52	8,446	231	17,408	180	232	3,527	69	251	124	556	3,743	n/a	**53,049**
SE	303	571	265	12	171	3,010	257	255	112	86	1,254	74	3,519	n/a	2,896	9	85	2,011	72	280	115	682	6,962	n/a	**23,000**
SI	411	149	148	63	47	492	79	n/a	69	37	1,231	14	637	9	1,332	20	25	275	21	66	16	142	576	n/a	**5,859**
SK	256	345	357	270	156	1,218	108	44	159	87	3,036	41	3,324	12	5,083	56	43	691	10	189	27	256	1,449	n/a	**17,219**
UK	1,505	3,740	2,551	60	291	4,205	1,263	740	850	393	3,521	193	7,677	4,602	11,934	201	501	7,843	597	1,638	1,191	2,970	37,197	3000	**98,662**

Table 3-8: Breakdown of potentially exposed workers to formaldehyde by MS																								
MS	A	C10	C13	C15	C16	C17	C20	C21	C22	C25	C27	C28	C29	C30.3	C31	E36	E38	F41	M72	M74.2	M75	P85.4	Q86	S96.03	TOTALS by MS
EU28	48,330	40,769	30,097	7,523	5,053	61,802	14,279	11,273	8,320	4,325	73,456	2,944	122,002	18,911	199,868	1,940	4,617	62,598	3,053	15,901	4,898	27,344	214,906	3,750	990,000
Sources: Eurostat Structural Business Statistics database; Labour Force Survey, consultation responses and data derived by the study team Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities. Data may not add up to the totals due to rounding.																								

3.5 Exposure concentrations

Agriculture, Forestry and Fishing (NACE Code A)

The use of formaldehyde for the treatment of parasites in fish farms has low levels of exposure from consultation. Personal Protection Equipment (PPE) is employed with exposure occurring outside with other risk management measures employed such as the use of masks. The concentration of formaldehyde used is 200 ppm (240 mg/m^3). No measurements of exposure concentrations are available; however, the exposure is assumed to be low (from consultation) and also for a short duration of time.

Manufacturing of food products (NACE Code C10)

No occupational exposure data was discussed in the most recent IARC assessment on formaldehyde (IARC, 2012) and the ANSES risk management option analysis (ANSES, 2016). There is also no occupational exposure levels report in the IARC 2002 assessment and no data has been identified in this study with no responses from the consultation process received, although it is reported that levels were above 0.1 ppm (0.12 mg/m^3) in food manufacturing for 1990 to 1993 (IARC, 2006).

The allowed concentration levels of formaldehyde in food products are covered by EU legislation. The concentrations of formaldehyde are regulated by Regulation (EC) No 231/2012/EC which limits the concentration to 50 mg/kg (50 ppm) in alganates and limits formaldehyde to a maximum of 0.1% of the food additive. The maximum quantity of formaldehyde allowed for sugar beet extraction is 400 mg/kg (400 ppm) every two hours (Aubrey and Gasnot, 2015). The use of formaldehyde in animal feed products is also regulated under EU legislation.

Manufacture of textiles (NACE Code C13)

Occupational exposure concentrations to formaldehyde in the manufacture of textiles are available for France (COLCHIC database) and Germany (MEGA database) from personal sampling measurements between 2002 and 2011. The exposure in the manufacturing of textiles in both countries is very similar (Clerc et al, 2015):

- In France, the P90 value for formaldehyde exposure is 0.3 ppm (0.37 mg/m^3); and
- In Germany, the P90 value for formaldehyde exposure is 0.32 ppm (0.39 mg/m^3) and the geometric mean is 0.03 mg/m^3.

Furthermore, in a study performed by TNO for Formacare (TNO Triskelion BV., 2013), exposure concentrations in textile manufacturing impregnation have been modelled using ECETOC TRA. For all the listed processes, there is enhanced general ventilation and PPE has been included in the modelling where indicated. Long term exposure is below 0.38 ppm (<0.46 mg/m^3) although for the highest exposure operation of industrial production for PROC codes 3 and 4 (PROC 3: Use in closed batch process (synthesis or formulation) and PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises), exposure is 0.32 ppm (0.38 mg/m^3) and below. Short term exposure is below 0.5 ppm (0.6 mg/m^3) for many of the operations apart from industrial compression/extraction; industrial production; industrial mixing/blending; and industrial calendaring where exposure is 0.62 ppm (0.75 mg/m^3). No responses were received during the consultation process for the manufacture of textiles.

Table 3-9: Leather and textile impregnation formaldehyde exposure						
Process	Concentration of formaldehyde (%)	PROC Code	Work area	PPE and efficiency	Long term Inhalation exposure (P75 value)	Short term Inhalation exposure (P95 value)
Industrial production	1-5	1,2	Indoors		0.16 ppm 0.19 mg/m^3	0.62 ppm 0.75 mg/m^3
Industrial production	1-5 (<=4 hours exposure)	3,4	Indoors		0.37 ppm 0.45 mg/m^3	N/A
Industrial production	1-5	3,4	Indoors	Respiratory; 90%	0.07 ppm 0.08 mg/m^3	0.15 ppm 0.18 mg/m^3
Industrial Mixing/Blending	1-5	5	Indoors		0.16 ppm 0.19 mg/m^3	0.62 ppm 0.75 mg/m^3
Industrial Calendaring	1-5	6	Indoors		0.16 ppm 0.19 mg/m^3	0.62 ppm 0.75 mg/m^3
Industrial Spraying	1-5 (<=1 hour exposure)	7	Indoors		0.32 ppm 0.38 mg/m^3	N/A
Industrial Spraying	1-5	7	Indoors	Respiratory; 90%	0.16 ppm 0.19 mg/m^3	0.12 ppm 0.15 mg/m^3
Industrial Transfers	1-5	8a, 8b, 9	Indoors	Respiratory; 90%	0.32 ppm 0.38 mg/m^3	0.12 ppm 0.15 mg/m^3
Industrial Rolling/Brushing	1-5	10	Indoors	Respiratory; 90%	0.32 ppm 0.38 mg/m^3	0.12 ppm 0.15 mg/m^3
Industrial Dipping/Pouring	1-5	13	Indoors		0.32 ppm 0.38 mg/m^3	0.12 ppm 0.15 mg/m^3
Industrial compression/extrusion	1-5	14	Indoors		0.16 ppm 0.19 mg/m^3	0.62 ppm 0.75 mg/m^3
Industrial cutting/cold rolling/assembly	1-5	21	Indoors	Respiratory; 90%	0.25 ppm 0.3 mg/m^3	0.1 ppm 0.12 mg/m^3
Industrial processing of minerals	1-5	22, 23	Indoors	Respiratory; 90%	0.25 ppm 0.3 mg/m^3	0.1 ppm 0.12 mg/m^3
Industrial cutting/sanding	1-5 (<=4 hours exposure)	24	Indoors		0.3 ppm 0.36 mg/m^3	N/A
Industrial cutting/sanding	1-5	24	Indoors	Respiratory; 90%	N/A	0.12 ppm 0.14 mg/m^3
Industrial welding/soldering	1-5	25	Indoors		0.12 ppm 0.15 mg/m^3	0.5 ppm 0.6 mg/m^3
Source: TNO Triskelion BV (2013): Analysis of worker exposure in manufacture and use of formaldehyde in Europe, including downstream applications. Available at: http://www.formacare.org/wp-content/uploads/2014/09/Worker-exposure-assessment-Formaldehyde-RMO_final.pdf						

Manufacture of leather and related products (NACE Code C15)

In the study performed by TNO for Formacare (TNO Triskelion BV, 2013), exposure concentrations for leather impregnation have been modelled using ECETOC TRA (listed in the above table alongside textile impregnation). For all of the listed processes, there is enhanced general ventilation and PPE has been included in the modelling where indicated. No information was received during the consultation process for the manufacture of leather and related products. Manufacture of wood and products of wood and cork; except furniture (NACE Code C16)

Occupational exposure concentrations to formaldehyde in the "manufacture of wood and products of wood and cork" are available for France (COLCHIC database) and Germany (MEGA database) from

personal sampling measurements performed between 2002 and 2011. These measurements also include exposure during the manufacturing of furniture.

The exposure in both countries is very similar (Clerc et al, 2015):

- In France, the P90 value for formaldehyde exposure is 0.34 ppm (0.41 mg/m^3); and
- In Germany, the P90 value for formaldehyde exposure is 0.39 ppm (0.47 mg/m^3).

In Italy, occupational exposure levels between 1996 to 2014 in the "manufacturing of wood and products of wood and cork; except furniture" were as follows (Scarselli et al, 2017):

- Manufacture of wood and of products of wood and cork except furniture; geometric mean of 0.08 ppm (0.10 mg/m^3) with a P75 of 0.17 ppm (0.20 mg/m^3);
- Manufacture of veneer sheets, plywood, particle board, other panels, and boards; geometric mean of 0.09 ppm (0.11 mg/m^3) with a P75 of 0.17 ppm (0.20 mg/m^3);
- Manufacture of builders' carpentry and joinery; geometric mean of 0.05 ppm (0.06 mg/m^3) with a P75 of 0.21 ppm (0.25 mg/m^3);
- Wood treaters; geometric mean of 0.14 ppm (0.17 mg/m^3) with a P75 of 0.16 ppm (0.19 mg/m^3);
- Woodworking machine setters and setter-operators; geometric mean of 0.017 ppm (0.02 mg/m^3) with a P75 of 0.17 ppm (0.20 mg/m^3);
- Wood processing plant operator; geometric mean of 0.08 ppm (0.10 mg/m^3) with a P75 of 0.17 ppm (0.20 mg/m^3); and
- Wood products machine operators; geometric mean of 0.083 ppm (0.01 mg/m^3) with a P75 of 0.08 ppm (0.10 mg/m^3).

Formaldehyde exposure during wood panel production from the TNO study (TNO Triskelion BV, 2013) is presented in the following table. The exposure levels are based on measured personal sampling. Long term exposure varies between 0.062 ppm (0.075 mg/m^3) and 0.36 ppm (0.43 mg/m^3). Short term exposure values vary from 0.08 ppm (0.12 mg/m^3) to 0.71 ppm (0.86 mg/m^3) for maintenance activities.

Exposure in the wood panel industry for manufacturers of particleboard, MDF, OSB, hardboard, softboard and plywood is currently between 0.4 ppm and 0.5 ppm (0.48 mg/m^3 to 0.6 mg/m^3). The industry is currently working towards an exposure concentration level of 0.3 ppm (0.37 mg/m^3) through investment and peak exposures are under control from consultation with the European Panel Federation.

Table 3-10: Panel production formaldehyde exposure					
Process	Concentration of formaldehyde (%)	Work area	PPE and efficiency	Long term Inhalation exposure)- P90 value	Short term Inhalation exposure)- P95 value
Operation of gluing, forming, pressing and cooling process (partial enclosure)	0.008-8	Indoors/outdoors	Respiratory; 90%	0.062 ppm 0.075 mg/m^3	0.12 ppm 0.15 mg/m^3
Paper impregnation (partial enclosure)	<0.2-1.5	Indoors		0.33 ppm 0.4 mg/m^3	0.66 ppm 0.79 mg/m^3
Paper lamination (partial enclosure)	<0.1-1	Indoors		0.12 ppm 0.15 mg/m^3	N/A
Paper lamination	<0.1-1	Indoors		N/A	0.4 mg/m^3
Operation of sanding and sawing line (partial enclosure)	0.008-1	Indoors		0.27 ppm 0.33 mg/m^3	N/A
Operation of sanding and sawing line	0.004-1	Indoors	Respiratory; 90%	N/A	0.12
Maintenance/Intervention of devices (partial enclosure)	0.008-1	Indoors		0.36 ppm 0.43 mg/m^3	0.71 ppm 0.86 mg/m^3
Cleaning (for example degreasing, blowing, sweeping)	0.1-1	Indoors	Respiratory; 90%	0.17 ppm 0.2 mg/m^3	0.33 ppm 0.4 mg/m^3
Sorting/Packing panels	0.008-1	Indoors		0.24 ppm 0.29 mg/m^3	N/A
Sorting/Packing panels	0.004-1	Indoors		N/A	0.7
Physical/Chemical testing	0.008-1	Indoors		0.25 ppm 0.3 mg/m^3	0.5 ppm 0.6 mg/m^3
Source: TNO Triskelion BV (2013): Analysis of worker exposure in manufacture and use of formaldehyde in Europe, including downstream applications. Available at: http://www.formacare.org/wp-content/uploads/2014/09/Worker-exposure-assessment-Formaldehyde-RMO_final.pdf					

Manufacture of paper and paper products (NACE Code C17)

In Italy, occupational exposure levels between 1996 to 2014 for paper products machine operators were 0.15 ppm (0.18 mg/m^3) (geometric mean) with a P75 value of 0.21 ppm (0.25 mg/m^3) from Scarselli *et al* (2017). No information was received during the consultation process for the manufacture of paper and paper products.

Modelled exposure values from the work carried out by TNO for exposure in paper and paper products are presented in the following table. In the modelling calculations, enhanced general ventilation (90% efficiency) is used for each process as the risk reduction measure. There are several operations in which long term exposure exceeds 0.3 ppm (0.37 mg/m^3) including in industrial spraying, industrial transfer, industrial dipping/pouring, industrial rolling/brushing paper impregnation.

Table 3-11: Production of foams, bonded particulates, bonded fibers/mats and paper formaldehyde exposure				
Process	**Concentration of formaldehyde (%)**	**Work area**	**Long term Inhalation exposure (P75 value)**	**Short term Inhalation exposure (P95 value)**
Industrial production	1-5	Indoors	0.16 ppm 0.19 mg/m^3	0.62 ppm 0.75 mg/m^3
Industrial production	1-5 (<=4 hours exposure)	Indoors	0.37 ppm 0.45 mg/m^3	N/A
Industrial production	1-5	Indoors	0.08 mg/m^3	0.15 ppm 0.18 mg/m^3
Industrial Mixing/Blending	1-5	Indoors	0.16 ppm 0.19 mg/m^3	0.62 ppm 0.75 mg/m^3
Industrial Calendaring	1-5	Indoors	0.16 ppm 0.19 mg/m^3	0.62 ppm 0.75 mg/m^3
Industrial Spraying	1-5 (<=1-hour exposure)	Indoors	0.32 ppm 0.38 mg/m^3	N/A
Industrial Spraying	1-5	Indoors	0.16 ppm 0.19 mg/m^3	0.12 ppm 0.15 mg/m^3
Industrial Transfers	1-5	Indoors	0.32 ppm 0.38 mg/m^3	N/A
Industrial Transfers	1-5	Indoors	N/A	0.12 ppm 0.15 mg/m^3
Industrial Rolling/Brushing	1-5	Indoors	0.32 ppm 0.38 mg/m^3	0.12 ppm 0.15 mg/m^3
Industrial Dipping/Pouring	1-5	Indoors	0.32 ppm 0.38 mg/m^3	0.12 ppm 0.15 mg/m^3
Industrial compression/extrusion	1-5	Indoors	0.16 ppm 0.19 mg/m^3	0.62 ppm 0.75 mg/m^3
Industrial cutting/cold rolling/assembly	1-5	Indoors	0.25 ppm 0.3 mg/m^3	0.1 ppm 0.12 mg/m^3
Industrial processing of minerals	1-5	Indoors	0.25 ppm 0.3 mg/m^3	0.1 ppm 0.12 mg/m^3
Industrial cutting/sanding	1-5 (<=4 hours exposure)	Indoors	0.3 ppm 0.36 mg/m^3	0.12 ppm 0.14 mg/m^3
Industrial welding/soldering	1-5	Indoors	0.12 ppm 0.15 mg/m^3	0.5 ppm 0.6 mg/m^3
Source: TNO Triskelion BV (2013): Analysis of worker exposure in manufacture and use of formaldehyde in Europe, including downstream applications. Available at: http://www.formacare.org/wp-content/uploads/2014/09/Worker-exposure-assessment-Formaldehyde-RMO_final.pdf Note: Exposure is based on the P95 value				

Manufacture of chemicals and chemicals products (NACE Code C20: C20.1, 20.2 and 20.4)

In Italy, occupational exposure levels between 1996 to 2014 in the manufacturing of chemicals and chemical products were as follows (Scarselli *et al*, 2017):

- Manufacture of chemicals and chemical products; geometric mean[15] of 0.0017 ppm (0.02 mg/m^3) with a P75 of 0.025 ppm (0.03 mg/m^3);
- Manufacture of other chemical products n.e.c; geometric mean of 0.0017 ppm (0.02 mg/m^3) with a P75 of 0.025 ppm (0.03 mg/m^3);

[15] The average set of products, the calculations of which is commonly used to determine the performance results of an investment or portfolio (Investopedia, accessed Feb 2018)

- Manufacture of man-made fibres; geometric mean of 0.025 ppm (0.03 mg/m^3) with a P75 of 0.033 ppm (0.04 mg/m^3);
- Chemical - still and reactor operators - except petroleum and natural gas; geometric mean of 0.0017 ppm (0.02 mg/m^3) with a P75 of 0.025 ppm (0.03 mg/m^3);
- Chemical processing plant operators not elsewhere classified; geometric mean of 0.0083 ppm (0.01 mg/m^3) with a P75 of 0.0083 ppm (0.01 mg/m^3); and
- Chemical and physical science technicians; geometric mean of 0.025 ppm (0.03 mg/m^3) with a P75 of 0.12 ppm (0.14 mg/m^3).

Measured exposure to formaldehyde in the chemicals industry in Germany from the MEGA database is listed below. These are for exposures longer than 6 hours except where stated.

Table 3-12: Exposure to formaldehyde in Germany for the chemicals industry (2002-2011)

Sampling method	LEV (with/without)	90th percentile	95th percentile
Personal sampling	Without differentiation	0.68 ppm 0.82 mg/m^3	0.85 ppm 1.036 mg/m^3
Personal sampling	With LEV	0.61 ppm 0.74 mg/m^3	0.73 ppm 0.876 mg/m^3
Personal sampling	Without LEV	0.72 ppm 0.862 mg/m^3	0.81 ppm 0.983 mg/m^3
Stationery sampling	Without differentiation	0.45 ppm 0.54 mg/m^3	0.87 ppm 1.05 mg/m^3
Stationery sampling	With LEV	0.79 ppm 0.956 mg/m^3	1.42 ppm 1.705 mg/m^3
Stationery sampling	Without LEV	0.074 ppm 0.0887 mg/m^3	0.26 ppm 0.318 mg/m^3
Personal sampling (<6 h exposure)	Without differentiation	0.67 ppm 0.812 mg/m^3	0.90 ppm 1.086 mg/m^3
Source: IFA (2013): MEGA-Auswertungen zur Erstellung von REACH-Expositionsszenarien Formaldehyd. Available at: http://www.dguv.de/medien/ifa/de/fac/reach/mega_auswertungen/formaldehyd.pdf			

Manufacture of formaldehyde

Measured data for processes involved in the manufacture of formaldehyde are presented in Table 3-13 below from the report prepared by TNO (TNO Triskelion BV, 2013). Long term exposure is <=0.19 ppm (<=0.23 mg/m^3) with short term exposure higher; the highest exposures (0.49 ppm= 0.59 mg/m^3) are associated with servicing, repairs, filter changing and cleaning activities. These values have been updated from consultation.

Updated information on exposure levels in the manufacturing of formaldehyde since the TNO report (TNO Triskelion BV, 2013) has been provided by Formacare, with reduced exposure levels from improved RMMs, as indicated in Table 3-14. Long term exposure values are 0.2 ppm (0.24 mg/m^3) or below, with the short term exposure levels 0.5 ppm (0.6 mg/m^3) or below.

Exposure levels below 0.3 ppm (0.37 mg/m^3) have also been confirmed during site visits, with measurements typically 0.22 ppm (0.27 mg/m^3) and below for long term exposure.

Table 3-13: Formaldehyde manufacturing exposure					
Process	**Concentration of formaldehyde (%)**	**Work area**	**PPE and efficiency**	**Long term Inhalation exposure (P90 value)**	**Short term Inhalation exposure (P95 value)**
Process control and sampling (Closed system; dedicated sampling points)	20-65	Indoor/outdoors		0.19 ppm 0.23 mg/m^3	N/A
Process control and sampling (Closed system and general ventilation; dedicated sampling points)	37-62	Indoor/outdoors	Respiratory; 90%	N/A	0.25 ppm 0.3 mg/m^3
Service/Repairs/Filter change/cleaning (Handling/Transfer in closed system; Drain down/Flush prior opening)	40-55	Indoor/outdoors		0.18 ppm 0.22 mg/m^3	N/A
Service/Repairs/Filter change/cleaning (Handling/Transfer in closed system; Drain down/Flush prior opening)	40-54	Indoor/outdoors	Respiratory; 90%	N/A	0.49 ppm 0.59 mg/m^3
Source: TNO Triskelion BV (2013): Analysis of worker exposure in manufacture and use of formaldehyde in Europe, including downstream applications. Available at: http://www.formacare.org/wp-content/uploads/2014/09/Worker-exposure-assessment-Formaldehyde-RMO_final.pdf					

Table 3-14: Exposure levels during the manufacture of formaldehyde		
Group	**Task**	**Exposure levels**
Process operators	Process control	0.2 ppm (long term); 0.24 mg/m^3 0.25 ppm (short term); 0.3 mg/m^3
Process operators	Product sampling	0.2 ppm (long term); 0.24 mg/m^3 0.25 ppm (short term); 0.3 mg/m^3
Loading operators	Loading/unloading and small (barrels) recipients	0.35 ppm (long term); 0.42 mg/m^3 0.22 ppm (short term); 0.26 mg/m^3
Process operators and laboratory personnel	Product analysis	0.2 ppm (long term); 0.24 mg/m^3 0.4 ppm (short term); 0.48 mg/m^3
Maintenance personnel	Service, repair, clean and/or perform filter change, prolonged interventions	0.18 ppm (long term); 0.22 mg/m^3 0.5 ppm (short term); 0.6 mg/m^3
Source: From consultation with Formacare (2017) Long term exposure values are the P90 value and short term exposure values are the P95 value Long term exposure measurements are not corrected for the effect of RPE (from correspondence, the effect of RPE could be exposure levels of up to ten times lower)		

Manufacture of resins

In the manufacture of resins (for example PF and UF resins), from consultation, the exposure levels for long term exposure are 0.3 ppm (0.36 mg/m^3) or below and for short term exposure levels are 0.5 ppm (0.6 mg/m^3) or below with RMMs employed, as indicated by the data presented in Table 3-15.

Table 3-15: Exposure during the manufacture of formaldehyde based resins

Group	Task	Exposure levels
Process operators	Process control	Long term: 0.3 ppm; 0.36 mg/m^3 Short term: 0.5 ppm; 0.6 mg/m^3
Process operators	Product sampling	Long term: 0.3 ppm; 0.36 mg/m^3 Short term: 0.5 ppm; 0.6 mg/m^3
Process operators	Operating semi-automated batch processes including charging raw materials and spray drying	Long term: 0.2 ppm; 0.24 mg/m^3 Short term: 0.17 ppm; 0.2 mg/m^3
Loading operators	Loading/unloading and small (barrels) recipients	Long term: 0.35 ppm; 0.42 mg/m^3 Short term: 0.22 ppm; 0.26 mg/m^3
Loading operators	Loading/unloading of solids into small (big bags) recipients	Long term: 0.25 ppm; 0.3 mg/m^3 Short term: 0.5 ppm; 0.6 mg/m^3
Process operators and laboratory personnel	Product analysis	Long term: 0.2 ppm; 0.24 mg/m^3 Short term: 0.4 ppm; 0.48 mg/m^3
Maintenance personnel	Service, repair, clean and/or perform filter change; prolonged and short interventions	Long term: 0.18 ppm; 0.22 mg/m^3 Short term: 0.5 ppm; 0.6 mg/m^3
Source: Consultation with Formacare (2017) Long term exposure values are the P90 value and short term exposure values are the P95 value		

Consultation has also found that exposure is typically below 0.3 ppm (0.37 mg/m^3) for long term exposure and exposure can be grouped into five similar exposed groups (SEGs)[16] for one facility:

- SEG 1: Workers in the production area and sampling;
- SEG 2: Workers involved in logistic work, packing and sampling;
- SEG 3: Workers involved in quality control (QC) and analysing;
- SEG 4: Sampling, analysing, and pilot work; and
- SEG 5: Field work, sampling, and maintenance workers.

From consultation and site visits, additional exposure concentrations for manufacturers of resins are:

- 0.17 ppm (0.21 mg/m^3), 0.22 ppm (0.27 mg/m^3) and 0.14 ppm (0.17 mg/m^3) at the reactors. There was one measurement of (1.11 mg/m^3) for sampling (~15 second process, performed ten times per batch), since this measurement additional risk management measures have been employed to achieve the SCOEL levels;

[16] A Similar Exposure Group (SEG) is a group of workers having the same general exposure profile for the chemical agent(s) being studied because of the similarity and frequency of the tasks they perform, the materials and processes with which they work and the similarity of the way they perform those tasks. A SEG can be constituted by one worker.

- 0.22 ppm (0.27 mg/m^3) for exposure in laboratories (analysing formaldehyde and urea-formaldehyde condensate and 0.11 ppm (0.13 mg/m^3) for the process man (takes samples outside, general verification and temperature measurement of the processes);

- Exposure concentrations of 0.083 ppm (0.1 mg/m^3) and below are generally measured at another resin manufacturing facility;
- Exposure concentrations of 0.19 ppm (0.23 mg/m^3) and below have been measured at another manufacturing facility with typical concentrations of 0.1 ppm to 0.12 ppm (0.12 mg/m^3 to 0.15 mg/m^3) measured; and
- The proposed SCOEL STEL of 0.6 ppm (0.72 mg/m^3) would present no issues.

Another formaldehyde and resin manufacturer reports that exposure levels to formaldehyde are below both the OEL (0.3 ppm) and the STEL (0.6 ppm). The OEL of 0.3 ppm (0.36 mg/m^3) may be exceeded during inspection and maintenance activities (short activities); however, the STEL of 0.6 ppm (0.72 mg/m^3) is not exceeded.

Consultation also found though that a reduction in the OEL and STEL may present issues for downstream users (discussed further in this section) and also countries with OELVs which are higher than 0.3ppm (0.37 mg/m^3).

Manufacture of other organic basic chemicals (NACE: 20.13)

Arithmetic mean exposure concentrations[17] in the range of 0.36 ppm to 0.4 ppm (0.43- 0.5 mg/m^3) (long-term exposure) and between 0.55-0.57 ppm (0.66-0.67 mg/m^3) (short-term exposure) have been reported through consultation.

Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms (NACE: 20.15)

Exposure concentration levels in the manufacture of fertiliser granules based on responses to consultation with Fertilizers Europe are given in Table 3-16.

An OEL of 0.3 ppm (0.37 mg/m^3) and a STEL of 0.6 ppm (0.72 mg/m^3) is regarded as the lowest technically feasible value. Exposure is below the SCOEL recommended OEL of 0.3 ppm (0.37 mg/m^3) with RMMs employed. The exposure measurements presented in the following table have been performed at urea-formaldehyde storage tank areas, the injection pump area, at the prilling tower top room or at the granulation equipment area (dependent on the applied technology) and at the storage and loading facilities. Maintenance activities on manufacturing equipment (such as columns, tanks, pumps and pipelines) are performed on previously cleaned systems to minimise formaldehyde exposure (from information received through consultation).

Exposure concentrations supplied by a manufacturer of slow-release fertilisers are reported to be generally below 0.22 ppm (0.27 mg/m^3).

[17] The arithmetic mean of a set of values is the quantity commonly called "the" mean or the average. Given a set of samples {xi}, the arithmetic mean is $\bar{x} \equiv 1/N \sum_{i=1}^{N} x_i$.

Table 3-16: Exposure concentrations in the manufacture of fertiliser granules			
Scenario	**Risk Management Measures**	**Type (unit)**	**Exposure value ppm (N)***
Process control including: Sampling; Indoor; and Urea-formaldehyde resin with 4.5% formaldehyde	General ventilation (natural and mechanical) Enclosed transfer Time duration: 4 hours max	Personal long term (raw value)	0.12 ppm (=0.14 mg/m^3) (N=1)
General operation, transfer, cleaning/maintenance, indoor/outdoor, 59% formaldehyde	Natural ventilation	Personal short-term (raw value)[2]	<0.16 ppm (=0.19 mg/m^3) (N=8)
Cleaning Indoor Urea-formaldehyde resin with 3% formaldehyde	General ventilation (mechanical) LEV	Stationary short-term (raw value)	0.22 ppm (=0.26 mg/m^3) (N=1)
Note: Exposure values not corrected for respiratory protection effect that may be used Source: Consultation with Fertilizers Europe			

Manufacture of plastics in primary forms (NACE Code C20.1.6)

From consultation with a manufacturer of resins for plastics in primary forms, exposure concentrations are below 0.2 ppm (0.24 mg/m^3) and below. Exposure levels from consultation with another manufacturer in the manufacture of plastics using formaldehyde in production and processing are between 0.4-0.5 mg/m^3 (0.33-0.42 ppm).

Table 3-17: Exposure concentrations in resin manufacturing for plastics	
Similar Exposed Groups (SEGs)	**Weighted geometric mean (Xgw)**
1	<0.1 ppm
2	< 0.1 ppm
3	0.17 ppm
4	0.17 ppm
5	0.16 ppm

Manufacturing of foams (such as UF and MF resin), bonded particulates and fibres/mats

Exposure levels to formaldehyde have been modelled for the processes involved in the manufacture of foams, bonded particulates, bonded fibers/mats and paper by TNO Triskelion. These are described in the following table. Typically, low concentrations are used (1-5%), with the highest long term exposure associated with spaying and transfer (0.32 ppm; 0.38 mg/m^3) and the highest short term exposure limit of 0.62 ppm; 0.75 mg/m^3 is associated with mixing/blending, calendaring, and compression/extrusion. The use of LEV has been used in the model calculations. More detailed information on foam production is presented in the following table based on modelling results (LEV is assumed to be in use in these cases). No information was received during the consultation process for the manufacturing of foams.

Table 3-18: Production of foams, bonded particulates, bonded fibers/mats and paper formaldehyde exposure				
Process	**Concentration of formaldehyde (%)**	**Work area**	**Long term Inhalation exposure (P75 value)**	**Short term Inhalation exposure (P95 value)**
Industrial production	1-5	Indoors	0.16 ppm (0.19 mg/m^3)	0.62 ppm (0.75 mg/m^3)
Industrial production	1-5 (<=4 hours exposure)	Indoors	0.37 ppm (0.45 mg/m^3)	N/A
Industrial production	1-5	Indoors	0.07 ppm (0.08 mg/m^3)	0.15 ppm (0.18 mg/m^3)
Industrial Mixing/Blending	1-5	Indoors	0.16 ppm (0.19 mg/m^3)	0.62 ppm (0.75 mg/m^3)
Industrial Calendaring	1-5	Indoors	0.16 ppm (0.19 mg/m^3)	0.62 ppm (0.75 mg/m^3)
Industrial Spraying	1-5 (<=1 hour exposure)	Indoors	0.38 mg/m^3)	N/A
Industrial Spraying	1-5	Indoors	0.16 ppm (0.19 mg/m^3)	0.12 ppm (0.15 mg/m^3)
Industrial Transfers	1-5	Indoors	0.32 ppm (0.38 mg/m^3)	N/A
Industrial Transfers	1-5	Indoors	N/A	0.12 ppm (0.15 mg/m^3)
Industrial Rolling/Brushing	1-5	Indoors	0.32 ppm (0.38 mg/m^3)	0.12 ppm (0.15 mg/m^3)
Industrial Dipping/Pouring	1-5	Indoors	0.32 ppm (0.38 mg/m^3)	0.12 ppm (0.15 mg/m^3)
Industrial compression/extrusion	1-5	Indoors	0.16 ppm (0.19 mg/m^3)	0.63 ppm (0.75 mg/m^3)
Industrial cutting/cold rolling/assembly	1-5	Indoors	0.25 ppm (0.3 mg/m^3)	0.1 ppm (0.12 mg/m^3)
Industrial processing of minerals	1-5	Indoors	0.25 ppm (0.3 mg/m^3)	0.1 ppm (0.12 mg/m^3)
Industrial cutting/sanding	1-5 (<=4 hours exposure)	Indoors	0.3 ppm (0.36 mg/m^3)	0.12 ppm (0.14 mg/m^3)
Industrial welding/soldering	1-5	Indoors	0.12 ppm (0.15 mg/m^3)	0.5 ppm (0.6 mg/m^3)
Source: TNO Triskelion BV (2013): Analysis of worker exposure in manufacture and use of formaldehyde in Europe, including downstream applications. Available at: http://www.formacare.org/wp-content/uploads/2014/09/Worker-exposure-assessment-Formaldehyde-RMO_final.pdf				

Table 3-19: Foam production formaldehyde exposure					
Process	Concentration of formaldehyde (%)	PROC Code	Work area	Long term Inhalation exposure (P75 value)	Short term Inhalation exposure (P90 value)
Professional mixing/blending	1-1.5 (<=1 hour exposure)	5	Indoors	0.29 ppm 0.35 mg/m^3	N/A
Professional mixing/blending	1-1.5	5	Indoors	0.14 ppm 0.18 mg/m^3	0.12 ppm 0.14 mg/m^3
Professional Transfer	1-1.5 (<=1 hour exposure)	8a	Indoors	0.08 ppm 0.09 mg/m^3	N/A
Professional Transfer	1-1.5	8a	Indoors	N/A	0.3 ppm 0.36 mg/m^3
Professional Transfer	1-1.5 (<=1 hour exposure)	8b	Indoors	0.14 ppm 0.18 mg/m^3	N/A
Professional Transfer	1-1.5	8b	Indoors	0.08 ppm 0.09 mg/m^3	0.58 ppm 0.7 mg/m^3
Professional Rolling/Brushing	1-1.5 (<=1 hour exposure)	10	Outdoors	0.37 ppm 0.44 mg/m^3	N/A
Professional Rolling/Brushing	1-1.5	10	Outdoors	N/A	0.73 ppm 0.88 mg/m^3
Professional Rolling/Brushing	1-1.5 (<=1 hour exposure)	10	Indoors	0.37 ppm 0.44 mg/m^3	N/A
Professional Rolling/Brushing	1-1.5	10	Indoors	N/A	0.73 ppm 0.88 mg/m^3
Professional Dipping/Pouring	1-1.5 (<=1 hour exposure)	13	Indoors	0.29 ppm 0.35 mg/m^3	N/A
Professional Dipping/Pouring	1-1.5	13	Indoors	N/A	0.12 ppm 0.14 mg/m^3
Professional Lab use	1-1.5 (<=1 hour exposure)	15	Indoors	0.14 ppm 0.18 mg/m^3	N/A
Professional Lab use	1-1.5	15	Indoors	0.08 ppm 0.09 mg/m^3	0.58 ppm 0.7 mg/m^3
Professional Cutting/cold rolling/assembly	1-1.5 (<=15 min exposure)	21	Indoors	0.23 ppm 0.28 mg/m^3	N/A
Professional Cutting/cold rolling/assembly	1-1.5	21	Indoors	0.23 ppm 0.28 mg/m^3	0.09 ppm 0.11 mg/m^3
Professional processing of minerals	1-1.5 (<=15 min exposure)	23	Indoors	0.33 ppm 0.4 mg/m^3	N/A
Professional processing of minerals	1-1.5	23	Indoors	0.33 ppm 0.4 mg/m^3	0.12 ppm 0.16 mg/m^3
Professional Cutting/sanding	1-1.5 (<=15 mins exposure)	24	Indoors	0.29 ppm 0.35 mg/m^3	N/A
Professional Cutting/sanding	1-1.5	24	Indoors	0.29 ppm 0.35 mg/m^3	0.12 ppm 0.14 mg/m^3
Professional welding/soldering	1-1.5 (<=1 hour exposure)	25	Indoors	0.33 ppm 0.4 mg/m^3	N/A
Professional welding/soldering	1-1.5	25	Indoors	0.17 ppm 0.2 mg/m^3	0.12 ppm 0.16 mg/m^3
Source: TNO Triskelion BV (2013): Analysis of worker exposure in manufacture and use of formaldehyde in Europe, including downstream applications. Available at: http://www.formacare.org/wp-content/uploads/2014/09/Worker-exposure-assessment-Formaldehyde-RMO_final.pdf					

Measured data for exposure to formaldehyde in fiber/mats production (application of adhesives and coatings) from the TNO report (TNO Triskelion BV, 2013) are given below. Curtain painting has the highest level of long term inhalation exposure (1.71 ppm; 2.06 mg/m^3), and is above all the considered OELs. No PPE or RMM measures are discussed for reducing exposure.

Table 3-20: Fiber/mats production (application of adhesives and coatings) formaldehyde exposure			
Process	**Concentration of formaldehyde (%)**	**Long term Inhalation exposure (P75 value)**	**Short term Inhalation exposure (P95 value)**
Roller painting	0.1	0.08 ppm 0.09 mg/m^3	0.14 ppm 0.17 mg/m^3
Rolling/brushing	0.1	0.1 ppm 0.12 mg/m^3	N/A
Dip painting	0.1	0.25 ppm 0.3 mg/m^3	N/A
Manual spraying	0.1	0.44 ppm 0.53 mg/m^3	N/A
Automatic spraying	0.1	0.18 ppm 0.22 mg/m^3	N/A
Curtain painting	0.1	1.71 ppm 2.06 mg/m^3	N/A
Source: TNO Triskelion BV (2013): Analysis of worker exposure in manufacture and use of formaldehyde in Europe, including downstream applications. Available at: http://www.formacare.org/wp-content/uploads/2014/09/Worker-exposure-assessment-Formaldehyde-RMO_final.pdf			

Manufacture of basic pharmaceutical products and pharmaceutical preparations (NACE Code C21)

From consultation, in "charging" processes (used in manufacturing), short term exposure (15 minutes) and long term exposure (8 hour TWA) are below 0.025 ppm (0.03 mg/m^3). Four scenarios have been used for this sector for exposure concentration; please see section 4.7.2 for more information.

Manufacture of rubber and plastic products (NACE Code C22)

Formaldehyde exposure can also occur during the production of tyres and plastic products with measured exposure values discussed in the following table from modelling performed by TNO Triskelion BV. Long term exposure varies between 0.017 ppm and 0.22 ppm (0.02 and 0.26 mg/m^3) and short term exposure varies between 0.025 ppm and 0.43 ppm (0.03 and 0.52 mg/m^3). The figures are for measured values with either natural ventilation, LEV or a combination of both employed. No information was received during the consultation process for the manufacture of rubber and plastic products.

Table 3-21: Tyre and rubber manufacturing formaldehyde exposure					
Process	**Concentration of formaldehyde (%)**	**Work area**	**Use of LEV**	**Long term Inhalation exposure (P90 value)**	**Short term Inhalation exposure (P95 value)**
Weighing & Loading chemicals	5	Indoors	Natural and mechanical	0.22 ppm 0.26 mg/m^3	0.43 ppm 0.52 mg/m^3
Mixing	5	Indoors	Natural and mechanical	0.06 ppm 0.07 mg/m^3	0.12 ppm 0.14 mg/m^3
Shaping	5	Indoors	Natural and/or mechanical	0.06 ppm 0.07 mg/m^3	0.11 ppm 0.13 mg/m^3
Vulcanization/Curing (partial enclosure)	Traces	Indoors	Natural and/or mechanical	0.017 ppm 0.02 mg/m^3	0.025 ppm 0.03 mg/m^3
Finishing; Adhesion/Glueing (partial enclosure)	0.53-7.4	Indoors	Natural and/or mechanical	0.066 ppm 0.08 mg/m^3	0.12 ppm 0.15 mg/m^3
Finishing; Cutting	Traces	Indoors	Natural and mechanical	0.017 ppm 0.02 mg/m^3	0.033 ppm 0.04 mg/m^3
Finishing; Tyre building	Traces	Indoors	Natural and mechanical	0.025 ppm 0.03 mg/m^3	0.05 ppm 0.06 mg/m^3
Source: TNO Triskelion BV (2013): Analysis of worker exposure in manufacture and use of formaldehyde in Europe, including downstream applications. Available at: http://www.formacare.org/wp-content/uploads/2014/09/Worker-exposure-assessment-Formaldehyde-RMO_final.pdf					

In Italy, occupational exposure levels for 1996 to 2014 in the manufacturing of rubber and plastic products are as follows (Scarselli et al, 2017):

- Manufacture of rubber and plastic products; geometric mean of 0.058 ppm (0.07mg/m^3) with a P75 of 0.24 ppm (0.29 mg/m^3);
- Manufacture of other plastic products; geometric mean of 0.058 ppm (0.07mg/m^3) with a P75 of 0.24 ppm (0.29mg/m^3); and
- Plastic products machine operators; geometric mean of 0.033 ppm (0.04 mg/m^3) with a P75 of 0.075 (0.09 mg/m^3).

In Germany, measured exposures to formaldehyde between 2002 and 2011 in the plastic industry are reported in the MEGA database, and presented in Table 3-22.

Table 3-22: Exposure to formaldehyde in Germany in the plastic industry (2002-2011)			
Sampling method	**LEV (with/without)**	**90th percentile**	**95th percentile**
Personal sampling (>6h exposure)	Without differentiation	0.31 ppm 0.37 mg/m^3	0.38 ppm 0.459 mg/m^3
Personal sampling (>6h exposure)	With LEV	0.31 ppm 0.373 mg/m^3	0.45 ppm 0.546 mg/m^3
Personal sampling (>6h exposure)	Without LEV	0.14 ppm 0.17 mg/m^3	0.22 ppm 0.26 mg/m^3
Stationery sampling (>6h exposure)	Without differentiation	0.19 ppm 0.23 mg/m^3	0.37 ppm 0.46 mg/m^3
Stationery sampling (>6h exposure)	With LEV	0.18 ppm 0.214 mg/m^3	0.43 ppm 0.521 mg/m^3
Stationery sampling (>6h exposure)	Without LEV	0.12 ppm 0.155 mg/m^3	0.19 ppm 0.225 mg/m^3
Personal sampling (<6 h exposure)	Without differentiation	0.48 ppm 0.582 mg/m^3	2.64 ppm 3.184 mg/m^3
Stationery sampling (<6 h exposure)	Without differentiation	0.29 ppm 0.35 mg/m^3	0.32 ppm 0.39 mg/m^3
Stationery sampling (<6 h exposure)	With LEV	0.32 ppm 0.38 mg/m^3	0.33 ppm 0.4 mg/m^3
Source: IFA (2013): MEGA-Auswertungen zur Erstellung von REACH-Expositionsszenarien Formaldehyd. Available at: http://www.dguv.de/medien/ifa/de/fac/reach/mega_auswertungen/formaldehyd.pdf			

Manufacture of fabricated metals, except machinery and equipment (NACE Code C25)

In Italy (Scarselli *et al*, 2017), occupational exposure levels for 1996 to 2014 for metal finishing, plating, and coating machine operators were 0.025 ppm (0.03 mg/m^3) (geometric mean) with a P75 of 0.05 ppm (0.06 mg/m^3).

Data for exposures in Germany, between 2002 and 2011, from the MEGA database for metal production are presented in Table 3-23 below. Exposure from foundries, based on consultation responses is in the range of 0.01-0.02 ppm (0.012-0.024 mg/m^3), with a maximum exposure concentration of 0.09 ppm (0.11 mg/m^3).

Table 3-23: Exposure to formaldehyde in Germany in metal production (2002-2011)			
Sampling method	**LEV (with/without)**	**90th percentile**	**95th percentile**
Personal sampling (>6h exposure)	Without differentiation	0.14 ppm 0.17 mg/m^3	0.25 ppm 0.298 mg/m^3
Personal sampling (>6h exposure)	With LEV	0.16 ppm 0.19 mg/m^3	0.28 ppm 0.341 mg/m^3
Personal sampling (>6h exposure)	Without LEV	0.14 ppm 0.17 mg/m^3	0.19 ppm 0.231 mg/m^3
Stationery sampling (>6h exposure)	Without differentiation	0.1 ppm 0.12 mg/m^3	0.17 ppm 0.2 mg/m^3
Stationery sampling (>6h exposure)	With LEV	0.12 ppm 0.14 mg/m^3	0.20 ppm 0.241 mg/m^3
Stationery sampling (>6h exposure)	Without LEV	0.085 ppm 0.102 mg/m^3	0.12 ppm 0.14 mg/m^3
Source: IFA (2013): MEGA-Auswertungen zur Erstellung von REACH-Expositionsszenarien Formaldehyd. Available at: http://www.dguv.de/medien/ifa/de/fac/reach/mega_auswertungen/formaldehyd.pdf			

Clerc *et al* (2015) have reported data for exposure to formaldehyde in France and Germany for the manufacture of basic metals as follows:

- In France, the geometric mean for formaldehyde exposure is 0.06 ppm (0.07 mg/m^3), with a P90 value of 0.26 ppm (0.29 mg/m^3); and
- In Germany, the geometric mean for formaldehyde exposure is 0.02 ppm (0.03 mg/m^3), with a P90 value of 0.12 ppm (0.14 mg/m^3).

Manufacture of electrical equipment (NACE Code C27)

In Germany, measured exposures to formaldehyde in the electrical engineering, mechanics and optics sectors from the MEGA database are as listed below.

From information received from consultation, exposure on metal coating lines is below 0.12 ppm (0.15 mg/m^3).

Table 3-24: Exposure to formaldehyde in Germany for electrical equipment (2002-2011)

Sampling method	LEV (with/without)	90th percentile	95th percentile
Personal sampling (>6h exposure)	Without differentiation	0.084 ppm 0.101 mg/m^3	0.17 ppm 0.203 mg/m^3
Personal sampling (>6h exposure)	With LEV	0.028 ppm 0.034 mg/m^3	0.08 ppm 0.098 mg/m^3
Personal sampling (>6h exposure)	Without LEV	0.16 ppm 0.192 mg/m^3	0.19 ppm 0.231 mg/m^3
Stationery sampling (>6h exposure)	Without differentiation	0.028 ppm 0.034 mg/m^3	0.05 ppm 0.06 mg/m^3
Stationery sampling (>6h exposure)	With LEV	0.028 ppm 0.033 mg/m^3	0.04 ppm 0.05 mg/m^3
Stationery sampling (>6h exposure)	Without LEV	0.028 ppm 0.034 mg/m^3	0.074 ppm 0.0887 mg/m^3
Average (>6h exposure)		0.059 ppm 0.071 mg/m^3	0.10 ppm 0.122 mg/m^3
Personal sampling (<6 h exposure)	Without differentiation	0.31 ppm 0.37 mg/m^3	0.37 ppm 0.445 mg/m^3
Personal sampling (<6 h exposure)	With LEV	0.15 ppm 0.178 mg/m^3	0.28 ppm 0.336 mg/m^3
Personal sampling (<6 h exposure)	Without LEV	0.33 ppm 0.4 mg/m^3	0.41 ppm 0.492 mg/m^3
Stationery sampling (<6h exposure)	Without differentiation	0.033 ppm 0.0402 mg/m^3	0.059 ppm 0.0709 mg/m^3
Stationery sampling (<6h exposure)	With LEV	0.033 ppm 0.04 mg/m^3	0.062 ppm 0.0745 mg/m^3
Stationery sampling (<6h exposure)	Without LEV	0.03 ppm 0.036 mg/m^3	0.035 ppm 0.0416 mg/m^3

Source: Source: IFA (2013): MEGA-Auswertungen zur Erstellung von REACH-Expositionsszenarien Formaldehyd. Available at: http://www.dguv.de/medien/ifa/de/fac/reach/mega_auswertungen/formaldehyd.pdf

Manufacture of machinery and equipment n.e.c. (NACE Code C28)

In the production of abrasive wheels, for mixing and pressing/liquid phenol formaldehyde resin, exposure is 0.12 ppm (0.15 mg/m^3) for an 8- hour TWA.

Manufacture of motor vehicles, trailers and semi-trailers (NACE Code C29)

In the transport sector, the P95 exposure concentration is reported in the MEGA database for Germany (2002-2011) as 0.087 ppm (0.105 mg/m^3), with no differentiation and 0.073 ppm (0.0876 mg/m^3) with differentiation (IFA, 2013). As discussed, in the production of abrasive wheels, for mixing and pressing/liquid phenol formaldehyde resin, exposure is 0.12 ppm (0.15 mg/m^3) for an 8-hour TWA.

Manufacture of furniture (NACE Code C31)

Occupational exposure concentrations to formaldehyde in the "manufacture of wood and products of wood and cork" are available for France (COLCHIC database) and Germany (MEGA database) from personal sampling measurements. These measurements also include exposure during the manufacturing of wood products.

The concentration in both countries is very similar (Clerc et al, 2015):

- In France, the P95 value for formaldehyde exposure is 0.34 ppm (0.41 mg/m^3); and
- In Germany, the P95 value for formaldehyde exposure is 0.39 ppm (0.47 mg/m^3).

In Italy, occupational exposure levels for 1996 to 2014 in the manufacturing of furniture are as follows (Scarselli *et al*, 2015):

- Manufacture of furniture: geometric mean of 0.017 ppm (0.02 mg/m^3), with a P75 of 0.21 ppm (0.25 mg/m^3); and
- Manufacture of other furniture: geometric mean of 0.017 ppm (0.02mg/m^3), with a P75 of 0.21 ppm (0.25mg/m^3).

From consultation, one furniture manufacturer is working to a higher OEL than the proposed SCOEL OEL. This OEL is the national OEL, so it may also be the case that other manufacturers are working to national OELs which are higher than the proposed SCOEL OEL.

Water supply, sewerage, waste management and remediation (NACE Code E)

Formaldehyde exposure for incinerator, water-treatment and related plant operators (NACE Code E) in Italy (Scarselli et al, 2017) between 1996 and 2014 was 0.083 ppm (0.01 mg/m^3) (geometric mean), with a P75 value of 0.0058 ppm (0.007 mg/m^3).

Construction of buildings (NACE Code F41)

ANSES (2016) state that the global exposure of formaldehyde has decreased from 1.28 ppm (1.54 mg/m^3) (2000-2006) to 0.4 ppm (0.48 mg/m^3) (2007-2013). In roofing, exposure from all materials (except for plumbing) is 0.62 ppm (0.75 mg/m^3) (P95) and for joinery activities (manufacture and installation, including or not the structural wood) exposure is 0.35 ppm (0.42 mg/m^3) (P90 values). For these two activities, ANSES conclude that further risk reduction measures are required. No information was received during the consultation process for construction.

In the MEGA database for Germany, the measured formaldehyde exposure in the construction industry is reported as follows:

Table 3-25: Exposure to formaldehyde in Germany for the construction industry			
Sampling method	**LEV (with/without)**	**90th percentile**	**95th percentile**
Personal sampling	Without differentiation	0.12 ppm 0.138 mg/m^3	0.18 ppm 0.213 mg/m^3
Personal sampling	With LEV	0.12 ppm 0.159 mg/m^3	0.21 ppm 0.258 mg/m^3
Stationery sampling	Without differentiation	0.068 ppm 0.0823 mg/m^3	0.09 ppm 0.11 mg/m^3
Stationery sampling	With LEV	0.044 ppm 0.053 mg/m^3	0.069 ppm 0.0828 mg/m^3
Stationery sampling	Without LEV	0.067 ppm 0.081 mg/m^3	0.074 ppm 0.089 mg/m^3
Source: IFA (2013): MEGA-Auswertungen zur Erstellung von REACH-Expositionsszenarien Formaldehyd. Available at: http://www.dguv.de/medien/ifa/de/fac/reach/mega_auswertungen/formaldehyd.pdf			

Professional, Scientific and Technical Activities: Photographic activities (NACE Code M74.2)

In the development of photographic films, formaldehyde exposure is usually well below 1 ppm (1.2 mg/m^3), although this was reported by IARC in 1995 (World Health Organisation, 2002). In a study performed by RPA in 2006, there was movement in the industry to formaldehyde free processes (formaldehyde is used as a stabiliser) due to the shift to digital films (RPA, 2006).

Professional, Scientific and Technical Activities: Scientific research and development (NACE Code M72)

Formaldehyde exposure in laboratories is reported in the MEGA database for Germany (2002-2011). The P95 values are as follows for personal sampling (IFA, 2013):

- For over 6 hours' exposure: 0.76 ppm (0.92 mg/m^3) without differentiation and 0.91 ppm (1.1 mg/m^3) with capture (ventilation etc.).

ANSES (2016) report that in France and for biological laboratories (from the COLCHIC database) the P90 concentration value is 0.89 ppm (1.07 mg/m^3).

The IARC monograph on formaldehyde (2012) also discusses occupational exposure to formaldehyde in laboratories with the following exposure levels reported (IARC, 2012):

- Exposure levels of 0.44 ± 0.08 ppm (0.53 ± 0.1 mg/m^3) were reported in an anatomy-pathological laboratory in Portugal based on a study published in 2008; and
- Exposure levels of up to 0.22 ppm (0.27 mg/m^3) were reported in a cancer research laboratory in Italy (2008).

No information was received for exposure levels during the consultation process for this sector.

Professional, Scientific and Technical Activities: Veterinary activities (NACE Code M75)

In the MEGA database for Germany, the measured formaldehyde exposure in the veterinary sector between 2002 and 2013 are as follows:

Table 3-26: Exposure to formaldehyde in Germany for veterinary activities (<6 hours exposure)			
Sampling method	**LEV (with/without)**	**90th percentile**	**95th percentile**
Personal sampling	Without differentiation	2.49 ppm 2.998 mg/m^3	3.191 ppm 3.845 mg/m^3
Personal sampling	With LEV	1.44 ppm 1.74 mg/m^3	1.69 ppm 2.03 mg/m^3
Personal sampling	Without LEV	3.352 ppm 4.039 mg/m^3	5.658 ppm 6.816 mg/m^3
Stationery sampling	Without differentiation	1.076 ppm 1.296 mg/m^3	1.981 ppm 2.387 mg/m^3
Stationery sampling	With LEV	0.537 ppm 0.647 mg/m^3	0.620 ppm 0.747 mg/m^3
Stationery sampling	Without LEV	2.03 ppm 2.44 mg/m^3	2.289 ppm 2.756 mg/m^3
Source: IFA (2013): MEGA-Auswertungen zur Erstellung von REACH-Expositionsszenarien Formaldehyd. Available at: http://www.dguv.de/medien/ifa/de/fac/reach/mega_auswertungen/formaldehyd.pdf			

No information was received during the consultation process for this sector.

Higher Education (NACE Code P85.4)

In the fixation of human bodies, exposure to formaldehyde is above both 0.3 ppm (0.37 mg/m^3) for long term exposure and 0.6 ppm for short term exposure (0.72 mg/m^3) and is regularly exceeded (Thullner *et al*, 2016). For this activity, exposure is for short periods (5-10 mins) and performed 5-50 times per year depending on the department.

Table 3-27: Formaldehyde exposure in German dissection halls					
Department	**Table extraction**	**ACH**	**Mean room temperature (°C)**	**Exposure levels**	**Formaldehyde used/body (L)**
A (27 samples)	Yes	7	20	0.37 ppm (0.17-0.83 ppm) 0.44 mg/m^3 (0.21-1.0 mg/m^3)	2.8
C (24 samples)	No	27	20	0.95 ppm (0.35-2.1 ppm) 1.14 mg/m^3 (0.42-2.5 mg/m^3)	3.0
E (8 samples)	No	7	20-25	0.47 ppm (0.3-0.66 ppm) 0.57 mg/m^3 (0.37-0.8 mg/m^3)	0.9
I (18 samples)	No	23	14	0.34 ppm (0.15-0.66 ppm) 0.41 mg/m^3 (0.18-0.79 mg/m^3)	0.1
N (21 samples)	No	6	18-20	0.47 ppm (0.2-1.6 ppm) 0.57 mg/m^3 (0.31-1.9 mg/m^3)	0.5
Source: Thullner I et al. (2016): Formaldehyde in preclinical medical training (anatomy) [German]. Gefahrstoffe – Reinhaltung der Luft, 76 (10), pp 219-228. ACH: Air changes per hour					

Exposure in dissection halls for teaching staff is for approximately 90-180 minutes per day for four months per year. From consultation, exposure to formaldehyde decreases as a course progresses (the

measurements in the above table are from the beginning of a course). One teaching hospital department has formaldehyde exposure below 0.3 ppm (0.37 mg/m^3) for long term exposure and measured at 0.61 ppm (0.74 mg/m^3) for short term exposure, although there are peak exposures above this level.

Human health and social work activities: Human health activities (NACE Code Q86)

Formaldehyde exposure for human health activities (for example for use in hospitals and dentistry) has been recorded for French and Germany (Clerc *et al*, 2015)

The concentrations reported in France and Germany in the health sector is as follows:

- In France, the geometric mean is 0.12 ppm (0.16 mg/m^3) and the P90 value for formaldehyde exposure is 0.89 ppm (1.07 mg/m^3); and
- In Germany, the geometric mean is 0.19 ppm (0.23 mg/m^3) and the P90 value for formaldehyde exposure is 0.78 ppm (0.94 mg/m^3).

In Italy, occupational exposure levels for 1996 to 2014 for health and social work are as follows (Scarselli *et al*, 2015):

- Health and social work: geometric mean of 0.14 ppm (0.17 mg/m^3), with a P75 of 0.34 ppm (0.41 mg/m^3);
- Hospital activities: geometric mean of 0.17 ppm (0.20 mg/m^3), with a P75 of 0.34 ppm (0.41 mg/m^3); and
- Medical doctors: geometric mean of 0.25 ppm (0.30 mg/m^3), with a P75 of 1.54 ppm (1.85 mg/m^3).

In consultation with the Dutch Hospital Association (Nederlandse Vereniging van Ziekenhuizen), exposure in hospitals in the Netherlands is below the SCOEL recommended limits. Exposure concentrations for short term and long term exposure are below 0.12 ppm (0.15 mg/m^3) in the use of formaldehyde in operating rooms; the use of formaldehyde in laboratories; the use of formaldehyde in paediatrics; and the use of formaldehyde in gynaecology. Two measurements are taken for each department per year.

Exposure in a pathological lab (from consultation) is 0.04 ppm (0.05 mg/m^3) for a shift (maximum of 4 hours exposure daily), whilst short term exposure is >0.62 ppm (0.75 mg/m^3).

Funeral services (NACE Code S96.0.3)

Exposure levels during embalming have been reported to be very high, with average levels greater than 0.5 ppm (0.6 mg/m^3) and maximum exposure up to 4 ppm (4.8 mg/m^3) (SUBSPORT, 2013). From consultation with the Dodge Company, in a UK HSE study for Dignity, <0.1 ppm (<0.083 mg/m^3) exposure to formaldehyde was measured if risk reduction measures are followed.

3.6 Current Risk Management Measures (RMMs)

3.6.1 Overview for formaldehyde

REACH registration dossier recommendations

For handling formaldehyde (specifically formalin), information on a number of recommended risk management measures (including recommended personal protection equipment) is publicly available. This includes information in the REACH registration dossier, in safety data sheets and in guidelines produced by member state authorities.

The REACH dossier for formaldehyde lists the following measures to reduce exposure (ECHA, 2017b):

- Ensure the ventilation of stores and work areas; and
- Handle formaldehyde in accordance with good hygiene and safety practice.

The recommended personal protection equipment (such as hand, eye and body protection) and respiratory protection to reduce exposure to formaldehyde is also listed in the registration dossier. These recommended measures are summarised in the table below. For respiratory protection, for low concentrations, the apparatus recommended can have an 95% efficiency (Cefic, undated).

Table 3-28: Recommended Personal Protection Equipment (PPE) for formaldehyde

Protection	Details
Respiratory protection	For short-term effect or lower concentrations: Use a gas filter for gases/vapours for inorganic compounds such as EN 14387 Type B; For long-term effect or higher concentrations: Use self-contained breathing apparatus
Hand protection	Use chemical resistant protective gloves (EN 374 standard); For prolonged, direct contact: use suitable materials such as Protective index 6, corresponding > 480 minutes of permeation time according to EN 374; butyl rubber (butyl) - 0.7 mm coating; or nitrile rubber (- 0.4 mm coating)
Eye protection	Use tightly fitting safety googles (splash goggles) such as EN 166
Body protection	Use chemical protection suit (confirms to EN 14605)
General hygiene and safety measures	Take all contaminated clothing off immediately
Source: ECHA (2017): Formaldehyde REACH dossier- Guidance for Safe Use. Available at https://echa.europa.eu/registration-dossier/-/registered-dossier/15858/9	

Safety Data Sheets

The recommended risk reduction measures for handling formalin (formaldehyde solution) are detailed in material data sheet provided for the substance. For handling formalin, respiratory protection is recommended along with the use of gloves, eye protection and body protection. This is discussed in more detail in the table below. The concentration of formaldehyde varies depending on formalin and on its required specifications, with 37% formaldehyde the most commonly used.

Table 3-29: Recommended Personal Protection Equipment (PPE) for formalin	
Protection	**Details**
Respiratory protection	Use a full face respirator if risk assessment shows air-purifying respirator with multi-purpose combination respirator cartridges is required; also use engineering controls
Hand protection	Use gloves that meet EU Directive 89/686/EEC and the standard EN 374 such as nitrile rubber gloves
Eye protection	Use tightly fitting safety goggles; use a face shield; use eye protection equipment that meets NIOSH (US) or EN 166 (EU) standard
Body protection	Use complete suit protection
Source: Sigma Aldrich (2017): Formaldehyde solution Safety Data Sheet. Available at: http://www.sigmaaldrich.com/MSDS/MSDS/DisplayMSDSPage.do?country=GB&language=en&productNumber=252549&brand=SIAL&PageToGoToURL=http%3A%2F%2Fwww.sigmaaldrich.com%2Fcatalog%2Fsearch%3Finterface%3DAll%26term%3DFormalin%2520Solution%2520252549%26N%3D0%2B%26focus%3Dproduct%26lang%3Den%26region%3DGB	

Measures for reducing exposure to formaldehyde based resins are also provided by suppliers to their downstream users. For example, for urea formaldehyde, the recommended measures to reduce exposure to formaldehyde are as described below.

Table 3-30: Recommended measures for handling urea-formaldehyde resin	
Protection	**Details**
Engineering controls	Use adequate ventilation
Respiratory protection	Use a gas filter for inorganic/gaseous compounds, such as EN 14387 type B when exposure is short-term effect or low concentrations are used; For high concentrations or if the exposure has a long-term effect use self-contained breathing apparatus
Hand protection	Use protective gloves
Eye protection	Use protective googles
Body protection	Use protective clothes
Source: Neochim plc (2010): Urea formaldehyde resin KFS E1 Safety Data Sheet. Available at: http://www.neochim.bg/files/sds_kfse1_en.pdf	

3.6.2 Consultation with OSH Experts

In order to reduce exposures so as to comply with lower OEL and STELs, consultation has been undertaken with OSH experts to determine the lowest possible exposure concentrations and the RMMs required to achieve these exposure levels.

From consultation with OSH experts, to reduce inhalation exposure to formaldehyde, the following risk management measures are generally recommended:

- Substitution and/or reduce the quantities of formaldehyde used;
- Reduce the number of workers who are exposed (for example rotating workers so that fewer workers exposed);
- Process-related measures, such as improved work processes design;
- Use of equipment to control exposure, for example enclosures, extraction or ventilation and use of LEV;
- Use of collective protective measures;

- Use of individual protective measures such as PPE;
- Improvements to air ventilation;
- Better visual marking of areas where formaldehyde is present;
- Regular monitoring (through measurements) of areas with formaldehyde; and
- Detecting unusual exposures.

Manufacture of wood and products of wood and cork; except furniture (NACE Code C16)

To lower formaldehyde exposure in panel production, the following RMMs have been suggested from consultation with OSH experts:

- Designing work processes and engineering control measures to avoid or minimise the exposure to formaldehyde in the workplace;
- Evaluating formaldehyde at its source, using local extraction or general ventilation;
- Collective protective measures and/or where exposure cannot be avoided by other means, individual protection measures;
- Reduce the number of workers exposed;
- Substitute/reduce quantities of the chemical agent being used; and
- Install additional control equipment to enclose, extract, or ventilate etc.

Spray Painting

An 8-hour TWA and short-term concentration value of <0.01pm (<0.012 mg/m^3) has been achieved in spray painting (chemical mixtures that contain formaldehyde) by use of LEV; OSH experts suggest that it is not feasible to achieve lower exposure levels in the majority of operations.

Manufacturing of chemicals and chemicals products (NACE Code C20: Resin Manufacturing)

An 8-hour TWA of <0.3 ppm has been achieved for formaldehyde in resin manufacture. The RMMs (with cost implications that require high investment indicated from consultation) that have been put in place to achieve this are:

- Minimising the number of workers exposed;
- Designing work places and engineering control measures to minimise formaldehyde exposure;
- Drawing up plans for dealing with high formaldehyde exposure levels; and
- Having a means for safe storage, handling and transportation, particularly by use of sealed and clearly labelled and visible containers.

A short exposure value (15 minutes) of less than 1 ppm (<1.2 mg/m^3) has been achieved by reducing the number of exposed workers. To achieve a lower exposure, investment, use of fresh air masks and minimising the number of exposed workers would be required.

Mixing applications

An 8-hour TWA air concentration of 0.083 ppm (0.01 mg/m^3) and a short-term concentration value of 0.025 ppm (0.03 mg/m^3) have been achieved for mixing applications where formaldehyde is an impurity or in specific situations. To achieve the 8-hour TWA concentration, the following RMM were employed:

- Designing work processes and engineering control measures to avoid or minimise the exposure to formaldehyde in the workplace;

- Evaluating formaldehyde at its source, using local extraction or general ventilation; and
- Collective protective measures and/or where exposure cannot be avoided by other means, individual protection measures.

The short term 15 minutes concentration value was achieved based on industrial process design and it would not be technically feasible to achieve lower exposure values.

Manufacture of fabricated metals, except machinery and equipment (NACE Code C25): Foundry Operations

Improved or better ventilation is considered the most feasible option for reducing exposure in foundries.

Higher Education (NACE Code P85.4)

For formaldehyde use in human pathology and in clinical areas in education, the following RMMs have been recommended from consultation:

- Substitute/reduce quantities of chemical agents: Replacing the 37% solution with 4% solution (this involves buying a dilute solution instead of preparing the diluted solution at the workplace). This would also eliminate the separate preparation of the liquid and the liquid discharge (reduce disposal of closed sample containers), however, it could lead to issues with waste incineration;
- Control equipment to enclose, extract, or ventilate, etc.: The use of fume cupboards, directed air flow (supply air/exhaust air) and the use of a vacuum disposal container;
- Organisational measures: This includes undertaking filling operations at workplaces that are well ventilated or in fume cupboards, providing appropriate containers for sending samples, rinsing large preparations when cutting, avoiding formaldehyde-wetted surfaces where appropriate, and buying the formaldehyde solution in containers for passing on to doctors; and
- Personal protection equipment: Use suitable hand protection such as nitrile gloves and use respiratory protection for activities with a short timeframe such as disposal, emptying and filling.

Human health and social work activities: Human health activities (NACE Code Q86)

In one member state country, an 8-hour TWA of 0.12 ppm (< 0.15 mg/m^3) and a STEL of 0.42 ppm (<0.5 mg/m^3) has been achieved for formaldehyde use in hospitals. No new measures were used to achieve this value; however, from consultation a lower value is not technically feasible. RMMs recommended to reduce inhalation exposure are:

- Reduce the number of workers exposed (fewer, rotate, etc.);
- Reduce the concentration in the workplace: Process-related measures and control equipment to enclose, extract, or ventilate, etc.; and
- Reduce worker exposure: Collective protective measures to reduce exposure to workers.

In sterilisation and tissue preservation, one OSH expert has recommended the following RMMs:

- Substitute/reduce quantities of formaldehyde;
- Reduce the number of workers exposed;
- Control equipment to enclose, extract, or ventilate etc.; and

- Collective protection measures to reduce exposure to workers.

In Spain from consultation with an OSH expert, in pathological anatomy laboratories, the following RMMs are recommended:

- Changes in the process;
- Process-related measures (design of work processes, etc.); and
- Control equipment to enclose, extract, or ventilate, etc.

For formaldehyde use in human pathology the following RMMs have been recommended:

- Substitute/reduce quantities of chemical agents: Replacing the 37% solution with 4% solution (this involves buying a dilute solution instead of preparing the diluted solution at the workplace). This would also eliminate the separate preparation of the liquid and the liquid discharge (reduce disposal of closed sample containers), however, it could lead to issues with waste incineration;
- Control equipment to enclose, extract, or ventilate, etc.: The use of fume cupboards, directed air flow (supply air/exhaust air) and the use of a vacuum disposal container;
- Organisational measures: This includes undertaking filling operations at workplaces that are well ventilated or in fume cupboards, providing appropriate containers for sending samples, rinsing large preparations when cutting, avoiding formaldehyde-wetted surfaces where appropriate, and buying the formaldehyde solution in containers for passing on to doctors; and
- Personal protection equipment: Use suitable hand protection such as nitrile gloves and use respiratory protection for activities with a short timeframe such as disposal, emptying and filling.

Further information on current RMMs in this sector from consultation and literature review are presented in section 3.6.4.

3.6.3 Efficiency and costs of RMMs

In terms of the costs and efficiency of the different identified risk reduction measures, information is presented below for options that are employed and could be employed to further reduce exposure. This is also discussed in more detail in Section 5 of this report. Information about the CAPEX calculations used are discussed in the methodology report.

For LEV costs and efficiency, these would be dependent on the type of LEV chosen (costs are shown for small business to large businesses and are CAPEX 2017 costs; these are discussed further in the methodology report):

- Open hood (>80% efficiency), the cost would vary from €7,000-€110,000;
- Partial enclosure (>90% efficiency), the cost would vary from €35,000-€150,000; and
- Full enclosure (>99.5% efficiency), the cost would vary from €65,000-€1,100,000.

For filters and respirators, this would be dependent on the equipment used (costs are shown for small business to large businesses):

- Simple mask (>60% efficiency), the cost would vary from €520 to €7,800;
- HEPA filter (>95% efficiency), the cost would vary from €660 to €9,000; and
- Breathing apparatus (>99.5% efficiency), the cost would vary from €2,540 to €38,100.

For the use of simple cabins (>80% efficiency), the cost would vary from €7,000-€110,000; and for the use of pressurised or sealed cabins (>99.5% efficiency), the cost would vary from €30,000 - €150,000. Further information on RMMs used in each sector is discussed in the following section.

3.6.4 Sector RMMs

Agriculture, Forestry and Fishing (NACE Code A)

For formaldehyde applications in fish farms, full PPE (rubber gloves and full-face mask with a filter) is used during the process of handling formalin. The process is also performed outside and the formalin dripped directly into the water from a barrel.

Manufacturing of food products (NACE Code C10)

There is limited information publicly available on the risk reduction measures employed in the food industry for handling formalin with no information received during the consultation process. In a study by Aubrey and Gasnot, for formaldehyde use in sugar manufacturing in France, body protection and the use of safety gloves are recommended with the following measures also employed for handling formalin (Aubrey and Gasnot, 2015):

- There is no direct manipulation: closed systems with identified circuits are used;
- Accurate application at the strict dosage is used; and
- Protection is used (following figure) during delivery and maintenance.

Figure 3-2: Risk reduction measures in sugar production in France
Source: Aubrey R and Gasnot L (2015): The fate of formaldehyde in sugar manufacturing and in products. Sugar Industry, 140, pp692-696.

Manufacture of textiles (NACE Code C13) and leather and related products (NACE Code C15)

The following risk reduction measures were identified for the study performed on formaldehyde by TNO (TNO Triskelion BV, 2013):

- The use of LEV and spray cabin for spraying and finishing leather by spraying (<0.1% formaldehyde);
- Natural ventilation and/or LEV for handling solid chemicals and treated leather (<0.1 wt.% formaldehyde); and
- Natural ventilation for handling chemicals in solution (<0.1 wt. % formaldehyde).

No further updated information for these sectors is available from literature review and no information was received during consultation.

Manufacture of wood and products of wood and cork; except furniture (NACE Code C16)

Manufacturers of wood boards (particleboard, MDF (Medium Density Fibrewood), OSB (Oriented Strandboard), hardboard, softboard and plywood) use various risk management measures to reduce exposure. This includes the use of respiratory protection equipment, and the use of a control room and ventilation (such as LEV) amongst others. In consultation with the European Panel Federation, the industry currently has an average exposure concentration of 0.4-0.5 ppm (0.48-0.6 mg/m^3) based on the currently used RMMs, and are working towards an exposure concentration of 0.3 ppm (0.37 mg/m^3). The association has also undertaken expert advice on reducing exposure below 0.3 ppm (0.37 mg/m^3), which indicates that exposure concentrations of 0.3 ppm (0.37 mg/m^3) can be achieved in the sector through a variety of measures: new guiding of air streams; partial enclosures; additional suction and exhaust treatment; and enclosures at machinery.

The reduction of formaldehyde to 0.3 ppm (0.37 mg/m^3) is also feasible using RMM in press halls where E1 glue is used. These include providing a sufficient fresh air supply to the press room and maintaining a consistent temperature.

The following RMMs are suggested:

- Use of wet extraction systems;
- Dry extraction systems at the forming line and along the press hall;
- Supply the production hall with fresh and preheated air;
- For areas with high emission rates have enclosures with extractors;
- Maintain a high air exchange rate in the production hall;
- Fresh air is brought into the production hall at ground level; and
- Preheated fresh air in the production hall.

Manufacture of chemicals and chemicals products (NACE Code C20: C20.1, 20.2 and 20.4)

Manufacture of chemicals

Risk reduction measures that have been identified for achieving exposures < 0.01 ppm (0.012 mg/m^3) are the use of LEVs, RPE, fume hoods, design of processes to reduce exposure, the use of ventilation and the use of PPE.

Manufacture of formaldehyde

Risk management measures employed during the manufacturing of formaldehyde are described in the following table from consultation with Formacare. The risk management measures employed include the use of closed systems, LEVs, respiratory protection equipment, and LEV and respiratory protection in combination. These measures result in exposure levels of 0.3 ppm (0.37 mg/m^3) for long term exposure and 0.4 ppm (0.48 mg/m^3) and below for short term exposure.

Table 3-31: Risk Management Measures (RMMs) used during the manufacture of formaldehyde			
Group	**Task**	**Risk management measures**	**Exposure levels**
Process operators	Process control	Closed system employed	0.2 ppm; 0.24 mg/m^3 (long term); 0.25 ppm; 0.3 mg/m^3 (short term)
Process operators	Product sampling	Dedicated sampling points; Respiratory protection equipment; closed sampling points	0.2 ppm; 0.24 mg/m^3 (long term); 0.25 ppm; 0.3 mg/m^3 (short term)
Loading operators	Loading/unloading and small (barrels) recipients	Closed dedicated transfer systems; LEV; LEV with vapour treatment; submerged loading; RPE where LEV is not used; RPP combined with LEV	0.35 ppm; 0.42 mg/m^3 (long term) 0.22 ppm; 0.26 mg/m^3 (short term)
Process operators and laboratory personnel	Product analysis	General ventilation; fume cupboard; closed sampling	0.2 ppm; 0.24 mg/m^3 (long term) 0.4 ppm; 0.48 mg/m^3 (short term)
Maintenance personnel	Service, repair, clean and/or perform filter change, prolonged interventions	Drain down/flush prior to open installations; handling and transfer liquids in closed systems	0.18 ppm; 0.22 mg/m^3 (long term) 0.5 ppm; 0.6 mg/m^3 (short term)
Source: Consultation with Formacare			

The replacement of older technology also reduces exposure and this is carried out over time (replacement of one unit costs in the region of €6-7 million). At loading stations, vapour return systems are in place and the pressure is controlled by the control room. Also, the filling nozzle is equipped with a sleeve that is pressurised into the manhole of the truck. In the production laboratory, there are over twenty-five air changes per hour (mechanical ventilation > 500 m^3/hour with a room volume of 20 m^3) with the ventilation automatically controlled in the control room. For maintenance operations involving the replacement of the catalyst, the system is first cleaned and the formaldehyde levels measured. This process is infrequent (information obtained from consultation with a manufacturer).

Manufacture of resins

Risk management measures employed during the manufacturing of formaldehyde based resins are described in the table below based on consultation with Formacare. The risk management measures employed to reduce exposure are similar to those employed in the manufacture of formaldehyde. Exposure from the current measures employed are 0.3 ppm (0.37 mg/m^3) and below for long term exposure and 0.5 ppm (0.6 mg/m^3) and below for short term exposure.

Table 3-32: Risk Management Measures (RMMs) used during the manufacture of formaldehyde based resins			
Group	**Task**	**Risk management measures**	**Exposure levels**
Process operators	Process control	Closed systems; use of high integrity equipment; minimise potential emission sources; LEX	Long term: 0.3 ppm; 0.36 mg/m^3 Short term: 0.5 ppm; 0.6 mg/m^3
Process operators	Product sampling	Closed sampling	Long term: 0.3 ppm; 0.36 mg/m^3 Short term: 0.5 ppm; 0.6 mg/m^3
Process operators	Operating semi-automated batch processes including charging raw materials and spray drying	Closed systems; LEV; submerged loadings; Respiratory protection equipment	Long term: 0.2 ppm; 0.24 mg/m^3 Short term: 0.17 ppm; 0.2 mg/m^3
Loading operators	Loading/unloading and small (barrels) recipients	Closed dedicated transfer systems; LEV; LEV with vapour treatment; submerged loading; RPP where LEV is not used; RPP combined with LEV	Long term: 0.35 ppm; 0.42 mg/m^3 Short term:0.22 ppm; 0.26 mg/m^3
Loading operators	Loading/unloading of solids into small (big bags) recipients	Closed transfer systems; LEV	Long term: 0.25 ppm; 0.3 mg/m^3 Short term: 0.5 ppm; 0.6 mg/m^3
Process operators and laboratory personnel	Product analysis	General ventilation; fume cupboard; closed sampling	Long term: 0.2 ppm; 0.24 mg/m^3 Short term: 0.4 ppm; 0.48 mg/m^3
Maintenance personnel	Service, repair, clean and/or perform filter change; prolonged and short interventions	Drain down/flush prior to open installations; LEV; respiratory protection equipment	Long term: 0.18 ppm; 0.22 mg/m^3 Short term: 0.5 ppm; 0.6 mg/m^3
Source: Consultation with Formacare			

The RMM used in the manufacture of resins has also been confirmed from consultation and site visits. For one manufacturer, further advanced ventilation is not considered to be feasible to reduce exposures below 0.2 ppm (0.24 mg/m^3) and would cost at least €5 million (estimated). In sampling and production analysis, LEV with a capturing hood is employed at the sampling points. Closed sampling points were not feasible after testing. Exposure levels with the RMMs employed at this manufacturer are 0.23 mg/m^3 and below.

At another manufacturer, LEV is used at the reactors and at the sampling points. The resin manufacturing process is also performed at a low pressure. Employees are supplied with instructions when they go to the reactors which provide details of the protection required and the process being performed. The process is not fully automated with sampling required (~10 times per batch for short periods). The RMM used by this manufacturer are summarised in Table 3-33. Exposure is typically 0.22 ppm (0.27 mg/m^3) and below.

Table 3-33: Risk Management Measures used by one resin manufacturer	
Task/conditions of use and RMMs	**Information**
Level of automation	Closed system; not fully automated (sampling is needed); process controlled by workers in cabins
Containment	Closed process
Type of process	Closed process
LEV type	LEV is used and is checked daily.
Respiratory protection	Respiratory protection (EN140) with cartridge (EN143)
Other protection	Safety helmet (EN 397); safety glasses (EN166); boots (EN345), gladiator protective gloves (EN388, EN374, EN407), and audio protection (EN 352)
Segregation of worker from the source	Workers are located near the reactor for one hour a day and a cabin is also used
Source: Consultation with industry.	

Another resin manufacturer uses the RMM summarised in the below table. Exposure has been measured generally at 0.08 ppm (0.1 mg/m^3) and below in the operations where exposure could occur (loading/unloading (up to 2 hours exposure) and during sampling which involves exposure up to ten minutes).

Table 3-34: Workroom characteristics for resin manufacturing	
Task/conditions of use and RMMs	**Information**
Level of automation	Components are put in manually; no open processes- closed system used; not fully automated process; control room is used
Containment	Closed process
Type of process	Closed process
LEV type	LEV used- LEV with hood goes from down to up. Local LEV is used inside and in the reactor. There is also emergency ventilation. A visual check-up is performed every month. Testing and maintenance are performed at least once a year. Low/natural ventilation is also used.
Respiratory protection	3M ABEK 1 mask filters
Segregation of worker from the source	No workers are located near exposure source; no separate cabin; control room is used
Worker - source distance	No workers are located near exposure source
Other RMMs used	Dupont Tychem coverall is used (€11,40 cost), special gloves, and boots are used during the transfer of chemicals or when taking measurements from reactors.
Source: Consultation with industry.	

RMMs employed by another manufacturer are summarised in the following table (from consultation). These have resulted in measured air samples of <0.025 ppm (<0.03 mg/m^3) for 8-hour TWA and <1 ppm (1.2 mg/m^3) for short term exposure (STEL). To achieve lower exposure values, would require further investment.

Table 3-35: Risk management measures employed in resin manufacturing		
Group	**Risk**	**Risk Management Measures**
1	Reduce the number exposed	Reduce the number of exposed workers (fewer, rotate etc)
	Reduce the concentration at the workplace	Process related measures; Control equipment to enclose, extract, or ventilate; Detect unusual exposures
	Reduce worker exposure	Collective protection measures to reduce exposure to workers: Limitation of work or workers for a certain time; Individual protection measures to reduce exposure to workers (PPE): PPEs, ventilated fresh air masks
2	Reduce the number exposed	RMMs sometimes employed
	Reduce the concentration at the workplace	Process-related measures (design of work processes, etc.); Control equipment to enclose, extract, or ventilate, etc.; Detect unusual exposures: limit working, use specific ventilated PPEs
	Reduce worker exposure	Collective protection measures to reduce exposure to workers: Limitation of work or workers for a certain time; Individual protection measures to reduce exposure to workers (PPE): PPs, ventilated fresh air masks: PPE used
3	Reduce the concentration at the workplace	Process-related measures (design of work processes, etc.): fume hood; Control equipment to enclose, extract, or ventilate, etc.: fume hood
	Reduce worker exposure	Individual protection measures to reduce exposure to workers (PPE): PPs, ventilated fresh air masks: PPE used
4	Substitute/reduce quantities of chemical agents	Find and test safer chemicals
	Reduce the concentration at the workplace	Process-related measures (design of work processes, etc.): fume hood; Control equipment to enclose, extract, or ventilate, etc.: fume hood
	Reduce worker exposure	Individual protection measures to reduce exposure to workers (PPE): PPs, ventilated fresh air masks: PPE, specific masks
5	Reduce the number exposed	Specify process workers, limit visitors passage to production areas
	Reduce the concentration at the workplace	Process-related measures; Control equipment to enclose, extract, or ventilate, etc.; Detect unusual exposures: limit passage to the production area
	Reduce worker exposure	Collective protection measures to reduce exposure to workers: emission control out of processes and tanks; Individual protection measures to reduce exposure to workers (PPE): PPEs specified
Source: Consultation with industry.		

Manufacture of other organic basic chemicals (NACE Code C20.13)

The following RMMs have been reported as being used to reduce exposure:

- Process-related measures (design of work processes etc.);
- Control equipment to enclose, extract, or ventilate etc.;
- Detection measures to identify unusual exposures;
- Collective protective measures to reduce exposure to workers; and
- Individual protection measures to reduce exposure to workers.

Manufacture of fertilisers and nitrogen compounds (NACE Code C20.1.5)

In the production of fertiliser granules, the following risk management measures are in place from consultation with Fertilizers Europe:

- Process control: general ventilation (natural and mechanical) and enclosed transfer (exposure of 0.12 ppm (0.14 mg/m^3));
- General operation, transfer, and cleaning/maintenance: natural ventilation (exposure of <0.16 ppm (0.19 mg/m^3)); and
- Cleaning: general ventilation (mechanical) and LEV (exposure of 0.2 ppm (0.24 mg/m^3)).

Manufacture of plastics in primary forms (NACE Code C20.1.6)

The risk management measures employed to reduce formaldehyde exposure by a manufacturer of resins for plastics in primary forms are described in the below table. There are five SEGs; however, the RMMs are the same for each SEG. Using these RMMs, average exposure is below 0.2 ppm (0.24 mg/$m^{3)}$ and below. These RMMs are also required for a STEL of 0.6 ppm (0.72 mg/m^3).

Table 3-36: Risk management measures employed in resin manufacturing for plastics		
SEGs	**Risk Management Measure**	**Detail**
1	Substitute/reduce quantities of chemical agents	N/A
		N/A
2	Reduce the number of workers exposed	Process related measures: work process planning, PPE;
3	Reduce the concentration at the workplace	Control equipment to enclose, extract, or ventilate, etc: automation of processes, encapsulation of process, local fume extractors and general ventilation
4		
5	Reduce worker exposure	Collective protection measures to reduce exposure to workers: general ventilation and local fume extractors; Individual protection measures to reduce exposure to workers: gloves (EN 374 standard), protective clothing, masks with absorbents, glasses, face shields and chemical resistant overalls

The lowest technical and economically feasible OELVs, with the RMMs required to reach these OELVs are also summarised in Table 3-37. This information has been supplied from consultation.

Table 3-37: Lowest feasible OELs in the manufacture of plastics		
SEG	**Technically feasible OELV and required RMMs**	**Economically feasible OELV and required RMMs**
1	0.066 ppm (0.08 mg/m^3): Full automation; robotisation; increasing efficiency and amount of ventilation	0.09 ppm (0.11 mg/m^3): Increasing efficiency and amount of mechanical ventilation; process automation
2	0.066 ppm (0.08 mg/m^3: Full automation; robotisation; increasing efficiency and amount of ventilation	0.083 ppm (0.1 mg/m^3): Increasing efficiency and amount of mechanical ventilation; robatisation of processes
3	0.11 ppm (0.13 mg/m^3): Full automation; robotisation; increasing efficiency and amount of ventilation	0.15 ppm (0.18 mg/m^3): Increasing efficiency and amount of mechanical ventilation; robatisation of processes
4	0.11 ppm (0.13 mg/m^3): Full automation; robotisation; increasing efficiency and amount of ventilation	0.15 ppm (0.18 mg/m^3): Increasing efficiency and amount of mechanical ventilation; automisation of measuring instruments
5	0.09 ppm (0.11 mg/m^3): Full automation; robotisation; increasing efficiency and amount of ventilation	0.12 ppm (0.14 mg/m^3): Increasing efficiency and amount of mechanical ventilation; robatisation of processes
Source: Consultation with industry.		

Manufacture of basic pharmaceutical products and pharmaceutical preparations (NACE Code C21)

From consultation, the following RMMs have been identified to be in use to reduce exposure during charging activities in pharmaceutical manufacturing:

- Reduction in the number of exposed workers;
- Reducing the concentration at the workplace: process related measures;
- Reducing the concentration at source, for example equipment to enclose, extract or ventilate;
- Reducing worker exposure: collective protective measures; and
- Reducing worker exposure: individual protective measures.

Manufacture of metals (NACE Code C25)

For foundry operations, protective equipment including masks are used and the area is properly ventilated. To further reduce exposure, only improved ventilation would be an option. In foundries, blowers are also used to transport formaldehyde fumes away from workers. Masks are available and air ventilation is also used.

On metal coating lines, where exposure to formaldehyde could occur, engineering measures have been adopted. In this process, metal strips are processed, coated and heated which could involve the release of formaldehyde. These include the use of suction; ventilation; increase in the air changes per hour; improving the efficiency of the ventilation and leak proofing some of the processes. Non-engineering measures include using a cabin for operators and also job rotation. Using these risk management measures results in exposure below 0.12 ppm (0.15 mg/m^3).

Manufacture of machinery and equipment n.e.c. (NACE Code C28)

In order to control exposure for workers employed in the production of abrasives wheels the following measures are in place from consultation:

- Use of local and general ventilation;
- Reducing the number of exposed workers; and
- Reducing the concentration at the workplace.

Manufacture of furniture (NACE Code C31)

Closed systems, the use of dosing equipment, mixing with wood flakes, press isolation and ventilation PPE are used from information obtained from consultation. From consultation with resin manufacturers, downstream users are also notified of the risks of formaldehyde through safety data sheets, which list the RMM to be undertaken.

The UK HSE recommends the following measures for working with Medium Density Fibreboard: (Health and Safety Executive, undated):

- Use a lower risk alternative if available;
- Use LEV;
- For limiting dust exposure, use a hose connected to the LEV or a vacuum cleaner with a high-performance filter; and
- The use of RPE may be needed with the use of FFP3 (20x protection) recommended for high levels of dust and RPE combined with an organic vapour filter is recommended for vapour.

Water collection, treatment and supply (NACE Code E38)

For the use of formaldehyde in water treatment and purification in Bulgaria, workers use PPE such as filters, masks, gloves, protective clothing, and goggles. The main risk is from the chlorine, especially in its gaseous state.

Professional, Scientific and Technical Activities: Scientific research and development (NACE Code M72)

In the use of formaldehyde in the preparation of gels for electrophoresis, the following risk reduction measures are recommended from safety data sheets (Sigma Aldrich, 2017):

- Wear tightly fitted googles and an 8-inch minimum face shield;
- Wear protective gloves that meet EN374 standards;
- Wear complete suit protection; and
- Use respiratory protection equipment with air-purifying respirator if the risk assessment shows this is necessary. A full-face respirator with respirator cartridges (EN 14387) is recommended.

No information was received during the consultation process for this sector.

Professional, Scientific and Technical Activities: Veterinary activities (NACE Code M75)

Risk reduction measures for veterinary use under BT 2 (use in veterinary hygiene biocidal products, for disinfecting animal housing) for compliance with the Biocidal Products Regulation have been discussed in the public consultation responses for the BPR application (ECHA, 2017c). The British Poultry Council have stated that full PPE is a legal obligation and the Formaldehyde Biocide Interest Group (FABI) have listed the following risk management measures as being in place:

- Formaldehyde containing products are applied in closed rooms/houses;
- Automated, computer controlled devices are used;
- Disinfection using formaldehyde is performed by professionals only; and
- Handling of the automated regime for disinfection requires full PPE.

Higher Education (NACE Code P85.4)

From consultation (and site visit), the risk management measures that are currently in place in teaching hospitals are described in the following table.

Table 3-38: Risk management measures used in teaching hospitals		
Task	**Risk management measures**	**Details**
Preparation of fixation solution (3-5% formaldehyde)	Use of air ventilation systems Respiratory protective equipment is used	Task performed by one staff member with a duration of up to one hour
Fixation of human bodies	Respiratory protection equipment is used	Performed 5-50 times per year for a short period of time; Exposure is above SCOEL limits (Thullner, 2016 study) so RPE is used
Storage (preservation) of bodies	Respiratory protection equipment is used	16-18 departments in two-member states use formaldehyde in this task
Use of bodies in student courses	Respiratory protection equipment is used for removing linen and plastic coverage	After removing the linen and plastic coverage, the formaldehyde is allowed to volatise for 30 minutes before staff and students are allowed in the dissection hall; Exposure is typically below 0.3 ppm (0.37 mg/m^3) in the hall although levels above this are sometimes observed
Other measures used	Table extraction ventilation Ventilation air changes	Table extraction is needed to achieve exposure levels below 0.3 ppm At one table, extraction is 60 m^3/hour. In the dissection hall extraction is 40,000 m3/hour (15 air changes per hour, range in Germany between 3 and 18 per hour)
Source: Consultation with industry.		

For one department, the costs of increasing ventilation was in the region of €2 million for a large operating theatre which included the cost for dissecting tables with extraction and refurbishment of the ventilation system. To undertake further improvements to ventilation would result in estimated costs of an additional €800,000. From consultation many dissection halls are old buildings, which leads to a limit in the air flow capacity.

Organisational measures to reduce formaldehyde exposure in dissection rooms were previously discussed by Thullner and Van Gelder (Thullner and Van Gelder, 2016). There are drawbacks to these organisational measures, (obtained through consultation) as follows:

- Reducing the temperature in the dissection halls: The temperature in the dissection halls has an influence on the exposure levels even though temperatures are well below 20 °C. The heat introduced by students and teaching staff at the table has an additional impact. Therefore, courses are held in winter terms, but cooling down operating theatres may nonetheless be required due to the heat of students introduced. Ensuring a low temperature therefore increases energy costs;
- Few bodies per dissection hall are recommended as this can decrease the background exposure: This can only be achieved, however, when new theatres are built and would certainly increase construction costs when compared with a single large dissection hall. In addition, since one supervisor (often the preparator) is present per dissection hall, having several dissection halls would also increase staff costs.
- Few students per table are also recommended (to reduce heat impact): From consultation about 8 students (and 1 teaching staff) are needed at least to make use of the entire body (which is the educational goal and is also considered a necessity, since people donated their body for that purpose);

- Uncovering bodies prior to the start of the course to allow volatilisation of formaldehyde: From consultation this is already undertaken, for example a thirty minute period is used in one hall;
- All theoretical explanations and instructions should be given outside the dissection hall: From consultation, these are given during lectures; and
- Students and teaching staff need to be instructed in relation to the hazard and made aware that they have to keep distance from the emission source (i.e. the body) as far as possible (e.g. bending over the body only when required for the preparation): Other solutions recommended for these purposes (e.g. magnifying glasses) are not considered practical from consultation.

Human health and social work activities: Human health activities (NACE Code Q86)

In hospitals, a variety of RMMs are in place from information received from consultation. General risk management measures for the laboratory are summarised in the below table. To minimise exposure to formaldehyde, job rotation is in place. The formaldehyde solution concentration used is 3-5%.

Table 3-39: General measures in place

RMM	Details
Occupational health and safety	Internal system in place
Training Management System	Training undertaken
Cleaning	Regular cleaning of workplace undertaken
Job rotation	Job rotation in place to minimise exposure
Source: Consultation with industry.	

The main activity is the treatment of articles and dipping (PROC Code 13) using formaldehyde solution (3-5%) for a maximum of four hours per day. The risk management measures in place for this process are described in Table 3-40. The use of a fully automated dilution apparatus (cost of €55,000-65,000), which is a closed process, allows the formaldehyde to be taken from barrels and then diluted and distributed to the workplaces. Workers are also supplied with a monitoring device that gives a signal when inhalation exposure is above 0.5 ppm (0.6 mg/m^3). The total cost of the RMMs is estimated to be in the region of €145,000-155,000. Using these RMMs has resulted in a shift exposure average of 0.05 mg/m^3. Short term exposure may be an issue (>0.58 ppm, >0.7 mg/m^3 average), although this may be from exposure to another substance and additional RMMs (staff to be more conscious and a checklist) have been introduced. Substituting formaldehyde is currently not possible for its use in this process.

Table 3-40: Risk management measures in a hospital laboratory for exposure to formaldehyde	
RMM	**Details**
PROC code	13; treatment of articles by dipping and pouring
Ventilation used	Mechanical; ventilation to outside air; >5 air changes per hour; ventilation also in lab and at source
Automation	Dilution fully automated and controlled; other work is manual and not contained
Process	Open on ventilation tables and half open (fume hood)
LEV	Open; 90% efficiency
Airflow	Away from worker
Shift average exposure	0.05 mg/m^3
Short term exposure	0.78 mg/m^3
PPE	Nitrile gloves; apron; and safety googles
Source: Consultation with industry.	

In consultation with the Dutch Hospital Association on current risk management measures, there are four similar exposure groups for hospitals:

- SEG 1: Formaldehyde in labs;
- SEG 2: Formaldehyde in operating rooms;
- SEG 3: Formaldehyde in paediatrics;
- SEG 4: Formaldehyde in gynaecology.

Risk management measures employed for each SEG are described in the following table.

Table 3-41: Risk management measures employed in hospitals		
Group	**Risk Management Measures**	**Details**
1,2,3,4	Reduce the number of workers exposed (fewer, rotate, etc.)	Labs are located in separate compartments.
	Reduce the concentration at the workplace: Process-related measures (design of work processes, etc.)	Hospitals work as much as possible with closed systems.
	Control equipment to enclose, extract, or ventilate, etc.	(i) Hospitals work with work tables that have air suction function. (ii) At the labs water is used before working with the organs (etc) being conserved in formaldehyde. (iii) Hospitals use pre-prepared baggage with formaldehyde.
	Reduce worker exposure: Collective protection measures to reduce exposure to workers	Air suction and separate compartments.
Source: Consultation with industry.		

Funeral services (NACE Code S96.0.3)

From consultation with the Dodge Company, there are currently no training or certification requirements for embalmers which include RMMs and embalmers can also work at one site or across a number of sites. The British Institute of Embalmers provides training courses which includes information on RMMs to reduce exposure. The UK HSE recommends the following measures to reduce exposure (Health and Safety Executive, 2003):

- Have a well-ventilated workplace with at least ten air changes per hour;
- Use an embalming table which has slots for extraction at a rate of 3.5 metres per second;
- Discharge the extracted air to a safe area;
- Use RPE where required;
- Wear protective gloves- nitrile gloves are recommended;
- Wear an impervious apron;
- Wear slip resistant and waterproof boots;
- Ensure training covers how to keep exposure at low levels; and
- Check for damage to the extraction once a week and also have ventilation engineer to check the system every 14 months.

Embalmers are told to mix the solution with ventilation and, after mixing, to put the top back on the container to minimise exposure. The use of shoe covers and ventilation at ground level is also recommended as formaldehyde is a heavier substance and will fall towards the ground (from consultation). The typical PPE for embalmers (such as shoe covers and masks) cost approximately €12.

3.7 Voluntary industry initiatives

Formacare members are working to an OELV of 0.3 ppm (0.37 mg/m^3) and a STEL of 0.6 ppm (0.72 mg/m^3) through risk management measures that have been put into place. Formacare consists of thirty-five companies and also the European Melamine Producers Association (EMPA). The estimated number of workers is between 5,250 workers and 5,750 members from figures provided by Formacare. Members of Formacare cover 90% of the EU formaldehyde production (on a tonnage basis).

Formacare also proposes that industry works to an OEL of 0.3 ppm (0.37 mg/m^3) on a voluntary basis by 2018. From information received during the consultation process, the European Phenolic Resin Association (EPRA) which consists of fourteen companies are working to this proposed OEL. The European Panel Federation and members of Fertilizer Europe are also working towards this proposed OEL. These associations may take into account 85,000-86,00 workers (see section 3.4) Furthermore, the European Trade Union Confederation and industry (Formacare, the European Panel Federation, the European Automobile Manufacturers Association, the European Tyre and Rubber Manufacturers Association and the European Phenolic Resins Association) signed a common letter in 2016 (could take into account in the region of 210,000-211,000 workers, which is 21% of number of workers calculated as being exposed to formaldehyde). This letter involved asking for formaldehyde to be included in Annex III of the Carcinogen and Mutagen Directive 2004/37/EC and to include the SCOEL proposed health based values.[18] During the consultation process, no information was received from

[18] Letter to Mr Michel Servoz (Director General, Directorate General for Employment, Social Affairs and Inclusion: Request to Include Formaldehyde in the Annex III of the Carcinogen and Mutagen Directive 2004/37/EC. Dated 15 July 2016

downstream users of formaldehyde (such as hospitals and embalmers) about this initiative and whether the sectors are working to this initiative.

Generally, as discussed in Section 3.5, exposures are 0.3 ppm and below apart from a small number of sectors. The measures put in place to achieve this level include use of closed processes, closed sampling, LEV, respiratory protection, and general ventilation. The average cost for complying with these levels, are €55,736 for formaldehyde and resin manufacturers and €13,854,771 for other intermediate uses of formaldehyde per company. It is estimated that 80% of the investment has already been undertaken.

The wood panel industry has also developed a voluntary European standard (E1) based on the WHO recommendation for indoor air levels of formaldehyde (WHO recommendation: 0.1 mg/m^3). The concentration of formaldehyde in resins in panels has decreased from 100 mg/100 g of panels in 1975, to less than 8 mg/100 g (Formacare, 2014d). The number of exposed workers calculated in the manufacture of furniture from section 3.4 is 199,898 workers (16.7%).

3.8 Best practice

Some associations provide best practice guidelines for reducing exposure. For example, the National Funeral Directors Association has a guide for best practice for formaldehyde (NFDA, 2010). One association is also presently using the draft European Action Guide on formaldehyde. There are also ISO quality standards which may be followed by companies.

As discussed above (Section 3.7), a number of sectors are working to an OEL of 0.3 ppm and a STEL of 0.6 ppm. In resin manufacturing, this involves the use of closed systems, respiratory protection (can have up to >95% efficiency depending on option chosen), the use of closed sampling points, fume hoods, general ventilation and LEV. In hospitals, exposure can be minimized to an 8-hour TWA by using mechanical ventilation, using automated processes where possible, LEV with 90% efficiency, ensuring air flow is away from the worker and the use of PPE.

Overall, the use of LEV (with at least 90% efficiency), the use of closed processes where technically possible, use of PPE, the use of RPE (which can have up to 99.5% efficiency) and limiting exposure (such as reducing the number of workers exposed) have been used in a variety of sectors to reduce formaldehyde exposure. Where closed processes are used, to further reduce exposure, then the use of LEV and RPE would need to be optimised. Organisational measures (such as training employees making them aware of the risks and limiting exposure time) are also used to reduce exposure levels. This is discussed in more detail in Sections 3.5 and 3.6.

3.9 Standard monitoring methods/tools

3.9.1 Available monitoring methods/tools

SCOEL (2016) discuss that measurements of exposure to formaldehyde are widely based on photometric measurements. For measuring formaldehyde concentration in air, this can be achieved by collecting formaldehyde in an absorbing medium by diffusion (referred to as a passive sampling with aqueous solutions used for measurement). The use of 2,4-dinitrophenylhydrazine (DNPH) in passive sampling is frequently used and is recommended by MAK for measuring occupational exposure to formaldehyde.

The “MAK Method 2” can also be used to measure occupational exposure to formaldehyde. This method involves drawing air by means of a sampling pump from the work place through impregnated

DNPH silica gel cartridges. In this process, the aldehydes and ketones in the air are transformed into their respective hydrazones. Acetonitrile is then used for desorption and High-Performance Liquid Chromatography (HPLC) is used to measure the concentration of formaldehyde present in the sample. The characteristics of this method are described by SCOEL. The method has a detection limit of 11 µg per cubic metre of air for a 6L volume sample of air and has a recovery rate of 101%.

Following on from the MAK Method 2, there is also a MAK Method 3. This method uses voltammetry combined with differential pulse polarography (DPP). Other methods for measuring formaldehyde are discussed by SCOEL and are summarised in the following table.

Table 3-42: Methods for measuring formaldehyde concentration in workplace air

Method	Measured Concentrations	Collection of samples	Analytical method details
OSHA Method No 1007	0.75 ppm (0.9 mg/m^3)	Diffusive samples. Collected by one of the following: Assay Technology ChemDisk Aldehyde Monitor 571 (ChemDisk-AL); SKC UMEx 100 Passive Sampler (UMEx 100); or Supelco DSD-DNPH Diffusive Sampling Device (DSD-DNPH)	Liquid Chromatography (LC) with Ultraviolet (UV) detector
NOISH Method 2016 (suitable also for STEL)	0.012 ppm-2.0 ppm (0.015-2.4 mg/m^3) for 15 litres	Collected with a silica gel cartridge coated with DNPH	HPLC and UV detector
NIOSH Method 2541	0.24 ppm-16 ppm (0.29-20 mg/m^3) for 10 litres	Solid sorbent tube containing 10% (2-hydroxymethyl) piperdine on XAD-2, 120 mg/60 mg)	Gas chromatography (GC)/Flame Ionisation Detector (FID)
NIOSH Method 3500	0.02 ppm-4 ppm (0.024-4.8 mg/m^3) for 80 litres	Samples collected by filters and impingers	Visible absorption spectrometry

Source: SCOEL (2016): SCOEL/REC/125 Formaldehyde. Available at https://publications.europa.eu/en/publication-detail/-/publication/7a7ae0c9-c03d-11e6-a6db-01aa75ed71a1

3.9.2 GESTIS- Analytical methods database

The GESTIS analytical methods database contains five methods for measuring formaldehyde exposure in the workplace (IFA, 2016a). Two of these methods have been assigned an 'A' ranking and three methods have been assigned a 'B' ranking. The 'A' ranking means the method meets all or most of the major requirements for EN 482 (1999) and a 'B' ranking means that validation data is incomplete but the method has the potential to meet the requirements for EN 482 (IFA, 2016b).

The two methods that have been assigned an 'A' ranking are described in the following table. These two methods do not cover OELs that would be well below the current SCOEL recommended levels.

Table 3-43: Analytical methods for formaldehyde ('A' ranking methods)					
Standard	Year	Principle of analysis	Flow rate/recommended air volume	LoQ [mg/m³]	Validated working range
MTA/MA-018/A89	1989	UV	1 L/min, 60 L	0.1-3.4 (0.083-2.8 mg/m³)	No data
OSHA ID-205	1990	UV	0.0614 L/min, 4-16 h	0.25-6.0 (0.21-4.98 mg/m³)	No data

The methods that have been assigned a 'B' ranking have lower LOQs/LODs (Limit of Quantification/Limit of Detection) (0.011-0.036 mg/m^3; 0.009-0.03 ppm) than the two methods assigned with an 'A' ranking. The current German IFA method (No. 6045, last updated 2007) has a lower LoQ of 0.01 mg/m^3 at a sampling volume of 40 L (sampling on silica gel cartridge, 20-80 L/h/min, analysis by HPLC). This method can be used for short-term measurements (lowest sampling duration: 15 mins with a sampling volume of 20 L, i.e. a flow rate 80 L/h) with a maximum sampling duration of three hours.

3.9.3 Information from Consultation

Generally, consultation indicates that exposure measurements are performed by an outside company. Sampling of workers exposure to formaldehyde is done periodically (1-2 times per year), depending on the sector. For example, in the heathcare sector, sampling can consist of two samples per department per year. In manufacturing, sampling is performed over a working day every year and sampling can be performed by an outside organisation. A foundry in Croatia monitors workers by taking three samples.

In Poland, monitoring has been performed by collecting samples through stationary sampling in employees breathing zones in accordance with PN-Z-04045/02 2002. The samples are then analysed by a colorimetric method (PN-76/Z-04045/02). PN-76/Z-04045/02 involves determining formaldehyde exposure using phenylhydrazine. To determine the formaldehyde concentration, this is determined by the reaction of formaldehyde with phenylhydrazine hydrochloride to form a phenylhydrazine. The phenylhydrazine compound reacts with potassium cyanosilazinate and hydrochloric acid which causes the solution to turn pink which underlays the assay measurement. The measurement has an LOD of 0.25 mg (0.21 ppm) of formaldehyde in 1 m^3 of air.

One manufacturer uses an external laboratory to undertake both personal sampling and static sampling for measuring exposure to formaldehyde. Personal sampling involves the the sensor being worn by the worker at the level of the respiratory tract. Static sampling involves the sensor being located at a fixed position in the room near the workstation, at the level of the respiratory tract. For the measurement of formaldehyde, 1L of air per minute is drawn into an absorption tube containing LpDNPH S10-Sipelco. The tube also contains 350 mg of silica gel loaded with DNPH. The formaldehyde reacts with the DNPH to form stable hydrazines. The layers of silica gel captured with formaldehyde are then extracted with acetonitrile in the laboratory. These solutions are then analysed by LC-UV. The quantification is carried out by external standardisation.

3.10 Relevance of REACH Restrictions or Authorisation

3.10.1 Overview

The REACH registration for formaldehyde covers its use in a wide variety of applications; however, not all of these are covered by the REACH Regulation. Formaldehyde use in biocidal applications is

covered by the Biocidal Products regulation; intermediate uses of formaldehyde in fertilisers and in resin production are registered under REACH but occupational exposures for such a use would not easily be regulated by REACH; while formaldehyde emissions from wood panels are subject to EN standards. These are discussed in this section where worker exposure could occur which is not covered by REACH.

3.10.2 REACH registration

Formaldehyde is registered under REACH in the 1 000 000 + tonnes per year tonnage band. The uses of formaldehyde that have been fully registered under REACH are summarised in the following table. There are currently 205 active registrants in the formaldehyde REACH registration dossier.

Table 3-44: REACH registration information for formaldehyde

Registration details	Details
EC Number	200-001-8
CAS Number	50-00-00
Chemical formula	CH_2O
Tonnage range	1 000 000 + tonnes per annum
Registration	Full
Uses by professional workers	Use as a laboratory chemical; cleaning agent; application of adhesives and coatings; professional use of resins in wood applications; professional use of formaldehyde based products; production of foams; use of firelighters; use in resins, glues and adhesives
Uses at industrial sites	Manufacturing of chemicals, resins and polymers; production of wood based materials; production of paper; use as an intermediate (including monomer use); production of bonded fibres or fiber mats; industrial use of formaldehyde based products; production of foams; end use of as monomer in an impacted polymer; production of firelighters; production of bonded particulates (abrasive, casting, moulding); production of leather; production of rubber; production of fertiliser granules; impregnation of textiles
Compositions listed in REACH dossier	Formalin; formaldehyde; aqueous formaldehyde solutions; formaldehyde monomer; 37 wt.% in water with 10-15% of methanol added as a stabiliser
Source: ECHA (2017): Formaldehyde REACH registration dossier. Available at https://echa.europa.eu/registration-dossier/-/registered-dossier/15858/1	

It is also worth noting that there is a registration dossier for Formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol (CAS number: 9003-36-5; EC number: 500-006-8). For this substance, there is no harmonised classification and no notified hazard information is available. As such, this substance has not been considered further (ECHA, 2017d).

Public Activities Coordination Toolbox (PACT)

ANSES (ANSES, 2016) has performed a Risk Management Option Analysis (RMOA) for formaldehyde. Their conclusions are that the use of formaldehyde in industry as an intermediate needs to be clarified. If the status of formaldehyde as an intermediate in resin synthesis and chemicals synthesis is confirmed by industry, then workplace legislation (such as CMD) and the appropriate BOELVs would be the only suitable RMOA. If the status of formaldehyde for these uses as an intermediate could not be confirmed by industry, then a restriction under REACH could be suitable and authorisation could be used to cover the uses with the highest occupational risks. Further discussion on the intermediate status is provided in Section 3.10.4.

3.10.3 Biocidal Product Regulation (BPR)

The use of formaldehyde as a biocide is covered under the Biocidal Products Regulation (BPR). This regulation concerns the placing onto the market and the use of biocidal products against harmful organisms and the regulation aims to ensure a high level of protection of human health and the environment whilst improving the functioning of the biocide market (ECHA, 2017e).

As discussed in Section 3.3, formaldehyde has uses as a biocide in hospitals, dentistry, embalming and in veterinary applications, amongst others. Under the BPR, the following uses have been listed and which are currently under review for approval under the Regulation (ECHA, 2017g):

- Use as disinfectants and algaecides not intended for direct application or humans (Biocidal Type (BT 2);
- Use in veterinary hygiene (BT 3); and
- Use in embalming and taxidermist fluids (BT 22).

The Biocidal Products Committee has recommended the use of formaldehyde in veterinary hygiene (ECHA, 2015). This use has also undergone public consultation, where information about its uses, risk reduction measures and alternatives were discussed (these are discussed in the relevant sections of this report).

For BT 22, the use of formaldehyde in embalming and taxidermist fluids is currently under review by the German Federal Institute for Occupational Safety and Health (BAuA). From consultation, this has been under review since 2006, with a Social-Economic Analysis (SEA) document also submitted (this is an option under REACH if the BPR application is rejected). Formaldehyde for use in embalming is also now being registered for use in individual countries, as it was expected that the use would be covered under the BPR application.

3.10.4 Intermediate uses and REACH

Use of formaldehyde in chemical synthesis

Formaldehyde is considered to be an intermediate in the manufacture of urea-formaldehyde resins (TNO Triskelion and RPA, 2013). ANSES (2016), in their risk management option analysis draft, discuss the use of formaldehyde as a non-isolated intermediate in the context of REACH for use in chemical synthesis: "*an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place"*). ANSES further notes that if formaldehyde is used for producing an article, then it should not be considered as an intermediate even though a chemical reaction takes place; however, for the production of resins or chemicals this is not the case.

ANSES concludes that no option under REACH could be proposed for the use of formaldehyde as an intermediate expect in the case where formaldehyde is an isolated transported intermediate. The conclusion of the draft report is that in order to minimise occupational exposures during the intermediate uses of formaldehyde, other risk management options (such as CMD directive) are more appropriate than REACH. ANSES have recently confirmed the status of formaldehyde as an intermediate in chemical synthesis (Formacare, 2017).

Production of fertilisers: Intermediate status under REACH

The manufacturing of slow release fertilisers is regarded as an intermediate; however, use of the formulation is not an intermediate. From consultation with Fertilizers Europe, methylene urea

(reaction product of urea and formaldehyde) is classified as polymer, so is exempt from registration under REACH.

3.10.5 REACH impact on worker exposure

Formaldehyde is not on the authorisation list at present with one current restriction intention on the use of formaldehyde and formaldehyde releasers in mixtures and articles for consumer uses. As such, these regulatory mechanisms are not imparting any direct impact on worker exposures.

The major use of formaldehyde is in the manufacture of formaldehyde resins (which are classed as polymers) which is classed as an intermediate use under REACH. ANSES (2016) concluded that in order to minimise occupational exposures during the intermediate uses of formaldehyde, the CMD directive would be needed to address occupational exposure to formaldehyde for this use.

The use of formaldehyde for biocidal applications is not covered under REACH, but under the Biocidal Product Regulation, in which the uses (for example in hospitals, veterinary applications and embalming) potentially involve a large number of occupational exposed workers; although the applications made for BPR are still under review. These uses cover 251,148 workers (as per section 3.4) which is over 25% of the workers exposed to formaldehyde.

3.10.6 Construction Products Regulation (EU) No 305/2011

The Construction Products Regulation (EU) No 305/2011 involves the harmonisation of conditions for the marketing of construction products (Official Journal of the European Union, 2011). In the regulation, the basic requirements are that construction works need to take into account the health and safety of the workers. The regulation, however, refers to REACH for hazardous substances.

3.10.7 Cosmetic Products Regulation (EC) No 1223/2009

The Cosmetic Products Regulation (EC) No 1223/2009 concerns the rules for the marketing of cosmetic products and to ensure human health and the internal market functioning (Official Journal of the European Union, 2009). Annex V states that "*all finished products containing formaldehyde and which release formaldehyde must be labelled with the warning 'contains formaldehyde' where the concentration of formaldehyde in the finished product exceeds 0,05%".*

Under REACH, restrictions with regard to human health do not apply for cosmetic products (article 67(2) of REACH), however if there is an environmental risk then restriction under REACH can be used to minimise the risk (ECHA, 2017h).

3.10.8 Food Regulation (EC) No 231/2012/EC

The concentrations of formaldehyde in food are regulated by Regulation (EC) No 231/2012/EC which limits the concentration to 50 mg/kg in alganates and limits formaldehyde to a maximum of 0.1% of the food additive when used in food additives.

3.10.9 European EN Standard 13986

The use of formaldehyde based resins in wood based panels is regulated by EN Standards, where panels are required to be tested and classified as either E1 or E2 class. Emissions of formaldehyde are classed in emissions class E1 and E2. These emission classes are defined under the standard EN 13986-A1. For emissions class E1, formaldehyde release is below 0.1 ppm (0.12 mg/m^3), and between 0.1

ppm and 0.3 ppm (0.12-0.37 mg/m^3) for emissions class E2 (UK Health and Safety Executive, undated). This standard is particularly relevant for downstream users.

Californian formaldehyde emission standards are also followed by a company in an EU member state (consultation with an expert academic). These standards, known as CARB (California Air Resources Board), for composite wood products are generally stricter than EN standards (California Air Resources Board, 2016).

Table 3-45: Formaldehyde emission standards in California

Product	Effective date	Formaldehyde emission ceiling (ppm)
Hardwood Plywood- Veneer Core	January 2010	0.05
Hardwood Plywood- Composite Core	July 2012	0.05
Particleboard	January 2011	0.09
MDF	January 2011	0.11
Thin MSF	January 2012	0.13
Source: Composite Panel Association (undated): California Passes Tough Limits on Formaldehyde Emissions from Composite Wood Panels. Available at: https://www.compositepanel.org/userfiles/filemanager/89/		

3.11 Market analysis

This section presents market data for sectors identified as relevant in Section 3.3.

3.11.1 Enterprises affected by formaldehyde by sector

The total numbers of enterprises and the estimated numbers of enterprises associated with formaldehyde use broken down by sector and member state are given in Tables 3-46 to 3-48 overleaf.

Data on the total numbers of enterprises in each sector have been retrieved from the following sources:

- Data for Agricultural, Fishing and Farming sectors (NACE A) were available from the Agriculture, forestry and fishery statistics statistical yearbook published yearly by Eurostat (Eurostat, 2016);
- Data for Manufacturing, Construction, Water Supply, Sewerage and Waste, and Professional, Scientific and Technical activity sectors (NACE C, F, E and M, respectively) were retrieved from Eurostat's Structural Business Statistics database;
- Data for the Education sector (NACE P) were available from the World Directory of Medical Schools[19] and the European Tertiary Education Register (ETER)[20]
- Data for the Human Health and Social Work Activities sector (NACE Q) were retrieved from the European Hospital and Healthcare Federation database[21]; and
- Other (Consultation).

[19] World Directory of Medical Schools, available at: https://archive.is/20141023092001/http://wdoms.org/
[20] European Tertiary Education Register (ETER), available at: https://www.eter-project.com/hei
[21] HOPE database, available at http://www.hope.be/wp-content/uploads/2015/09/

Table 3-46: Total number of enterprises																								
MS	A	C10	C13	C15	C16	C17	C20	C21	C22	C25	C27	C28	C29	C30.3	C31	E36	E38	F41	M72	M74.2	M75	P85.4	Q86	S96.03	TOTALS by MS
AT	140,000	3,539	594	175	2,729	140	362	84	600	3,810	472	1,366	229	18	3,201	589	767	4,504	1,037	2,003	1,884	71	278	253	**168,705**
BE	38,000	6,665	1,159	164	1,547	239	588	100	726	6,955	553	1,276	383	28	1,670	46	902	22,763	800	2,417	4,175	94	195	329	**91,774**
BG	254,000	5,285	602	495	1,958	511	591	45	1,762	3,590	488	936	118	8	2,169	65	600	7,106	382	778	735	60	344	208	**282,836**
CY	35,000	805	103	0	855	41	18	7	79	1,083	82	56	74	0	332	6	22	2,208	0	272	97	42	88	25	**41,295**
CZ	26,000	7,436	2,424	719	27,672	950	1,762	78	3,572	44,931	12,689	5,194	1,105	0	6,419	559	5,258	32,254	1,045	0	2,636	76	255	307	**183,341**
DE	285,000	25,768	4,055	1,293	13,039	1,640	3,056	554	6,859	43,289	5,950	15,717	2,583	23	10,475	1,630	1,616	25,308	6,824	10,678	10,114	469	3,278	2,388	**481,606**
DK	39,000	1,458	300	61	487	138	245	102	518	2,773	453	1,663	153	19	489	1,975	294	3,267	591	1,459	692	37	40	166	**56,380**
EE	19,000	552	267	70	1,102	61	111	14	213	1,223	131	175	68	0	704	77	149	3,385	247	250	117	34	55	38	**28,043**
EL	710,000	16,068	1,711	828	3,107	686	1,034	94	1,071	9,443	970	1,991	421	17	4,195	700	939	24,151	6,246	2,901	1,309	64	313	313	**788,572**
ES	965,000	22,215	6,011	4,863	9,941	1,652	3,420	342	4,383	33,045	1,953	5,327	1,640	111	11,883	2,888	2,580	195,655	4,415	10,202	9,376	81	763	1,350	**1,299,096**
FI	54,000	1,742	714	183	1,853	178	292	31	541	4,470	414	1,369	235	9	908	717	503	18,120	578	1,218	1,126	31	275	159	**89,666**
FR	472,000	56,859	5,722	2,318	10,028	1,424	3,168	335	4,126	19,492	2,063	4,218	1,716	220	9,252	2,384	8,118	59,726	5,770	17,516	8,428	333	2,698	1,940	**699,854**
HR	157,000	2,759	467	189	1,680	301	341	49	1,126	3,200	423	729	120	12	937	151	539	6,425	227	508	261	39	58	122	**177,663**
HU	491,000	4,525	1,145	501	3,299	522	657	83	1,887	8,043	835	2,386	494	35	2,618	250	1,044	13,596	4,015	2,084	1,196	75	173	286	**540,749**
IE	140,000	1,637	421	60	947	205	299	23	475	3,041	262	163	123	9	1,110	188	575	13,798	573	0	1,198	27	98	137	**165,369**
IT	1,010,000	53,096	13,866	15,235	28,035	3,723	4,308	453	9,971	63,185	8,363	22,761	2,242	188	18,108	829	6,205	119,414	8,557	13,608	12,746	248	1,182	1,763	**1,418,086**
LT	172,000	1,578	914	172	3,924	96	149	22	371	1,769	108	187	49	4	2,023	73	299	3,862	506	2,451	567	49	105	84	**191,362**
LV	82,000	987	507	83	2,008	101	220	28	243	1,086	129	197	61	9	769	69	203	3,600	220	442	452	58	70	57	**93,599**
LX	2,000	128	19	0	23	3	16	1	24	181	11	24	10	0	27	7	49	1,387	30	108	145	1	12	17	**4,223**
MT	9,000	347	0	0	69	13	42	7	36	347	30	0	0	0	493	0	109	1,105	24	0	36	2	7	13	**11,680**

Table 3-46: Total number of enterprises																								
MS	A	C10	C13	C15	C16	C17	C20	C21	C22	C25	C27	C28	C29	C30.3	C31	E36	E38	F41	M72	M74.2	M75	P85.4	Q86	S96.0.3	TOTALS by MS
NL	67,000	5,615	2,126	540	2,516	378	873	218	1,405	11,181	1,193	3,047	746	63	8,308	29	936	66,526	4,426	17,637	2,316	61	259	493	**197,892**
PL	1,429,000	13,938	5,040	2,756	16,845	2,618	2,221	329	8,371	33,721	2,236	5,008	1,329	99	16,105	630	4,561	62,098	1,764	8,044	6,550	469	968	1,103	**1,625,803**
PT	264,000	9,337	3,480	3,182	5,208	572	779	134	1,074	11,437	608	1,523	684	22	4,446	151	1,028	37,704	1,606	2,244	2,267	141	224	301	**352,152**
RO	3,630,000	8,149	1,325	1,563	5,213	743	871	131	2,726	5,759	615	1,236	456	23	3,448	303	2,495	24,725	800	1,244	2,378	95	491	574	**3,695,363**
SE	67,000	3,777	2,130	497	5,245	393	828	146	1,540	10,622	956	3,109	1,050	44	2,361	259	863	22,463	3,882	8,545	1,357	52	79	286	**137,484**
SI	72,000	2,066	334	151	1,996	177	198	23	999	4,292	404	751	173	18	1,116	74	256	2,856	1,221	571	159	76	29	60	**90,000**
SK	24,000	2,390	1,252	310	10,618	289	385	30	1,437	26,290	1,372	1,371	366	0	1,200	38	930	12,129	636	0	1,082	33	140	158	**86,456**
UK	185,000	7,502	4,078	580	8,249	1,498	2,735	574	5,821	26,477	3,022	7,817	2,860	774	5,998	103	5,329	82,342	4,919	8,046	3,731	184	168	1,900	**369,707**
EU 28	**10,838,000**	**266,223**	**60,766**	**36,988**	**170,193**	**19,292**	**29,569**	**4,037**	**61,956**	**384,735**	**46,785**	**89,597**	**19,488**	**1,753**	**120,764**	**14,790**	**47,169**	**872,477**	**61,341**	**115,226**	**77,130**	**3,002**	**12,645**	**14,829**	**13,370,000**

Source: Eurostat – Structural Statistics database

Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities.

Values may not add up to totals due to rounding.

Table 3-47: Predicted number of enterprises associated with formaldehyde																								
MS	A	C10	C13	C15	C16	C17	C20	C21	C22	C25	C27	C28	C29	C30.3	C31	E36	E38	F41	M72	M74.2	M75	P85.4	Q86	S96.0.3	TOTALS by MS
AT	159	165	88	4	31	50	19	10	16	17	76	7	62	2	1,083	1	14	294	10	170	45	6	167	n/a	**2,498**
BE	63	185	149	4	14	146	40	16	19	19	106	5	82	7	926	1	14	576	10	167	47	10	117	n/a	**2,723**
BG	642	191	94	56	9	327	27	6	29	13	167	4	34	0	1,719	2	11	350	4	68	13	6	206	n/a	**3,978**
CY	36	24	11	0	2	19	3	1	1	1	9	0	4	0	70	0	0	67	0	19	2	4	53	n/a	**325**
CZ	59	177	183	26	126	350	41	10	51	56	877	14	249	18	2,018	5	40	758	7	0	38	5	153	n/a	**5,262**
DE	421	1,301	705	27	138	626	226	81	216	223	1,163	93	1,145	2	3,747	35	81	2,046	92	982	464	39	1,967	n/a	**15,819**
DK	45	70	44	0	14	77	16	29	14	12	99	8	38	1	367	2	5	137	10	101	28	4	24	n/a	**1,146**
EE	21	21	36	5	28	32	3	1	5	5	46	1	14	0	658	1	2	126	2	19	4	1	33	n/a	**1,064**
EL	1,071	287	116	13	4	142	27	9	14	13	81	4	30	1	747	8	9	382	26	218	19	7	188	n/a	**3,414**
ES	1,311	724	697	271	78	838	172	40	92	91	496	24	393	51	4,967	18	51	3,953	42	773	201	37	458	n/a	**15,780**
FI	41	55	49	2	42	89	15	3	12	9	98	6	46	1	406	3	8	526	0	78	24	5	165	n/a	**1,684**
FR	615	1,056	559	73	66	953	151	62	106	96	635	25	548	120	2,939	16	84	791	49	914	238	34	1,619	n/a	**11,751**
HR	388	99	46	14	44	133	11	5	15	24	102	2	20	1	587	6	12	257	3	53	20	4	35	n/a	**1,880**
HU	807	169	109	38	44	362	26	10	34	26	278	7	130	2	1,862	4	18	476	22	133	25	4	104	n/a	**4,691**
IE	156	50	38	0	6	65	11	10	9	6	26	2	16	0	293	1	7	243	2	0	37	6	59	n/a	**1,044**
IT	1,480	1,280	1,942	679	116	1,448	232	54	212	212	1,549	102	571	50	8,579	11	112	2,907	38	905	153	41	709	n/a	**23,381**
LT	252	52	70	5	66	69	7	1	8	5	29	1	15	3	1,119	2	7	285	3	86	10	2	63	n/a	**2,159**
LV	134	35	38	2	26	25	8	2	5	3	11	1	11	2	241	1	4	167	2	32	8	2	42	n/a	**800**
LX	3	6	n/a	0	1	n/a	1	n/a	n/a	1	4	0	0	0	18	0	0	58	0	6	2	0	7	n/a	**109**
MT	13	10	n/a	0	0	n/a	2	n/a	n/a	1	8	0	0	0	166	0	1	27	0	0	1	1	4	n/a	**234**
NL	223	226	162	6	7	111	50	16	29	31	105	13	125	6	1,032	1	15	974	32	638	94	9	155	n/a	**4,058**
PL	4,099	580	544	92	81	900	100	29	131	77	456	17	318	16	6,259	20	60	1,971	0	557	137	19	581	n/a	**17,042**
PT	675	257	471	282	50	285	34	9	24	31	175	5	113	2	2,821	4	10	1,142	8	155	46	8	134	n/a	**6,743**
RO	3,628	312	235	158	145	374	36	14	47	24	208	5	205	7	2,820	8	38	1,196	9	125	61	13	295	n/a	**9,963**
SE	54	101	65	4	47	178	28	10	23	28	152	9	164	0	701	1	5	603	19	133	48	7	47	n/a	**2,427**
SI	184	31	31	4	10	50	7	n/a	12	11	68	2	31	2	431	2	3	103	8	37	8	2	17	n/a	**1,056**

Table 3-47: Predicted number of enterprises associated with formaldehyde																								
MS	**A**	**C10**	**C13**	**C15**	**C16**	**C17**	**C20**	**C21**	**C22**	**C25**	**C27**	**C28**	**C29**	**C30.3**	**C31**	**E36**	**E38**	**F41**	**M72**	**M74.2**	**M75**	**P85.4**	**Q86**	**S96.0.3**	**TOTALS by MS**
SK	36	69	66	23	19	134	11	4	19	30	223	4	80	0	810	0	10	286	4	0	14	3	84	n/a	**1,929**
UK	**190**	396	642	15	123	561	178	49	152	112	566	33	610	167	2,967	45	126	2,563	78	658	459	25	101	1080	**11,898**
EU28	**16,807**	**7,928**	**7,192**	**1,805**	**1,339**	**8,344**	**1,481**	**481**	**1,296**	**1,177**	**7,814**	**393**	**5,053**	**461**	**50,353**	**197**	**749**	**23,263**	**480**	**7,026**	**2,246**	**304**	**7,587**	**1,350**	**160,000**

Source: data estimated by the study team

Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities.

Values may not add up to totals due to rounding.

Table 3-48: Percentage (%) share of enterprises associated with formaldehyde out of total enterprises in each sector																							
MS	**A**	**C10**	**C13**	**C15**	**C16**	**C17**	**C20**	**C21**	**C22**	**C25**	**C27**	**C28**	**C29**	**C30.3**	**C31**	**E36**	**E38**	**F41**	**M72**	**M74.2**	**M75**	**P85.4**	**Q86**	**S96.0.3**
AT	0.11%	5%	15%	2%	1%	36%	5%	12%	3%	0.5%	16%	0.5%	27%	11%	34%	0.2%	2%	7%	1.0%	8%	2%	8%	60%	n/a
BE	0.17%	3%	13%	3%	1%	61%	7%	16%	3%	0.3%	19%	0.4%	21%	26%	55%	2.1%	2%	3%	1.2%	7%	1%	11%	60%	n/a
BG	0.25%	4%	16%	11%	0%	64%	4%	14%	2%	0.4%	34%	0.5%	29%	3%	79%	3.2%	2%	5%	1.0%	9%	2%	10%	60%	n/a
CY	0.10%	3%	11%	n/a	0%	45%	14%	13%	2%	0.1%	11%	0.4%	5%	n/a	21%	4.0%	0%	3%	n/a	7%	2%	10%	60%	n/a
CZ	0.23%	2%	8%	4%	0%	37%	2%	13%	1%	0.1%	7%	0.3%	23%	n/a	31%	1.0%	1%	2%	0.7%	n/a	1%	7%	60%	n/a
DE	0.15%	5%	17%	2%	1%	38%	7%	15%	3%	0.5%	20%	0.6%	44%	8%	36%	2.1%	5%	8%	1.4%	9%	5%	8%	60%	n/a
DK	0.12%	5%	15%	0%	3%	56%	7%	29%	3%	0.4%	22%	0.5%	25%	6%	75%	0.1%	2%	4%	1.6%	7%	4%	11%	60%	n/a
EE	0.11%	4%	14%	8%	3%	52%	3%	8%	2%	0.4%	35%	0.5%	21%	n/a	93%	1.9%	2%	4%	0.6%	7%	3%	3%	60%	n/a
EL	0.15%	2%	7%	2%	0%	21%	3%	10%	1%	0.1%	8%	0.2%	7%	8%	18%	1.1%	1%	2%	0.4%	8%	1%	11%	60%	n/a
ES	0.14%	3%	12%	6%	1%	51%	5%	12%	2%	0.3%	25%	0.4%	24%	46%	42%	0.6%	2%	2%	0.9%	8%	2%	46%	60%	n/a
FI	0.08%	3%	7%	1%	2%	50%	5%	10%	2%	0.2%	24%	0.4%	20%	12%	45%	0.4%	2%	3%	0.0%	6%	2%	16%	60%	n/a
FR	0.13%	2%	10%	3%	1%	67%	5%	19%	3%	0.5%	31%	0.6%	32%	54%	32%	0.7%	1%	1%	0.9%	5%	3%	10%	60%	n/a

Table 3-48: Percentage (%) share of enterprises associated with formaldehyde out of total enterprises in each sector																							
MS	**A**	**C10**	**C13**	**C15**	**C16**	**C17**	**C20**	**C21**	**C22**	**C25**	**C27**	**C28**	**C29**	**C30.3**	**C31**	**E36**	**E38**	**F41**	**M72**	**M74.2**	**M75**	**P85.4**	**Q86**	**S96.0.3**
HR	0.25%	4%	10%	8%	3%	44%	3%	9%	1%	0.8%	24%	0.3%	17%	9%	63%	3.7%	2%	4%	1.2%	10%	8%	10%	60%	n/a
HU	0.16%	4%	10%	8%	1%	69%	4%	12%	2%	0.3%	33%	0.3%	26%	7%	71%	1.5%	2%	4%	0.5%	6%	2%	5%	60%	n/a
IE	0.11%	3%	9%	1%	1%	32%	4%	45%	2%	0.2%	10%	1.2%	13%	0%	26%	0.8%	1%	2%	0.4%	n/a	3%	22%	60%	n/a
IT	0.15%	2%	14%	4%	0%	39%	5%	12%	2%	0.3%	19%	0.4%	25%	26%	47%	1.3%	2%	2%	0.4%	7%	1%	17%	60%	n/a
LT	0.15%	3%	8%	3%	2%	72%	5%	5%	2%	0.3%	27%	0.5%	30%	63%	55%	3.2%	2%	7%	0.6%	3%	2%	4%	60%	n/a
LV	0.16%	4%	7%	2%	1%	25%	4%	7%	2%	0.3%	8%	0.4%	17%	21%	31%	1.8%	2%	5%	0.8%	7%	2%	3%	60%	n/a
LX	0.15%	5%	n/a	n/a	4%	n/a	9%	n/a	n/a	0.7%	36%	0.7%	0%	n/a	67%	0.0%	0%	4%	0.0%	5%	2%	0%	60%	n/a
MT	0.15%	3%	n/a	n/a	0%	n/a	4%	n/a	n/a	0.2%	27%	n/a	n/a	n/a	34%	n/a	1%	2%	0.0%	n/a	2%	50%	60%	n/a
NL	0.33%	4%	8%	1%	0%	29%	6%	7%	2%	0.3%	9%	0.4%	17%	9%	12%	2.0%	2%	1%	0.7%	4%	4%	15%	60%	n/a
PL	0.29%	4%	11%	3%	0%	34%	4%	9%	2%	0.2%	20%	0.3%	24%	16%	39%	3.2%	1%	3%	0.0%	7%	2%	4%	60%	n/a
PT	0.26%	3%	14%	9%	1%	50%	4%	7%	2%	0.3%	29%	0.4%	16%	10%	63%	2.4%	1%	3%	0.5%	7%	2%	6%	60%	n/a
RO	0.10%	4%	18%	10%	3%	50%	4%	11%	2%	0.4%	34%	0.4%	45%	30%	82%	2.6%	2%	5%	1.2%	10%	3%	14%	60%	n/a
SE	0.08%	3%	3%	1%	1%	45%	3%	7%	2%	0.3%	16%	0.3%	16%	0%	30%	0.2%	1%	3%	0.5%	2%	4%	13%	60%	n/a
SI	0.26%	2%	9%	3%	0%	29%	4%	n/a	1%	0.2%	17%	0.3%	18%	10%	39%	2.7%	1%	4%	0.7%	6%	5%	3%	60%	n/a
SK	0.15%	3%	5%	7%	0%	47%	3%	13%	1%	0.1%	16%	0.3%	22%	n/a	68%	0.5%	1%	2%	0.6%	n/a	1%	9%	60%	n/a
UK	0.10%	5%	16%	3%	1%	37%	7%	9%	3%	0.4%	19%	0.4%	21%	22%	49%	43.3%	2%	3%	1.6%	8%	12%	14%	60%	57%
EU28	**0.15%**	**3%**	**12%**	**5%**	**1%**	**43%**	**5%**	**12%**	**2%**	**0.3%**	**17%**	**0.4%**	**26%**	**26%**	**42%**	**1.3%**	**2%**	**3%**	**0.8%**	**6%**	**3%**	**10%**	**60%**	**9%**

Source: data estimated by the study team

Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities.

Values may not add up to totals due to rounding.

3.11.2 Enterprises associated with formaldehyde by sector and firm size

Definitions of SMEs and large enterprises

The number of small, medium and large enterprises associated with formaldehyde is an important input into the calculation of potential costs and benefits (Sections 4 and 5).

As already noted above, formaldehyde is used in a broad range of sectors. For most sectors, data were compiled using the standard definition of an SME (defined by the European Commission as having less than 250 persons employed); however, for the agricultural sector, a different definition applies (see table below).

Table 3-49: Definitions of SMEs and large enterprises for different sectors

Size band	Most sectors: NACE C, E, F, M, P, Q, S	Agricultural sector: NACE A
Small	Less than 49 employees	Very small and small farms are defined by a utilised agricultural area of less than 20 hectares
Medium	Between 50 and 249 employees	Medium farms are defined by a utilised area of >=20 and <100 hectares
Large	More than 250 employees	Large farms are defined by an utilised agricultural area of >= 100 hectares.
Source: Eurostat, RPA		

A breakdown of affected enterprises by firm size and member state are provided in Tables 3-50 to 3-52.

Table 3-50: Predicted number of enterprises affected by formaldehyde – SMALL enterprises																								
MS	A	C10	C13	C15	C16	C17	C20	C21	C22	C25	C27	C28	C29	C30.3	C31	E36	E38	F41	M72	M74.2	M75	P85.4	Q86	S96.0.3	TOTALS by MS
AT	151	154	80	4	30	30	15	6	14	16	52	5	36	1	1,053	1	14	275	9	169	44	0	0	n/a	**2,158**
BE	58	173	134	4	13	122	29	9	17	18	91	4	59	3	885	0	13	562	8	166	47	0	0	n/a	**2,417**
BG	635	176	83	49	8	305	23	3	27	12	138	4	19	0	1,647	1	9	334	4	67	13	0	0	n/a	**3,559**
CY	35	22	11	n/a	2	18	2	0	1	1	9	0	4	0	70	0	n/a	66	n/a	19	2	0	0	n/a	**264**
CZ	51	160	159	24	123	294	34	7	43	53	770	12	127	11	1,931	4	38	743	6	n/a	38	0	0	n/a	**4,627**
DE	370	1,173	631	25	132	446	155	41	174	207	896	73	531	2	3,511	32	81	1,990	79	970	462	0	0	n/a	**11,980**
DK	41	61	41	0	13	67	13	21	13	12	87	7	33	1	332	2	5	129	9	101	28	0	0	n/a	**1,013**
EE	20	18	32	5	25	32	3	1	5	4	35	1	11	0	612	1	2	126	2	19	4	0	0	n/a	**958**
EL	1,061	276	112	13	4	130	25	5	13	13	78	4	29	0	738	7	8	382	25	218	19	0	0	n/a	**3,160**
ES	1,264	680	676	266	76	747	153	25	85	89	436	23	275	33	4,883	14	43	3,931	38	772	201	0	0	n/a	**14,710**
FI	34	49	48	2	40	54	12	2	10	9	82	5	40	0	392	3	8	517	n/a	77	24	0	0	n/a	**1,407**
FR	544	989	532	66	62	807	119	34	94	92	523	21	377	39	2,818	13	76	755	45	911	238	0	0	n/a	**9,156**
HR	384	91	42	10	42	120	10	3	15	23	85	2	18	0	550	5	11	250	3	53	20	0	0	n/a	**1,736**
HU	794	153	97	32	42	316	23	4	30	25	204	6	62	2	1,799	2	16	476	21	133	25	0	0	n/a	**4,262**
IE	136	42	38	0	6	61	9	5	8	5	23	2	16	n/a	289	1	7	243	2	n/a	36	0	0	n/a	**929**
IT	1,439	1,244	1,874	661	116	1,350	209	32	199	206	1,444	95	447	25	8,366	8	101	2,887	37	904	153	0	0	n/a	**21,797**
LT	246	45	61	4	64	59	6	1	8	4	21	1	11	3	1,021	2	6	274	3	85	10	0	0	n/a	**1,935**
LV	130	31	35	2	25	23	7	1	5	3	9	1	9	2	229	1	4	162	2	32	8	0	0	n/a	**720**
LX	3	5	n/a	n/a	1	n/a	1	n/a	n/a	1	3	0	n/a	n/a	18	n/a	0	54	n/a	6	2	0	0	n/a	**94**
MT	13	9	n/a	n/a	0	n/a	2	0	n/a	1	8	n/a	n/a	n/a	166	n/a	1	26	n/a	n/a	1	0	0	n/a	**227**
NL	210	207	154	5	6	87	40	11	26	29	94	11	108	2	1,011	0	13	955	30	636	94	0	0	n/a	**3,729**
PL	4,049	513	500	86	72	781	83	21	113	71	352	14	176	4	5,845	17	54	1,930	n/a	556	137	0	0	n/a	**15,373**
PT	667	245	437	263	48	257	32	6	22	30	151	5	85	1	2,732	2	9	1,128	8	155	46	0	0	n/a	**6,328**
RO	3,616	286	208	134	139	343	30	10	42	22	155	4	84	3	2,573	5	34	1,157	8	125	61	0	0	n/a	**9,041**
SE	49	92	61	4	45	131	23	5	21	27	132	8	110	n/a	663	0	3	584	18	133	47	0	0	n/a	**2,157**
SI	183	29	27	3	9	42	6	n/a	11	10	49	2	20	1	418	2	3	101	8	37	8	0	0	n/a	**969**
SK	33	64	59	19	19	114	9	3	16	29	168	3	26	0	742	n/a	10	282	4	n/a	14	0	0	n/a	**1,613**
UK	161	332	602	14	119	460	153	35	136	107	495	30	479	92	2,805	43	118	2,478	68	658	449	0	0	900	**10,735**
EU28	**16,375**	**7,319**	**6,733**	**1,694**	**1,282**	**7,198**	**1,227**	**294**	**1,145**	**1,119**	**6,590**	**343**	**3,193**	**226**	**48,098**	**167**	**687**	**22,798**	**434**	**7,002**	**2,232**	**0**	**0**	**1,125**	**140,000**

Table 3-50: Predicted number of enterprises affected by formaldehyde – SMALL enterprises																								
MS	A	C10	C13	C15	C16	C17	C20	C21	C22	C25	C27	C28	C29	C30.3	C31	E36	E38	F41	M72	M74.2	M75	P85.4	Q86	S96.0.3	TOTALS by MS
Source: data estimated by the study team Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities. Values may not add up to totals due to rounding																								

Table 3-51: Predicted number of enterprises affected by formaldehyde - MEDIUM enterprises																								
MS	A	C10	C13	C15	C16	C17	C20	C21	C22	C25	C27	C28	C29	C30.3	C31	E36	E38	F41	M72	M74.2	M75	P85.4	Q86	S96.0.3	TOTALS by MS
AT	9	8	7	0	1	11	2	1	2	1	9	1	10	1	26	0	n/a	15	1	1	1	0	50	n/a	**158**
BE	5	8	11	0	1	14	6	2	2	1	8	0	7	1	40	0	1	12	1	1	0	0	35	n/a	**154**
BG	4	13	8	5	1	16	2	1	2	1	17	0	3	0	64	0	1	15	0	0	0	0	62	n/a	**216**
CY	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	n/a	1	n/a	0	0	0	16	n/a	**20**
CZ	2	13	18	2	2	44	4	2	5	2	49	2	30	2	81	1	2	13	1	n/a	0	0	46	n/a	**321**
DE	41	84	61	2	4	111	31	11	29	12	121	10	95	n/a	202	2	n/a	48	6	8	2	0	590	n/a	**1,472**
DK	3	5	3	0	1	6	2	1	1	1	9	1	4	n/a	31	0	0	6	1	0	0	0	7	n/a	**81**
EE	1	2	3	1	2	0	n/a	0	0	0	8	0	2	0	44	n/a	n/a	n/a	0	0	0	0	10	n/a	**73**
EL	9	8	3	0	0	10	2	3	1	0	1	n/a	1	n/a	9	1	0	n/a	0	0	0	0	56	n/a	**104**
ES	38	31	21	5	2	72	14	8	6	2	33	1	47	6	79	2	3	18	3	1	0	0	137	n/a	**529**
FI	7	3	1	0	1	14	2	0	1	0	10	1	4	n/a	12	0	0	7	n/a	0	0	0	50	n/a	**114**
FR	56	39	25	5	4	106	17	8	9	4	56	2	51	12	104	1	4	15	3	3	0	0	486	n/a	**1,009**
HR	3	4	3	2	2	13	1	0	1	1	13	0	1	1	31	1	1	5	0	0	0	0	10	n/a	**93**
HU	9	12	8	4	1	28	2	1	3	1	39	1	17	1	50	1	2	n/a	0	0	0	0	31	n/a	**210**
IE	19	5	1	0	0	4	1	2	1	0	2	0	n/a	n/a	4	0	0	n/a	0	n/a	0	0	18	n/a	**58**
IT	38	26	58	15	0	73	17	11	10	5	67	5	45	6	196	2	7	18	1	1	0	0	213	n/a	**815**
LT	4	5	6	0	2	7	1	0	n/a	0	6	0	1	0	79	0	1	10	0	0	0	0	19	n/a	**143**

Table 3-51: Predicted number of enterprises affected by formaldehyde - MEDIUM enterprises																								
MS	A	C10	C13	C15	C16	C17	C20	C21	C22	C25	C27	C28	C29	C30.3	C31	E36	E38	F41	M72	M74.2	M75	P85.4	Q86	S96.0.3	TOTALS by MS
LV	3	3	2	0	1	2	1	0	0	0	2	0	2	0	10	0	0	5	0	0	0	0	13	n/a	**44**
LX	0	1	n/a	n/a	0	n/a	0	n/a	n/a	0	1	0	n/a	n/a	0	n/a	0	3	n/a	0	0	0	2	n/a	**8**
MT	0	0	n/a	n/a	0	n/a	0	n/a	n/a	0	1	n/a	n/a	n/a	0	n/a	0	1	0	n/a	0	0	1	n/a	**3**
NL	12	14	7	0	1	21	6	3	3	1	7	1	9	4	20	0	2	15	1	2	0	0	47	n/a	**175**
PL	46	44	33	4	7	88	10	4	13	5	53	2	43	2	295	2	5	34	n/a	1	0	0	174	n/a	**866**
PT	7	10	27	17	2	24	2	2	2	1	13	0	12	1	82	1	1	12	0	1	0	0	40	n/a	**257**
RO	8	19	17	20	4	25	3	2	3	2	28	1	18	1	201	1	3	36	1	0	0	0	88	n/a	**480**
SE	4	5	4	0	2	15	3	1	2	1	11	1	16	n/a	34	0	1	12	1	1	1	0	14	n/a	**127**
SI	1	1	3	1	1	5	1	n/a	1	0	6	0	4	0	13	n/a	0	2	0	0	0	0	5	n/a	**46**
SK	1	5	6	2	0	11	1	0	2	1	29	0	15	0	54	0	1	4	0	n/a	0	0	25	n/a	**157**
UK	20	36	36	1	3	89	19	6	14	5	58	3	65	25	146	0	7	72	6	n/a	9	0	30	120	**771**
EU28	**351**	**408**	**372**	**87**	**46**	**807**	**151**	**70**	**111**	**48**	**657**	**32**	**501**	**62**	**1,907**	**15**	**43**	**380**	**27**	**21**	**14**	**0**	**2,276**	**150**	**10,000**

Source: data estimated by the study team

Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities.

Values may not add up to totals due to rounding

Table 3-52: Predicted number of enterprises affected by formaldehyde - LARGE enterprises																								
MS	A	C10	C13	C15	C16	C17	C20	C21	C22	C25	C27	C28	C29	C30.3	C31	E36	E38	F41	M72	M74.2	M75	P85.4	Q86	S96.0.3	TOTALS by MS
AT	0	3	1	0	0	9	2	3	1	0	15	1	16	0	3	0	n/a	4	0	0	0	6	117	n/a	**182**
BE	0	4	4	0	0	10	4	6	1	0	8	0	16	3	1	0	0	2	0	0	0	10	82	n/a	**152**
BG	3	2	3	1	0	6	1	2	1	0	12	0	13	0	8	1	0	1	0	0	0	6	144	n/a	**204**
CY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	n/a	0	n/a	0	0	4	37	n/a	**42**
CZ	5	5	7	0	1	12	2	2	3	1	58	1	92	5	6	1	1	2	0	n/a	0	5	107	n/a	**314**

Table 3-52: Predicted number of enterprises affected by formaldehyde - LARGE enterprises																									
MS	A	C10	C13	C15	C16	C17	C20	C21	C22	C25	C27	C28	C29	C30.3	C31	E36	E38	F41	M72	M74.2	M75	P85.4	Q86	S96.0.3	TOTALS by MS
DE	11	44	13	1	1	68	40	29	13	4	146	9	519	n/a	34	1	n/a	7	7	4	0	39	1,377	n/a	**2,366**
DK	2	4	0	0	0	3	2	8	0	0	4	0	1	n/a	4	0	0	2	1	0	0	4	17	n/a	**52**
EE	1	1	1	0	1	0	n/a	0	0	0	3	0	1	0	2	n/a	n/a	n/a	0	0	0	1	23	n/a	**33**
EL	0	3	1	0	0	2	0	1	0	0	1	n/a	0	1	0	0	0	n/a	1	0	0	7	131	n/a	**149**
ES	9	13	1	0	0	19	5	7	2	0	28	0	71	12	5	2	5	3	1	0	0	37	320	n/a	**540**
FI	1	2	0	0	1	22	1	1	0	0	7	0	2	1	2	0	0	3	n/a	0	0	5	116	n/a	**163**
FR	15	28	3	2	1	40	15	20	4	1	56	1	121	69	16	2	3	20	2	0	0	34	1,133	n/a	**1,586**
HR	0	3	1	2	0	1	0	1	0	0	4	0	1	0	6	0	0	1	0	0	0	4	24	n/a	**51**
HU	5	4	4	2	0	18	1	4	1	0	36	0	51	0	13	1	0	n/a	0	0	0	4	73	n/a	**219**
IE	1	3	0	0	0	0	1	3	0	0	1	0	n/a	n/a	0	0	0	n/a	0	n/a	0	6	41	n/a	**56**
IT	4	10	10	3	0	25	6	11	2	1	37	2	79	19	17	1	4	2	0	0	0	41	496	n/a	**769**
LT	2	2	2	0	0	3	1	0	n/a	0	2	0	2	0	20	0	0	1	0	0	0	2	44	n/a	**81**
LV	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	2	29	n/a	**36**
LX	0	0	n/a	n/a	0	n/a	0	n/a	n/a	0	0	0	n/a	n/a	0	n/a	n/a	1	n/a	0	0	0	5	n/a	**6**
MT	0	0	n/a	n/a	0	n/a	0	n/a	n/a	0	0	n/a	n/a	n/a	0	n/a	0	0	0	n/a	0	1	3	n/a	**4**
NL	1	6	2	0	0	4	4	2	0	0	3	0	7	n/a	1	0	1	3	1	0	0	9	109	n/a	**155**
PL	4	23	11	1	3	31	7	4	5	1	51	1	99	9	119	1	1	7	0	0	0	19	407	n/a	**803**
PT	1	2	7	2	1	4	0	1	0	0	11	0	16	0	7	0	0	2	0	0	0	8	94	n/a	**158**
RO	4	7	10	5	1	6	2	1	2	0	25	0	104	3	45	2	1	3	0	0	0	13	206	n/a	**442**
SE	1	3	1	0	1	31	2	3	0	0	9	1	38	n/a	4	0	1	7	0	0	0	7	33	n/a	**143**
SI	0	1	0	1	0	4	1	n/a	0	0	13	0	6	0	1	n/a	0	0	0	0	0	2	12	n/a	**41**
SK	2	1	1	2	0	9	1	0	1	0	25	0	38	0	14	n/a	0	0	0	n/a	0	3	59	n/a	**159**
UK	8	28	5	0	0	12	6	8	3	1	13	1	66	50	16	1	1	12	4	n/a	0	25	71	60	**391**
EU28	**81**	**202**	**88**	**23**	**11**	**339**	**103**	**117**	**40**	**11**	**567**	**18**	**1,360**	**172**	**348**	**15**	**20**	**85**	**18**	**4**	**1**	**304**	**5,311**	**75**	**10,000**

Table 3-52: Predicted number of enterprises affected by formaldehyde - LARGE enterprises																							
MS	A	C10	C13	C15	C16	C17	C20	C21	C22	C25	C27	C28	C29	C30.3	C31	E36	E38	F41	M72	M74.2	M75	P85.4	Q86	S96.0.3	TOTALS by MS
Source: data estimated by the study team Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities. Values may not add up to totals due to rounding																							

3.12 Alternatives

Overview

Alternatives to formaldehyde for many of its uses have been investigated in the literature, although the available information is very limited. The alternatives identified from a literature review have been further updated by consultation and are discussed in this section together with their feasibility. For many of the identified alternatives, limited information about the technical and economic feasibility is available and, in some sectors, no alternatives have been found to be suitable (ANSES, 2016). Where available, information on the health hazards from the ECHA CLP database is also presented for the alternatives.

Agriculture, Forestry and Fishing (NACE Code A)

Fertilisers

Possible alternatives to formaldehyde in fertilisers are discussed in the manufacturing of chemicals and chemical products.

Aquaculture

In a Scottish Aquaculture Research Forum (SARF) study, a number of alternatives to formaldehyde (formalin) for the treatment of white spot were identified and assessed (SARF, 2015). The most promising formalin alternatives identified were:

- Salt (sodium chloride- no classified hazards): Salt can be effective in controlling white spot, however, most systems are not readily adaptable for salt applications and there may be issues with discharge consents;
- Bronopol (classified as Acute Tox. 4, Skin Irrit. 2, Eye Dam. 1 and STOT SE 3): Novartis produce Pyceze™ which can be used for the prevention and reduction of fungal infections in salmon and trout in fish farms; however, information about its field effectiveness is limited;
- Praziquantal: A product containing 50% praziquantal is available in the UK. It may be more effective than formalin, however, the cost effectiveness of the product may be an issue;
- Peracetic acid (classified as Acute Tox. 4, Skin Corr. 1A and Acute Tox. 4): This has been recommended as an alternative to formalin. It is likely to be a useful treatment; however, its use needs to be tailored for the aquaculture sector;
- Hydrogen peroxide (classified as Acute Tox. 4 and Skin Corr. 1A): This can be used for the treatment of other external parasites, but its effectiveness against white spot is not high; the decomposition products are also toxic;
- Chlormaine T: This alternative requires further investigation;
- Green tea extract and epigallocatechin gallate (EGCG): Has the potential to be used as an in-feed treatment, an in-feed prophylactic or a bath treatment, although its toxicity and long-term exposure needs further investigation;
- Quinine (classified as Acute Tox. 4, Skin Irrit. 2, Skin Sens. 1, Eye Irrit. 2 and Resp. Sens. 1): This has potential in aquaculture, however, requires further investigation; and
- Mechanical and management measures: Reducing stocking densities, reducing the temperature that fish are reared in; minimising live fish movements between sites; and employing a mechanical system to remove cysts from commercial trout raceways can also be used as alternatives to formaldehyde.

Manufacturing of food products (NACE Code C10)

ANSES (2016) have performed a review of the alternatives to formaldehyde in the manufacturing of food products. In the manufacturing of food sugar, the extract of hop in aqueous solution that contains 10% beta acids is authorised in France as a technological auxiliary in the manufacture of sugar and could be a replacement for formaldehyde. No further information is available for this alternative. Formaldehyde alternatives for food additives include ozone (classified as Skin Irrit. 2, Eye Irrit. 2, Acute Tox. 1, STOT SE 3, Muta. 2 and STOT RE 2), hydrogen peroxide, quaternary ammonium (classified as Skin Irrit. 2 and Eye Dam. 1) and dry salting; however, information for these potential alternatives is limited. In animal feed vegetal tannins, essential oils, microbiological preservatives, latoperoxydase system, hydrogen peroxide, lactobacillus and organic acids may also be potential alternatives to formaldehyde, although further information is required (ANSES, 2016).

Manufacture of textiles (NACE Code C13)

For wrinkle resistance in the finishing of textiles; chitosan (Skin Irrit. 2, Eye Irrit. 2 and STOT SE 3), dimethyl urea glyoxal, polyvinylpyrrolidone (no CLP notifications from the majority of notifications) and polymaleic acid (Eye Irrit. 2, Skin Corr. 1B and Skin Irrit. 2) have been identified as possible alternatives to the use of UF resins in textiles (SUBSPORT, 2013). HeiQ Ecodry is marketed as a formaldehyde-free repellent textile technology for protection against water and stains (ChemSec, undated).

Manufacture of leather and related products (NACE Code C15)

Alternatives are available to formaldehyde for tanning in the manufacture of leather. Arkema market a formaldehyde alternative, THPS for use in the final stages of leather processing (Arkema, undated). Chromogenia manufacture a formaldehyde free product, Retanal 301FF, which is a re-tanning agent (Chromogenia, 2015).

Manufacture of wood and products of wood and cork; except furniture (NACE Code C16)

Urea-formaldehyde (UF) resins are used in the manufacture of wood panels. Alternatives and their feasibility have been investigated in a study for Formacare (TNO Triskelion BV and RPA, 2013). These are summarised in Table 3-53. The conclusions for these as alternatives to formaldehyde were that:

- None of the technically feasible alternatives are available across all grades of wood based panels; and
- The alternatives also possess other risks.

In addition, further information has been obtained from consultation. Some of these alternatives also use formaldehyde as a precursor, so formaldehyde exposure would still occur. This includes in the synthesis of p-MDI and isocyanates. PVA (polyvinyl acetate) also involves using vinyl acetate monomer which is classified as a carcinogenic category 2 substance.

Table 3-53: Alternatives to formaldehyde in wood based panels				
Resin	**Technical Feasibility**	**Economic Feasibility**	**Environmental/Health Considerations**	**CLP Classification**
Polymeric Diphenylmethane Diisocyanate (p-MDI)	Excellent strength, heat, water and humidity resistance; Suitable for exterior grade boards; Not suitable for existing plants or equipment	More expensive than UF (around x4) and PF resin; Smaller dosage required; Major supply issues; Cost of achieving suitable plant and equipment; Additional costs of maintaining safe operations in plant due to hazards	No formaldehyde emission from cured product; Potential exposure to isocyanate for workers; Health risks to workers from p-MDI	Skin Irrit. 2, Eye Irrit. 2, Acute Tox. 2, Resp. Sens. 1, STOT SE 3 and STOT RE 2
Emulsion Polymer Isocyanates (EPI)	Excellent high dry/wet strength, durable bonds, cold cured and fast setting speeds; Short pot life; May be suitable with existing equipment; Additional process steps and equipment required for mixing and metering and for tackiness of EPI; Sticks to metals	High cost; Additional equipment and processing steps required	No environmental threat; No formaldehyde emissions; Potential workplace exposure during manufacturing to isocyanate	N/A
Polyurethanes	High wet and dry strength; Resistance in water and damp atmospheres; Cures well at room temperature; Stains easily; Sticks to press platens	High cost; Additional release agent is required to avoid sticking to press platens	IARC group 3 carcinogen; Workplace exposure to isocyanates possible	N/A
Epoxy Adhesives	Excellent moisture and weather resistance; Strong bonds; Additional metering and	Expensive and unattractive market price; Typically used at greater weights per bonded surface	Inert; Potential risks to workers as many components are toxic or irritants; Potential environmental concerns	N/A

Table 3-53: Alternatives to formaldehyde in wood based panels				
Resin	**Technical Feasibility**	**Economic Feasibility**	**Environmental/Health Considerations**	**CLP Classification**
	mixing equipment needed; Can be difficult to use and requires long cure times			
PVA (Plywood) and EVA	Good dry strength; Easy to use; Poor moisture resistance; Poor thermoplastic; Lack required technical characteristics	Slightly more expensive than UF	No health risks; no/low VOCs and solvent free; Environmentally friendly	N/A
Protein Glues	Poor water and mould resistance; Limited durability; Uncross-linked glues typically lack the required properties; Requires a cross-linker (typically formaldehyde) to be technically viable	Generally low cost; Critical supply problems are likely to exist for blood and casein	No formaldehyde emissions from final product; Environmentally safe; Health and safety concerns over the use of blood and also in relation to the additional crosslinkers needed to produce technically suitable boards	N/A
Tannins	Low performance; Material inconsistency-difficult to manufacture with consistent properties; Short pan life and weak bond formation; Requires a cross-linker (typically formaldehyde) to be technically viable	Expensive; Limited supply	No health and environmental concerns for uncross-linked tannin additives; The extent of actual risk reduction is unclear when cross-linked with formaldehyde	Eye Irrit. 2

Table 3-53: Alternatives to formaldehyde in wood based panels				
Resin	**Technical Feasibility**	**Economic Feasibility**	**Environmental/Health Considerations**	**CLP Classification**
Lignin Adhesives	High temperature and long duration is needed for curing; Can be corrosive for machinery; Requires a cross-linker (typically formaldehyde) to be technically viable	Available in large quantities at low cost	No health and environmental concerns for uncross-linked lignin additives; The extent of actual risk reduction is unclear when cross-linked with formaldehyde	N/A
Source: TNO Triskelion BV and RPA (2013): Analysis of the most appropriate risk management measure for formaldehyde. Available at http://www.formacare.org/wp-content/uploads/2014/09/RMO-Report-Final-Report-_final-_version_clean_20131114.pdf				

Manufacture of paper and paper products (NACE Code C17)

RIVM concluded that for the use of formaldehyde as a slimicide in the paper and pulp industry, alternatives are expected to be available (RIVM, 2015). Over thirty products were found for this process based on ten active substances, although four of these are not suitable as they contain bronopol (classified as Acute Tox. 4, Skin Irrit. 2, Eye Dam. 1 and STOT SE 3) which can release formaldehyde.

Manufacture of chemicals and chemicals products (NACE Code C20: C20.1, 20.2 and 20.4)

Manufacture of resins

ANSES discuss alternatives based on a literature review; however, they note that information on these alternatives and their feasibility is limited (ANSES, 2016). No technically and economically feasible alternatives have been identified from consultation.

For alternatives to UF resins, the most promising identified were (ANSES, 2016):

- Soybean adhesives (particle board, MDF and plywood): These have good availability, are technically feasible and are low cost, but need to be improved;
- Blood adhesive (particleboard and MDF): These have limited availability, are low cost; however, there are issues for workplace exposure due to odour and vermin;
- Casein adhesive (MDF and particleboard): Limited feedstock, are technically feasible and cost competitive, however requires a long cure time;
- Lignocellulosic residue from wood (MDF and particle board): Have an uncertain availability, are technically feasible, however, they are not as durable as synthetic resins and there is no information available for economic feasibility; and
- Lignin adhesives (plywood): are feasible, however there is limited information.

For alternatives to MF resins, a number of alternatives were identified by ANSES such as polyester (Acute Tox. 4, Skin, Corr. 1A and STOT SE 3), epoxy (epoxy resin is classified as Skin Irrit. 2, Skin Sens. 1 and Eye Irrit. 2) and acrylic, however information is very limited on their feasibility as alternatives. For PF resin alternatives, ANSES notes that modified soybean adhesives are under development for

wood products, however at the present time these are lower strength and less tolerant to moisture and also need to be technically and economically feasible. A number of other alternatives are also discussed; however, these are generally not both technically and economically feasible. For POM resin alternatives, polystyrene (for consumer applications), ABS (Acrylonitrile butadiene styrene-for consumer applications) and polyesters (for automotive applications) have been identified as possible alternatives (ANSES, 2016).

Manufacture of other organic basic chemicals (NACE Code C20.13)

Alternatives to formaldehyde in chemical synthesis processes have also been identified by ANSES, however, information on these alternatives and their feasibility is also very limited. In the synthesis of MDI, TDI and other isocyanates are possible alternatives; however, these are not economically feasible at the present time. In the synthesis of BDO (butanediol), propylene oxide (Acute Tox. 3, Eye Irrit. 2, STOT SE 3, Muta. 1B and Carc. 1B) has been identified as possibly being feasible but would require further capital investments. For synthesis of penta, BDO and HTMA (Hexamethylenetetramine), the information on the feasibility of alternatives is also very limited (ANSES, 2016).

Manufacture of fertilisers and nitrogen compounds (NACE Code C20.1.5)

Possible alternatives to formaldehyde in fertilisers have been discussed by ANSES, although limited information is available for these alternatives (ANSES, 2016).

Table 3-54: Alternatives to formaldehyde in fertiliser manufacturing

Alternative	End-use market	Technical feasibility	Economic feasibility
Natural organic fertilisers	Agricultural and non-agricultural	+ Increased convenience	+ Lower cost
IBDU (urea-isobutyraldehyde)	Non-agricultural (professional turf and landscaping)	+	
CDU (urea crotonaldehyde)	Non-agricultural (professional turf and landscaping)	+	
SCU (sulfur coated fertilisers)	Not specified	+	- Twice most costly
FRF (fast-release fertiliser)	Not specified	- Many disadvantages	+ Cheaper

Source: ANSES (2016): Analysis of the most appropriate risk management option (RMOA) - formaldehyde. Available at http://www.consultations-publiques.developpement-durable.gouv.fr/IMG/pdf/RMOA_Formaldehyde_040716.pdf

Manufacture of metals (NACE Code C25)

No suitable alternatives have so far been identified from a response received during consultation.

Professional, Scientific and Technical Activities: Photographic activities (NACE Code M74.2)

In a study carried out by RPA in 2006, there was movement in the industry to formaldehyde-free processes (formaldehyde is used as a stabiliser) due to the change to digital films (RPA, 2006).

Higher Education (NACE Code P85.4)

Ethanol, 70% solution (Acute Tox. 4, Eye Irrit. 2 and STOT SE 2 is being used in one facility to replace formaldehyde in the storage of bodies. This is technically feasible, however, reconstruction of preservative facilities may be required (which may result in a large cost); the substitution with ethanol also may not be viable due to the explosion risks, and there is also limited information so far on the quality when ethanol is used as an alternative to formaldehyde (from consultation).

Human health and social work activities: Human health activities (NACE Code Q86)

ANSES (2016) concluded that alternatives to formaldehyde for histology and anatomopathological applications are specific to applications and no universal alternative is currently available (ANSES, 2016). Paxgene®, Finefix®, Histochoice® and RCL2® are available, however, these are only feasible under specific non-universal conditions which are not compatible with international standards in cleaning applications (such as sterilisation). Alternatives that have been suggested for formaldehyde include hydrogen peroxide, ortho-phthaladehyde, chlorine dioxide (Skin Corr. 1B and Acute Tox. 2) and benzalkonium chloride. RIVM concluded there were sufficient alternatives available for cleaning applications, with at least eight alternatives for cleaning and at least six alternatives for equipment and instruments (RIVM, 2015).

Funeral services

In embalming, the following substances are being approved in France as alternatives to formaldehyde (ANSES, 2016):

- Ethanol;
- Peracetic acid (Acute Tox. 4 and Skin Corr. 1A); and
- Propolis alcholate.

The Champion Company also produce an embalming substance which is based on plant oils (The Champion Company, undated). Consultation with a funeral services provider regarding these alternatives suggested that none are actually suitable alternatives for formaldehyde in embalming. Ethanol is hazardous and would also increase exposure to other chemicals. Peracetic acid and propolis alcholate do not cross-link to proteins, which is a key function of formaldehyde and stops bacteria nourishment.

From consultation, the alternatives available on the market can be effective in the short term, however, they are not suitable for cases where decomposition has started or where bodies have to be kept for long periods.

Other sectors of exposure

Alternatives to formaldehyde in flower bulb treatment have been subject to investigation. In a submission by the Royal General Bulb Growers Association to a consultation on the Biocidal Products Regulation, the following substances have been the focus on research as alternatives to formaldehyde, although the use of formaldehyde is still required (Royal General Bulb Growers Association, undated):

- Ascorbic acid (no hazards have been identified according to the majority of notifications);
- Chlorine dioxide (Skin Corr. 1B and Acute Tox. 2);
- Electrolysed water;
- Hydrogen peroxide (Acute Tox. 4 and Skin Corr. 1A);
- Ozone (Skin Irrit. 2, Eye Irrit. 2, Acute Tox. 1, STOT SE 3, Muta. 2 and STOT RE 2;

- Peracetic acid (Acute Tox. 4 and Skin Corr. 1A;
- Potassium iodide (STOT RE 1);
- Potassium peroxymonosulfate (Acute Tox. 4, Skin Corr. 1B and Eye Dam. 1);
- Potassium thiocyanate (Acute Tox. 4); and
- Sodium hypochlorite (Skin Corr. 1B).

3.13 Summary of the current burden of disease

The current burden of disease has been estimated using the data in the preceding sections and assumes that the number of workers in the relevant sectors has been decreasing by just 5% per annum and the exposure concentrations have not changed. This trend is approximated by applying the ERR and/or DRR to an estimated workforce/concentration halfway through a past assessment period of 40 years.

Table 3-55: Current burden of disease due to past exposure	
Endpoint	**CBD**
Nasopharyngeal cancer	330 per year (due to past exposure)
Sensory irritation	19,200 workers affected on any given day
Source: Derived by the study team.	

The estimates presented above only relate to the sectors where exposure to formaldehyde currently occurs and do not represent the total burden of past occupational exposure to formaldehyde. The total burden from all past occupational exposure to formaldehyde would require consideration of sectors where occupational exposure no longer takes place (e.g. use of photographic activities M74.2) and which are not relevant to the problem definition for this Impact Assessment.

3.14 Future burden of disease

The number of cases expected to occur in the future is given below. These estimates are based on the assumption that the number of workers and exposure concentrations will remain unchanged.

Table 3-56: Baseline burden of disease – constant workforce			
Endpoint	**Number of cases over 40 years**	**Number of cases over 60 years**	**Monetary value PV 60 years (Additional cases only)**
			Static discount rate
Nasopharyngeal cancer	CBD+4	CBD+7	€4 million-€3bilion
Sensory irritation	19,200 workers affected on any given day	19,200 workers affected on any given day	€1 billion-€5billion
Source: Derived by the study team.			

3.15 Summary of the baseline scenario

Table 3-57 provides a summary of the baseline scenario for this impact assessment.

Table 3-57: Formaldehyde – summary of the baseline scenario	
Carcinogen	Formaldehyde (CAS 50-00-0)
Classification	Carc. 1B

Table 3-57: Formaldehyde – summary of the baseline scenario	
Key sectors used	Agriculture, Forestry and Fishing Manufacturing of food products Manufacture of textiles Manufacture of leather and related products Manufacture of wood and products of wood and cork - except furniture Manufacture of paper and paper products Manufacture of chemicals and chemical products Manufacture of basic pharmaceutical products and pharmaceutical preparations Manufacture of rubber and plastic products Manufacture of fabricated metals, except machinery and equipment Manufacture of electrical equipment Manufacture of machinery and equipment Manufacture of motor vehicles, trailers and semi-trailers Manufacture of air and spacecraft and related machinery Manufacture of furniture Water collection, treatment and supply Waste collection, treatment and disposal activities; materials recovery Construction of buildings Professional, Scientific and Technical Activities: Scientific research and development Professional, Scientific and Technical Activities: Photographic activities Professional, Scientific and Technical Activities: Veterinary activities Higher education Human health activities Funeral and related activities
Cancer endpoint(s)	Nasopharyngeal cancer (NFC)
Non-cancer endpoint(s)	Sensory irritation
No. of exp. Workers	990,000 (current number of exposed workers under the baseline)
Change exp. level	Past: -5 p.a. (estimated) Future: 0% (expected slight decline in the number of exposed workers but not included in the model)
Period for estimation	60 years (future)
Current disease burden (CDB) - no. of cancer cases	330 per year (due to past exposure)
Future disease burden (FDB) - no. of **cancer** cases	CBD+ 7 additional cases over 60 years
CDB no. of **other** adverse health effects	19,200 workers affected on any given day
FDB no. of **other** adverse health effects	19,200 workers affected on any given day
Exp. no. of **deaths** FDB cancer	CBD and 3 additional over 60 years
Exp. no. of **deaths** FDB other adverse health effects	0 over 60 years

Table 3-57: Formaldehyde – summary of the baseline scenario	
Monetary value FDB cancer	Additional cases only: €4 million over 60 years (Method 1), €3 billion (Method 2)
Monetary value FDB other adverse health effects	Additional cases only: €1 billion over 60 years (Method 1), €5 billion (Method 2)
Source: Derived by the study team.	

4 Benefits of the measures under consideration

4.1 Introduction

This section comprises the following subsections:

- Section 4.2: Summary of the assessment framework
- Section 4.3: Avoided cases of ill health
- Section 4.4: Benefits to workers & families
- Section 4.5: Benefits to employers
- Section 4.6: Benefits to the public sector
- Section 4.7: Aggregated benefits & sensitivity analysis

4.2 Summary of the assessment framework

A number of scenarios have been developed for this study, reflecting a range of assumptions about methods of compliance with the OELs and the exposure concentrations that are used to estimate the ill health effects of formaldehyde exposure. The results presented in the following two sections are based on Scenario S3 (P75) which relies on measured exposure data converted to values which reflect the 75th percentile of the samples taken. An overview of the other scenarios that have been estimated is provided in Limitations & Sensitivity analysis section, i.e. Section 10.

4.2.1 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 takes into account the cost categories set out in the table below.

Table 4-1: The benefits framework

Category	Cost	Notes
Direct	Healthcare	Cost of medical treatment, including hospitalisation, surgery, consultations, radiation therapy, chemotherapy/immunotherapy, etc.
	Informal care[22]	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

[22] 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.

Table 4-1: The benefits framework			
Category	**Cost**		**Notes**
Intangible	Approach 1 Mortality	WTP[23]:	A monetary value of the impact on quality of life of affected workers
	Approach 1 Morbidity	WTP:	
	Approach 2 Mortality	DALY[24]:	
	Approach 2 Morbidity	DALY:	

The total avoided cost of ill health is calculated using the following two methods:

Method 1: Ctotal= Ch+Ci+Cp+Cvsl+Cvsm

Method 2: Ctotal= Ch+Ci+Cp+Cl+Cdaly

The abbreviations are explained below.

Table 4-2: 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

Ce is not considered in the totals under both Method 1 and 2 to avoid double-counting. *Cl* is not considered under Method 1 since *Cvsl* may already include these costs.

The outputs of the model include:

- The number of new cases for each health endpoint assigned to a specific year in the 60 year assessment period;
- The Present Value (PV) of the direct, indirect, and intangible costs of each case.

Two key scenarios are modelled for the exposed workforce. These are:

- **ExW-Constant:** It is assumed that the workforce remains unchanged over 40 years (the same individuals, no replacement of workers afflicted by ill health), the whole workforce is replaced in year 41 with these individuals remaining in the exposed workforce over the next 40 years.

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

[24] Disability Adjusted Life Year. DALY is whereby one year of health is lost. It is used to caculate the gap between current health status and the ideal health situation (WHO, accessed feb 2018, Metrics: Disability-Adjusted Life Year (DALY)).

This scenario does not take into account either the natural turnover of workers changing jobs or the turnover due to the ill health caused by exposure to the relevant chemical agents.

- **ExW-Turnover**: It is assumed that there is a turnover of 5% per year (although this 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, a ratio of 5% is deemed appropriate to account for the fact that some workers may continue to work in the same sector and continue to be exposed). This means that the whole workforce is replaced every 20 years and no worker is exposed for the full 40 year period (this is modelled here as a group of workers being exposed for a 20 year period, followed by another group of workers exposed over the subsequent 20 years). This increases the number of cases for non-cancer endpoints. The turnover caused by treatment or early retirement due to the conditions considered in this report has not been modelled.

In case of formaldehyde due to the cumulative nature of cancer risk (as modelled in this study), the burden caused by the two modelled health endpoints is the same under both the 'turnover' and 'no turnover' scenarios.

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.

4.2.2 Relevant health endpoints for formaldehyde

For formaldehyde, the benefits (i.e. changes in the costs caused by ill health) have been quantified for two health endpoints:

- nasopharyngeal cancer (NFC); and
- sensory irritation.

4.2.3 Summary of the key assumptions for formaldehyde

Onset of the disease

The time of diagnosis of the cases calculated over an average working life is determined taking 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 nasopharyngeal cancer and sensory irritation are summarised below.

Table 4-3: Minimum & maximum exposure duration to develop a condition (MinEx & MaxEx)		
Endpoint	**MinEx**	**MaxEx**
NFC	2 years	40 years
Sensory irritation	1 day	1 day
Notes: *MinEx* *The minimum exposure duration required to develop the endpoint* *MaxEx* *The time required for all workers at risk to develop the endpoint* Source: Study team assumptions.		

For NFC, it is assumed that no risk (i.e. not incidence but risk since incidence is delayed due to latency) arises until MinEx has expired. It is assumed that, subsequently, the distribution of risk is linear, i.e. 0% of the excess risk arises in year 2 and 100% of the excess risk arises by year 40.

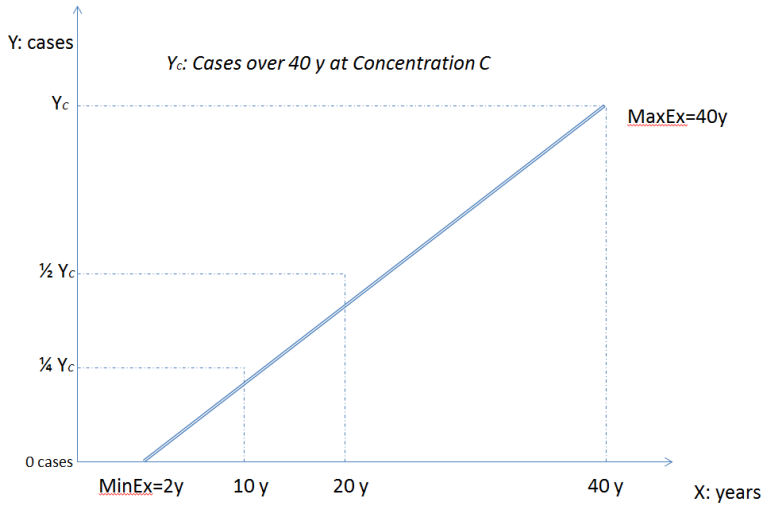


Figure 4-1: NFC risk – distribution over time
Source: Study team assumptions.

For NFC, a latency period of 10 years is used in this study. Although longer latency periods are often estimated for solid tumours, a short latency period is used to be protective to workers and ensure that relevant cancer cases are assessed within the 60 year assessment period for this study.

As regards sensory irritation, the DRR only tells us that the fraction affected = 2% (1 day), 2% (1 year), 2% 20 years, 2% (40 years). Workers may be affected after a few hours.

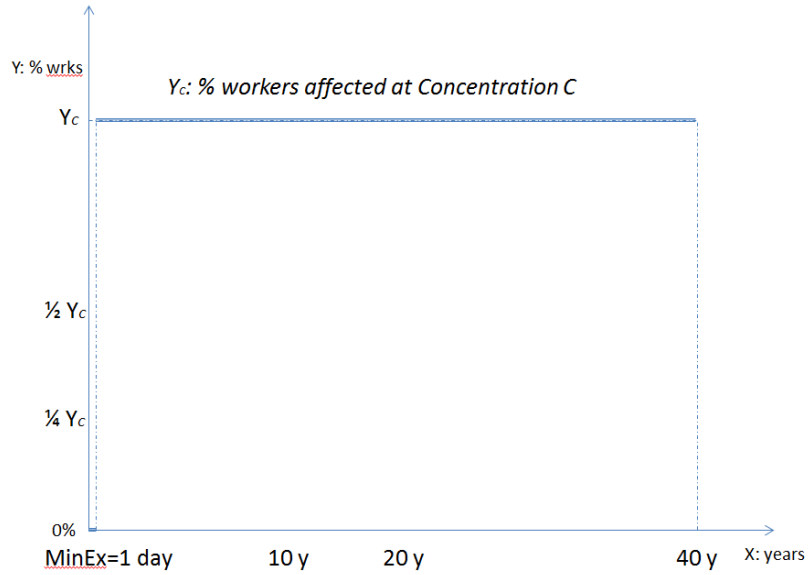


Figure 4-2: Sensory irritation – fraction affected over time
Source: Study team assumptions.

The effects of the disease

The key assumptions used for the modelling of the benefits from reduced exposure to formaldehyde are summarised below. For a detailed explanation of the model and the assumptions, please refer to the methodology report.

The key inputs and assumptions include:

- treatment periods;
- fatality rates;
- treatment cost;
- values for the Willingness to Pay (WTP) to avoid cases of fatal and non-fatal cancer and sensory irritation; and
- disability weights for the relevant endpoints.

Treatment period

The treatment periods used in the model are given below.

Table 4-4: Treatment period

Endpoint	Treatment period (years)
Cancer	5
Sensory irritation	No treatment required in most cases but where treatment required modelled as 1 year
Source: Study team assumptions.	

Mortality rate

The mortality rates used in the model are given below.

Table 4-5: Fatality rates (MoR)	
Endpoint	**MoR (years)**
NFC	47%
Sensory irritation	0%
Source: Study team assumptions.	

Cost of treatment

No data identified. Assumed €200 /year since different severities are covered (from mild which require no treatment to severe).

Willingness to Pay (WTP) values

The WTP values for a case of fatal and non-fatal cancer are €4,100,000 and €420,000; this is in line with the approach taken across all the reports produced under this contract, see the methodology report for details.

The WTP value for a case of sensory irritation has been estimated at €500. There is no data and this is an assumption based on a comparison with other endpoints covered under this contract.

Disability weights

The disability weights used are summarised below.

Table 4-6: Disability weights		
Type of cancer	**Stage of disease**	**Disability Weight**[25]
NFC	Disseminated	0.27
Sensory irritation	-	0.1
Source: Study team assumptions.		

Summary

Table 4-7: Unit costs			
Category	**Cost**	**NFC**	**Sensory irritation**
Direct	Healthcare	€7,000 /year	€200 /year*
	Informal care	€3,000 /year	€100 /year*
	Cost for employers	€12,000 /case	€0 /case
Indirect	Mortality – productivity loss	€5,000 /year	n/a
	Morbidity – lost working days	€1,000 /year	€ 100 /year**
Intangible	Approach 1 WTP: Mortality	€4,100,000 /case	n/a
	Approach 1 WTP: Morbidity	€420,000 /case	€500 /case*
	Approach 2 DALY: Morbidity	Value of a DALY: €100,000	

[25] Cancer takes into account the different stages, sensory irritation is based on similar endpoints – see the methodology report.

Table 4-7: Unit costs			
Category	**Cost**	**NFC**	**Sensory irritation**
*Assumed since no data available. Source: Study team assumptions.			

4.3 Avoided cases of ill health (cancer and non-cancer)

The avoided cases of ill health at the reference OELV levels are summarised below.

Table 4-8: Cases of nasopharyngeal cancer and sensory irritation for each reference OELV				
Reference point (inhalable fraction)	nasopharyngeal cancer		sensory irritation	
	40 years	**60 years**	**40 years**	**60 years**
Baseline	CBD+4	CBD+7	19,200	19,200
0.15 mg/m^3	CBD+0	CBD+0	0	0
0.37 mg/m^3	CBD+0	CBD+0	0	0
0.60 mg/m^3	CBD+0	CBD+0	0	0
Source: Derived by the study team.				

The number of avoided cases of ill health at reference STEL levels could not be estimated due to the fact that there are insufficient criteria for developing a dose response relationship needed for the estimation of the number of cases under baseline and other reference STEL levels (this topic was discussed in more detail in section 3.14).

4.4 Benefits to workers & families

The benefits (avoided costs of ill health) for workers and their families are calculated using the two methods summarised below. These equal the cost of ill health under the baseline scenario, less the cost of ill health following the introduction of an OELV.

Table 4-9: 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*

The benefits of each reference OELV are summarised below. Method 1 relies on WTP values for morbidity, with the resulting estimates given in Table 4-10.

Table 4-10: METHOD 1: benefits to WORKERS & FAMILIES (reference OELVs vs baseline)			
Reference (inhalable)	**0.15 mg/m^3**	**0.37 mg/m^3**	**0.6 mg/m^3**
Constant workforce			
Nasopharyngeal cancer	€950	€950	€950
Sensory irritation	€3.5	€3.5	€3.5
Total	**€954**	**€954**	**€954**
Source: Derived by the study team.			

Method 2 relies on monetised DALYs, with the estimates given in table 4-11.

Table 4-11: METHOD 2: benefits to WORKERS & FAMILIES (reference OELVs vs baseline)			
Reference (inhalable)	**0.15 mg/m³**	**0.37 mg/m³**	**0.6 mg/m³**
Constant workforce			
Nasopharyngeal cancer	€5,023 million	€5,023 million	€5,023 million
Sensory irritation	€2.8 million	€2.8 million	€2.8 million
Total	**€5,026 million**	**€5,026 million**	**€5,026 million**
Source: Derived by the study team.			

4.5 Benefits to the public sector

The benefits (avoided costs of ill health) for the public sector are calculated using the method summarised below.

Table 4-12: 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)*[26]

The benefits of each reference OELV are summarised below.

Table 4-13: Benefits to the PUBLIC SECTOR (reference OELVs vs baseline)			
Reference (inhalable)	**0.15 mg/m³**	**0.37 mg/m³**	**0.6 mg/m³**
Constant workforce			
Nasopharyngeal cancer	€181 million	€181 million	€181 million
Sensory irritation	€0.06 million	€0.06 million	€0.06 million
Total	**€181 million**	**€181 million**	**€181 million**
Source: Derived by the study team.			

4.6 Benefits to employers

The benefits accrued from reduced ill health by employers are calculated using the method summarised below.

Table 4-14: Benefits to EMPLOYERS (avoided cost of ill health)		
Group	**Costs**	**Method of summation**
Employers	Ce, Cp	*CtotalEmployer=Ce+0.8*Cp*

The benefits of each reference OELV are summarised below.

Table 4-15: Benefits to EMPLOYERS (reference OELVs vs baseline)			
Reference (inhalable)	**0.15 mg/m³**	**0.37 mg/m³**	**0.6 mg/m³**
Constant workforce			
Nasopharyngeal cancer	€0.03 million	€0.03 million	€0.03 million

[26] Assumes 20% tax.

Table 4-15: Benefits to EMPLOYERS (reference OELVs vs baseline)			
Reference (inhalable)	**0.15 mg/m³**	**0.37 mg/m³**	**0.6 mg/m³**
Sensory irritation	0	0	0
Total	**€0.03 million**	**€0.03 million**	**€0.03 million**
Source: Derived by the study team.			

4.7 Aggregated benefits & sensitivity analysis

4.7.1 Aggregated benefits

Benefits from reduced ill health

The total benefits that accrue from reduced ill health (over 60 years) are summarised below for each of the five reference OELVs.

Method 1 relies on WTP values for morbidity, with the results given in Table 4-16 and depicted in Figure 4-3.

Table 4-16: METHOD 1: total benefits over 60 years of reduced ill health			
Reference (inhalable)	**0.15 mg/m³**	**0.37 mg/m³**	**0.6 mg/m³**
Constant workforce			
Nasopharyngeal cancer	€0.004 billion	€0.004 billion	€0.004 billion
Sensory irritation	€1 billion	€1 billion	€1 billion
Total	**€1 billion**	**€1 billion**	**€1 billion**
Source: Derived by the study team.			

The results for Method 2, which relies on monetised DALYs, are given in Table 4-17 and depicted in Figure 4-3.

Table 4-17: METHOD 2: total benefits over 60 years of reduced ill health (baseline line and reference OELVs)			
Reference (inhalable)	**0.15 mg/m³**	**0.37 mg/m³**	**0.6 mg/m³**
Constant workforce			
Nasopharyngeal cancer	€0.004 billion	€0.004 billion	€0.004 billion
Sensory irritation	€5.1 billion	€5.1 billion	€5.1 billion
Total	**€5.1 billion**	**€5.1 billion**	**€5.1 billion**
Source: Derived by the study team.			

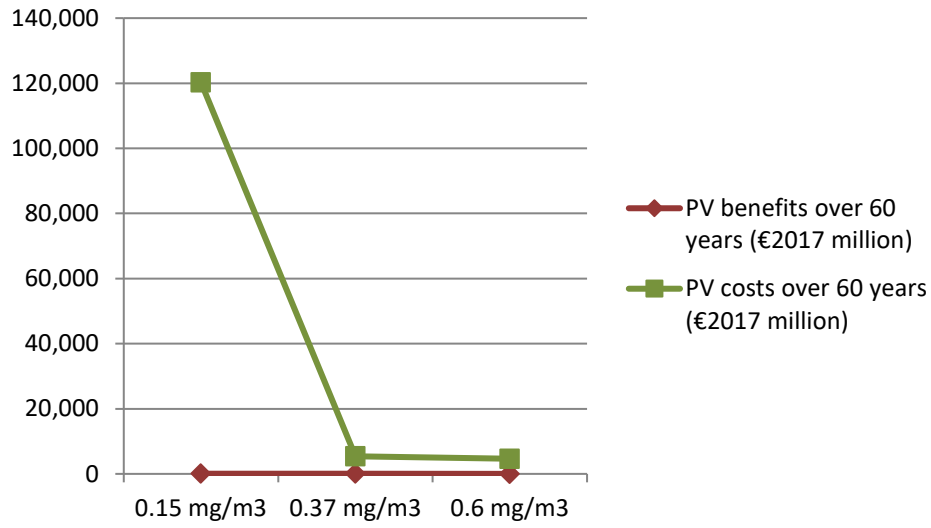


Figure 4-3: METHOD 1&2: Total benefits (avoided costs of ill health) (for all reference OELVs)
Source: Derived by the study team.

4.7.2 Sensitivity analysis

Scenarios

The assessment of benefits is sensitive to a number of uncertainties, including the exposure concentrations in the workplace (in particular in some Member States) and the impact that the aerospace (NACE C30.3), health (Q86) and veterinary sectors (M75) and embalmers (S96.0.3) have on the overall results. The key scenarios that have been estimated under sensitivity analysis are:

- Scenario 1: Exposure concentrations: measured concentrations collected through consultation and desk research, AM/GM for the benefits, P95 for the costs;
- Scenario 3: Exposure concentrations: measured concentrations collected through desk research and consultation, P75, P90, or P95 for both the costs and the benefits;
- Scenario 4: Exposure concentrations: assumes that companies comply with 50% of the OEL or with an estimated GM; and
- Scenarios 2a, 2b, and 2c which mirror the scenarios above but without the aerospace (NACE C30.3), health (Q86) and veterinary (M75) and funeral services (S96.0.3) sectors.

The results for all scenarios are summarized in tables overleaf. In addition, results under scenario 1[27] are presented in more detail in Annex 2.

[27] The methodology approach under this scenario corresponds to the ones used in the other substance impact assessment reports under this study.

Table 4-18: Formaldehyde – Additional assessment scenarios – ALL sectors							
Scenario	Sub-scenario	Reference point (mg/m³)	Cases (40 years)		Additional Benefits PV 60y (€ billion)		
			Can	Sen Irr	Can	Sen Irr	Total
S4 Upper bound – OELs	50% OEL	Baseline	**21**	**105,414**			
		0.6	0	0	0.02	5.2-28	5.2-28
		0.37	0	0	0.02	5.2-28	5.2-28
		0.15	0	0	0.02	5.2-28	5.2-28
	Est GM	Baseline	**4**	**16,270**			
		0.6	0	0	0.003	0.9-4.3	0.9-4.3
		0.37	0	0	0.003	0.9-4.3	0.9-4.3
		0.15	0	0	0.003	0.9-4.3	0.9-4.3
S3 Measured – percentiles – P95, P90, P75	P95	Baseline	**34**	**152,000**			
		0.6	13	66,197	0.01	4.6-22.8	4.7-22.8
		0.37	0	0	0.02	8.2-40.4	8.2-40.4
		0.15	0	0	0.02	8.2-40.4	8.2-40.4
	P90	Baseline	**16**	**77,136**			
		0.6	0	0	0.01	4.2-20.5	4.2-20.5
		0.37	0	0	0.01	4.2-20.5	4.2-20.5
		0.15	0	0	0.01	4.2-20.5	4.2-20.5
	P75	Baseline	**4**	**19,234**			
		0.6	0	0	0.004	1-5.1	1-5.1
		0.37	0	0	0.004	1-5.1	1-5.1
		0.15	0	0	0.004	1-5.1	1-5.1
S1 Measured – percentiles – AM/GM	AM/GM	Baseline	**0.52**	**2,406**			
		0.6	0	0	0	0	0
		0.37	0	0	0.0005	0.045-1.15	0.046-1.16
		0.15	0	0	0.0005	0.045-1.15	0.046-1.16
Source: Derived by the study team.							

Table 4-19: Formaldehyde – alternative scenarios without Aerospace sector (C30.3), Veterinary services (M75), Health activities (Q86) and Funeral services (S96.0.3)							
Scenario	Sub-scenario	Reference point (mg/m³)	Cases		Additional Benefits PV 60y (€ billion)		
			Can	Sen Irr	Can	Sen Irr	Total
S2a Upper bound – OELs	50% OEL	Baseline	**14**	**71,411**			
		0.6	0	0	0.01	3.9-19	3.9-19
		0.37	0	0	0.01	3.9-19	3.9-19
		0.15	0	0	0.01	3.9-19	3.9-19
	Est GM	Baseline	**2**	**10,770**			
		0.6	0	**0**	0.002	0.6-2.9	0.6-2.9
		0.37	0	0	0.002	0.6-2.9	0.6-2.9
		0.15	0	0	0.002	0.6-2.9	0.6-2.9
S2b Measured – percentiles – P95, P90, P75	P95	Baseline	**12**	**60,268**			
		0.6	8	42,335	0.004	1-4.8	1-4.8
		0.37	0	0	0.01	3.3-16	3.3-16
		0.15	0	0	0.01	3.3-16	3.3-16
	P90	Baseline	**5**	**24,682**			
		0.6	4	18,243	0.001	0.4-1.7	0.4-1.7
		0.37	0	0	0.005	1.3-6.6	1.3-6.6
		0.15	0	0	0.005	1.3-6.6	1.3-6.6
	P75	Baseline	**1**	**4,447**			
		0.6	1	2,847	0.0005	0.1-0.4	0.1-0.4
		0.37	0	0	0.001	0.2-1.2	0.2-1.2
		0.15	0	0	0.001	0.2-1.2	0.2-1.2
S2c Measured – percentiles – AM/GM	Measured-high	Baseline	**0.52**	**2,406**			
		0.6	0	0	0.001	0.1-0.6	0.1-0.6
		0.37	0	0	0.001	0.1-0.6	0.1-0.6
		0.15	0	0	0.001	0.1-0.6	0.1-0.6
Source: Derived by the study team.							

5 Costs of the measures under consideration

5.1 Introduction

This section comprises the following subsections:

- Section 5.2: The cost framework
- Section 5.3: OELVs – compliance and administrative costs for companies
- Section 5.4: OELVs – indirect costs for companies
- Section 5.5: STELs – direct and indirect costs for companies
- Section 5.6: OELVs, STELs – costs for public authorities
- Section 5.7: Aggregated costs & sensitivity analysis

5.2 The cost framework

The first step in estimating the economic impacts of introducing a new OELV for formaldehyde was the development of a cost framework describing the different cost components (direct, indirect and intangible; one-off versus recurring) and the determination of the assessment period.

In line with the more general IA requirements of BR Tool #19, this first involved determining which of the potentially relevant impacts are expected to be significant and should thus be subject to a detailed cost assessment.

Taking into account the direct and indirect behavioural changes, as well as potential ultimate impacts, the most relevant impacts were selected on the basis of the following factors:

- The relevance of the impact within the intervention logic;
- The absolute magnitude of the expected impacts;
- The relative size of expected impacts for specific stakeholders (such as impacts which may be small in absolute terms but may be particularly significant to specific types of companies, regions, sectors, etc.); and
- The importance of the impacts for Commission horizontal objectives and policies.

The table below summarises the impact categories that could be significant and that are thus assessed in this report, together with the relevant questions considered in this section (costs for companies and public authorities) and the next section (impacts on competitiveness, etc.).

Table 5-1: Assessment of the most significant economic impact categories

Impact category	Key impacts
Operating costs and conduct of business	Will it impose additional adjustment, compliance or transaction costs on businesses? Does it impact on the investment cycle? Will it entail the withdrawal of certain products from the market? Will it lead to new or the closing down of businesses? Are some products or businesses treated differently from others in a comparable situation?

Table 5-1: Assessment of the most significant economic impact categories	
Impact category	**Key impacts**
Administrative burdens on businesses	Does it affect the nature of information obligations placed on businesses?
Trade and investment flows	How will the option affect exports and imports out of and into the EU? Will imported products be treated differently to domestic goods? How will investment flows be affected and the trade in services? Will the option affect regulatory convergence with third countries? Have international standards and common regulatory approaches been considered?
Public authorities	Does the option have budgetary consequences for public authorities at different levels of government (EU own resources, national, regional, local), both immediately and in the long run? Does it bring additional governmental administrative burden? Does the option require the creation of new or restructuring of existing public authorities?
Consumers and households	Does the option affect the prices consumers pay for goods and services? Does it have an impact on the quality or safety of the goods/services consumers receive? Does it affect consumer choice, trust or protection? Does it have an impact on the availability or sustainability of consumer goods and services?
Specific regions or sectors	Does the option have significant effects on certain sectors? Will it have a specific impact on certain regions, for instance in terms of jobs created or lost? Is there a single Member State, region or sector which is disproportionately affected (so-called "outlier" impact)?
Source: BR Tool #19	

The costs assessed in this section, together with an indication of which stakeholders are likely to be affected, are as follows. These costs are assessed qualitatively and, whenever possible, quantitatively. A continuous cost function has been developed to provide the means of estimating the costs for the reference OELVs and other significant tipping points; it also provides the basis for integrating these so as to estimate the costs for the intervening OELV values.

Table 5-2: Cost impacts on different stakeholders						
Type of cost		**Citizens**	**Consumers**	**Workers**	**Enterprises**	**Public authorities**
Direct	Compliance costs				✓	✓
Indirect	Product choice/price		✓*		✓	
Enforcement	Measurements & inspections				✓	✓
Notes: *Considered in Section 6 Market effects.						

5.3 OELVs – compliance and administrative costs for companies

5.3.1 Current level of actual exposure in the companies

The exposure concentrations assumed to be occurring in the workplace by sector are shown in Table 5-3. As regards the exposure concentrations, the 75th percentile value has been estimated for each sector using the data reported in Section 3.5. The following approach has been applied:

- Data based on shoulder/waist apparatus are used in preference to fixed measurement data;
- The most recent data are preferred;
- A lognormal distribution hypothesisis is assumed;
- For each sector/use, an arithmetic mean or geometric mean, 75th, 90th and 95th percentile on a lognormal distribution have been calculated.
- For the calculation of costs, the P75 measurements were used (where 75th percentile value was not available, the 75th percentile has been estimated using a multiplier derived from the average difference for other processes within the same sector); and
- Where data for multiple processes were available, a weighted average of all 75th percentile values has been calculated (taking into account the relative importance of each process within the sector).

Table 5-3: Number of enterprises affected by formaldehyde at different exposure concentration by size of enterprise by sector

Sector	P75 (actual exposure mg/m^3(ppm))	Small enterprises	Medium enterprises	Large
A	0.01 (0.01)	16,375	351	81
C10	0.01 (0.01)	7,319	408	202
C13	0.20 (0.17)	6,733	372	88
C15	0.20 (0.17)	1,694	87	23
C16	0.17 (0.14)	1,282	46	11
C17	0.31 (0.26)	7,198	807	339
C20	0.38 (0.32)	1,227	151	103
C21	0.03 (0.02)	294	70	117
C22	0.21 (0.17)	1,145	111	40
C25	0.08 (0.07)	1,119	48	11
C27	0.02 (0.02)	6,590	657	567
C28	0.15 (0.12)	343	32	18
C29	0.04 (0.03)	3,193	501	1,360
C30.3	0.74 (0.62)	226	62	172
C31	0.21 (0.17)	48,098	1,907	348
E36	0.01 (0.01)	167	15	15
E38	0.01 (0.01)	687	43	20
F41	0.13 (0.11)	22,798	380	85
M72	0.33 (0.27)	434	27	18
M74.2	0.01 (0.01)	7,002	21	4
M75	0.71 (0.59)	2,232	14	1
P85.4	0.78 (0.65)	0	0	304
Q86	0.48 (0.4)	0	2,276	5,311

Table 5-3: Number of enterprises affected by formaldehyde at different exposure concentration by size of enterprise by sector				
Sector	**P75 (actual exposure mg/m³(ppm))**	**Small enterprises**	**Medium enterprises**	**Large**
S96.0.3	1.14 (0.95)	1,125	150	75

Source: Derived by the study team.

Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities.

5.3.2 Estimated breakdown of RMMs used by enterprises

In order to calculate costs, the model needs estimates for the current primary RMM in use and these have been developed as a percentage of all enterprises of a given size as shown in Table 5-4 based on the data presented in Section 3.

Table 5-4: Percentage breakdown of RMMs currently used by enterprises			
Type of RMM	**% of small enterprises currently with this type of RMM**	**% of medium enterprises currently with this type of RMM**	**% of large enterprises currently with this type of RMM**
Agriculture, Forestry and Fishing			
Full enclosure	0%	0%	0%
Partial enclosure	0%	0%	0%
Open hood	0%	0%	0%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	0%	0%	0%
Breathing apparatus	0%	0%	0%
HEPA filter	90%	90%	90%
Simple mask	0%	0%	0%
Organisational measures	10%	10%	10%
General dilution ventilation	0%	0%	0%
Nothing	0%	0%	0%
Manufacturing of food products			
Full enclosure	0%	0%	0%
Partial enclosure	15%	15%	15%
Open hood	0%	0%	0%

Table 5-4: Percentage breakdown of RMMs currently used by enterprises			
Type of RMM	**% of small enterprises currently with this type of RMM**	**% of medium enterprises currently with this type of RMM**	**% of large enterprises currently with this type of RMM**
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	0%	0%	0%
Breathing apparatus	0%	0%	0%
HEPA filter	70%	70%	75%
Simple mask	0%	0%	0%
Organisational measures	10%	10%	10%
General dilution ventilation	0%	0%	0%
Nothing	5%	5%	0%
Manufacture of textiles			
Full enclosure	0%	0%	0%
Partial enclosure	15%	15%	15%
Open hood	0%	0%	0%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	0%	0%	0%
Breathing apparatus	0%	0%	0%
HEPA filter	20%	20%	20%
Simple mask	15%	15%	15%
Organisational measures	10%	10%	10%
General dilution ventilation	40%	40%	40%
Nothing	0%	0%	0%
Manufacture of leather and related products			
Full enclosure	0%	0%	0%
Partial enclosure	15%	15%	15%
Open hood	0%	0%	0%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	0%	0%	0%
Breathing apparatus	0%	0%	0%
HEPA filter	35%	35%	35%
Simple mask	0%	0%	0%
Organisational measures	10%	10%	10%
General dilution ventilation	40%	40%	40%
Nothing	0%	0%	0%
Manufacture of wood and products of wood and cork - except furniture			
Full enclosure	0%	0%	0%
Partial enclosure	30%	30%	30%
Open hood	0%	0%	0%
Pressurised or sealed	0%	0%	0%

Table 5-4: Percentage breakdown of RMMs currently used by enterprises			
Type of RMM	**% of small enterprises currently with this type of RMM**	**% of medium enterprises currently with this type of RMM**	**% of large enterprises currently with this type of RMM**
Simple enclosed cab	10%	10%	10%
Breathing apparatus	0%	0%	0%
HEPA filter	25%	25%	25%
Simple mask	0%	0%	0%
Organisational measures	10%	10%	10%
General dilution ventilation	25%	25%	25%
Nothing	0%	0%	0%
Manufacture of paper and paper products			
Full enclosure	0%	0%	0%
Partial enclosure	30%	30%	30%
Open hood	0%	0%	0%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	0%	0%	0%
Breathing apparatus	0%	0%	0%
HEPA filter	20%	20%	20%
Simple mask	10%	10%	10%
Organisational measures	10%	10%	10%
General dilution ventilation	30%	30%	30%
Nothing	0%	0%	0%
Manufacture of chemicals and chem. products			
Full enclosure	0%	0%	0%
Partial enclosure	35%	35%	35%
Open hood	0%	0%	0%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	15%	15%	15%
Breathing apparatus	0%	0%	0%
HEPA filter	35%	35%	35%
Simple mask	0%	0%	0%
Organisational measures	15%	15%	15%
General dilution ventilation	0%	0%	0%
Nothing	0%	0%	0%
Manufacture of basic pharmaceutical products and pharmaceutical preparations			
Full enclosure	0%	0%	0%
Partial enclosure	35%	35%	35%
Open hood	0%	0%	0%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	15%	15%	15%

Table 5-4: Percentage breakdown of RMMs currently used by enterprises			
Type of RMM	**% of small enterprises currently with this type of RMM**	**% of medium enterprises currently with this type of RMM**	**% of large enterprises currently with this type of RMM**
Breathing apparatus	0%	0%	0%
HEPA filter	35%	35%	35%
Simple mask	0%	0%	0%
Organisational measures	15%	15%	15%
General dilution ventilation	0%	0%	0%
Nothing	0%	0%	0%
Manufacture of rubber and plastics products			
Full enclosure	0%	0%	0%
Partial enclosure	40%	40%	40%
Open hood	0%	0%	0%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	0%	0%	0%
Breathing apparatus	0%	0%	0%
HEPA filter	40%	40%	40%
Simple mask	0%	0%	0%
Organisational measures	10%	10%	10%
General dilution ventilation	10%	10%	10%
Nothing	0%	0%	0%
Manufacture of fabricated metals, except machinery and equipment			
Full enclosure	0%	0%	0%
Partial enclosure	35%	35%	35%
Open hood	0%	0%	0%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	5%	5%	5%
Breathing apparatus	0%	0%	0%
HEPA filter	40%	40%	40%
Simple mask	0%	0%	0%
Organisational measures	10%	10%	10%
General dilution ventilation	10%	10%	10%
Nothing	0%	0%	0%
Manufacture of electrical equipment			
Full enclosure	0%	0%	0%
Partial enclosure	35%	35%	35%
Open hood	0%	0%	0%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	5%	5%	5%
Breathing apparatus	0%	0%	0%

Table 5-4: Percentage breakdown of RMMs currently used by enterprises			
Type of RMM	**% of small enterprises currently with this type of RMM**	**% of medium enterprises currently with this type of RMM**	**% of large enterprises currently with this type of RMM**
HEPA filter	40%	40%	40%
Simple mask	0%	0%	0%
Organisational measures	10%	10%	10%
General dilution ventilation	10%	10%	10%
Nothing	0%	0%	0%
Manufacture of machinery and equipment			
Full enclosure	0%	0%	0%
Partial enclosure	35%	35%	35%
Open hood	0%	0%	0%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	5%	5%	5%
Breathing apparatus	0%	0%	0%
HEPA filter	40%	40%	40%
Simple mask	0%	0%	0%
Organisational measures	10%	10%	10%
General dilution ventilation	10%	10%	10%
Nothing	0%	0%	0%
Manufacture of motor vehicles, trailers and semi-trailers			
Full enclosure	0%	0%	0%
Partial enclosure	35%	35%	35%
Open hood	0%	0%	0%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	5%	5%	5%
Breathing apparatus	0%	0%	0%
HEPA filter	40%	40%	40%
Simple mask	0%	0%	0%
Organisational measures	10%	10%	10%
General dilution ventilation	10%	10%	10%
Nothing	0%	0%	0%
Manufacture of air and spacecraft and related machinery			
Full enclosure	0%	0%	0%
Partial enclosure	35%	35%	35%
Open hood	0%	0%	0%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	5%	5%	5%
Breathing apparatus	0%	0%	0%
HEPA filter	40%	40%	40%

Table 5-4: Percentage breakdown of RMMs currently used by enterprises			
Type of RMM	**% of small enterprises currently with this type of RMM**	**% of medium enterprises currently with this type of RMM**	**% of large enterprises currently with this type of RMM**
Simple mask	0%	0%	0%
Organisational measures	10%	10%	10%
General dilution ventilation	10%	10%	10%
Nothing	0%	0%	0%
Manufacture of furniture			
Full enclosure	0%	0%	0%
Partial enclosure	0%	0%	0%
Open hood	15%	20%	20%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	0%	0%	0%
Breathing apparatus	0%	0%	0%
HEPA filter	15%	20%	30%
Simple mask	30%	30%	30%
Organisational measures	10%	10%	10%
General dilution ventilation	0%	0%	0%
Nothing	30%	20%	10%
Water collection, treatment and supply			
Full enclosure	0%	0%	0%
Partial enclosure	0%	0%	0%
Open hood	50%	50%	50%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	0%	0%	0%
Breathing apparatus	0%	0%	0%
HEPA filter	40%	40%	40%
Simple mask	0%	0%	0%
Organisational measures	10%	10%	10%
General dilution ventilation	0%	0%	0%
Nothing	0%	0%	0%
Waste collection, treatment and disposal activities; materials recovery			
Full enclosure	0%	0%	0%
Partial enclosure	0%	0%	0%
Open hood	50%	50%	50%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	0%	0%	0%
Breathing apparatus	0%	0%	0%
HEPA filter	40%	40%	40%
Simple mask	0%	0%	0%

Table 5-4: Percentage breakdown of RMMs currently used by enterprises			
Type of RMM	**% of small enterprises currently with this type of RMM**	**% of medium enterprises currently with this type of RMM**	**% of large enterprises currently with this type of RMM**
Organisational measures	10%	10%	10%
General dilution ventilation	0%	0%	0%
Nothing	0%	0%	0%
Construction of buildings			
Full enclosure	0%	0%	0%
Partial enclosure	0%	0%	0%
Open hood	10%	10%	10%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	5%	5%	5%
Breathing apparatus	0%	0%	0%
HEPA filter	5%	5%	5%
Simple mask	20%	20%	20%
Organisational measures	10%	10%	10%
General dilution ventilation	10%	10%	10%
Nothing	40%	40%	40%
Professional, Scientific and Technical Activities: Scientific research and development			
Full enclosure	0%	0%	0%
Partial enclosure	0%	0%	0%
Open hood	50%	50%	50%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	0%	0%	0%
Breathing apparatus	0%	0%	0%
HEPA filter	10%	10%	10%
Simple mask	25%	25%	25%
Organisational measures	10%	10%	10%
General dilution ventilation	0%	0%	0%
Nothing	5%	5%	5%
Professional, Scientific and Technical Activities: Photographic activities			
Full enclosure	0%	0%	0%
Partial enclosure	0%	0%	0%
Open hood	0%	0%	0%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	0%	0%	0%
Breathing apparatus	0%	0%	0%
HEPA filter	0%	0%	0%
Simple mask	10%	10%	10%

Table 5-4: Percentage breakdown of RMMs currently used by enterprises			
Type of RMM	**% of small enterprises currently with this type of RMM**	**% of medium enterprises currently with this type of RMM**	**% of large enterprises currently with this type of RMM**
Organisational measures	10%	10%	10%
General dilution ventilation	0%	0%	0%
Nothing	80%	80%	80%
Veterinary activities			
Full enclosure	20%	20%	20%
Partial enclosure	0%	0%	0%
Open hood	0%	0%	0%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	0%	0%	0%
Breathing apparatus	0%	0%	0%
HEPA filter	20%	20%	20%
Simple mask	50%	50%	50%
Organisational measures	10%	10%	10%
General dilution ventilation	0%	0%	0%
Nothing	0%	0%	0%
Higher education			
Full enclosure	0%	0%	0%
Partial enclosure	0%	0%	0%
Open hood	10%	10%	10%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	0%	0%	0%
Breathing apparatus	0%	0%	0%
HEPA filter	50%	50%	50%
Simple mask	0%	0%	0%
Organisational measures	10%	10%	10%
General dilution ventilation	30%	30%	30%
Nothing	0%	0%	0%
Human health and social work activities: Human health activities			
Full enclosure	0%	0%	0%
Partial enclosure	0%	0%	0%
Open hood	10%	10%	10%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	0%	0%	0%
Breathing apparatus	0%	0%	0%
HEPA filter	20%	20%	20%
Simple mask	30%	30%	30%

Table 5-4: Percentage breakdown of RMMs currently used by enterprises			
Type of RMM	**% of small enterprises currently with this type of RMM**	**% of medium enterprises currently with this type of RMM**	**% of large enterprises currently with this type of RMM**
Organisational measures	10%	10%	10%
General dilution ventilation	30%	30%	30%
Nothing	0%	0%	0%
Funeral and related activities			
Full enclosure	0%	0%	0%
Partial enclosure	0%	0%	0%
Open hood	20%	20%	20%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	0%	0%	0%
Breathing apparatus	0%	0%	0%
HEPA filter	0%	0%	0%
Simple mask	30%	30%	30%
Organisational measures	10%	10%	10%
General dilution ventilation	0%	0%	0%
Nothing	40%	40%	40%
Source: RPA, manufacturers of RMMs and TNO (2013)			

5.3.3 Suitability of RMMs

There are certain characteristics about each sector and the kind of work that is carried out using formaldehyde or leading to exposures within each sector that impact on the suitability of different RMMs for that sector. The different work characteristics split into three groups:

- Duration of exposure over a day;
- Form of formaldehyde to which workers are exposed; and
- Extent to which exposure stems from a local source, a diffuse source or a peripheral source.

The duration of exposure is split into activities where the worker is exposed to formaldehyde for less than an hour a day and for more than an hour a day. Where the exposure is less than an hour a day, it is acceptable, and often more cost-effective, to use personal protective equipment (PPE) 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 advised 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 referred to 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 can cause exposure to workers beyond the area where formaldehyde is being used. This means that administrators, managers and sales staff may be exposed.

In Table 5-5, the percentage split between each form of substance that is assumed in the analysis is given for each sector. In Table 5-6, the types of RMM that are suitable or not for each duration of exposure, form of substance and extent of spread are shown. These values were built into the cost model.

Appropriate percentages were estimated based on the information presented in Sections 3.3., 3.5 and 3.6, which summarise relevant processes and current RMMs within each sector.

Table 5-5: Fomaldehyde: duration of exposure, form of formaldehyde and extent of spread by sector

Sector	<1h	>1h	Dust	Gas	Local	Diffuse	Peripheral
A	95%	5%	0%	100%	0%	100%	0%
C10	95%	5%	0%	100%	0%	100%	0%
C13	25%	75%	30%	70%	0%	100%	0%
C15	50%	50%	50%	50%	60%	40%	0%
C16	50%	50%	80%	20%	40%	50%	10%
C17	50%	50%	80%	20%	40%	50%	10%
C20	80%	20%	50%	50%	20%	70%	10%
C21	80%	20%	50%	50%	20%	70%	10%
C22	50%	50%	50%	50%	50%	40%	10%
C25	50%	50%	50%	50%	50%	40%	10%
C27	50%	50%	50%	50%	50%	40%	10%
C28	50%	50%	50%	50%	50%	40%	10%
C29	50%	50%	50%	50%	50%	40%	10%
C30.3	50%	50%	50%	50%	50%	40%	10%
C31	25%	75%	90%	10%	70%	20%	10%
E36	75%	25%	0%	100%	20%	70%	10%
E38	75%	25%	0%	100%	20%	70%	10%
F41	75%	25%	100%	0%	0%	100%	0%
M72	50%	50%	20%	80%	30%	60%	10%
M74.2	90%	10%	0%	100%	50%	50%	0%
M75	50%	50%	10%	90%	20%	70%	10%
P85.4	50%	50%	10%	90%	20%	70%	10%
Q86	50%	50%	10%	90%	20%	70%	10%
S96.0.3	80%	20%	0%	100%	30%	70%	0%

Table 5-5: Fomaldehyde: duration of exposure, form of formaldehyde and extent of spread by sector							
Sector	**<1h**	**>1h**	**Dust**	**Gas**	**Local**	**Diffuse**	**Peripheral**
Source: Derived by the study team.							
Note: Dust = dust and fibres, Gas = vapour, fumes, gas, mist and aerosol Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities.							

Table 5-6: Suitability of various RMMs to duration of exposure, form of formaldehyde emmissions and extent of spread							
Type of RMM	**<1h**	**>1h**	**Dust**	**Gas**	**Local**	**Diffuse**	**Peripheral**
Discontinuation & Substitution	Y	Y	Y	Y	Y	Y	Y
Rework	Y	Y	Y	Y	Y	Y	Y
Full enclosure	Y	Y	Y	Y	Y	Y	Y
Partial enclosure	Y	Y	Y	Y	Y	Y	Y
Open hood	Y	Y	Y	Y	Y	Y	Y
No LEV	Y	Y	Y	Y	Y	Y	Y
Pressurised or sealed	N	Y	Y	Y	N	Y	Y
Simple enclosed cab	N	Y	Y	Y	N	Y	Y
No enclosure	Y	Y	Y	Y	Y	Y	Y
Breathing apparatus	Y	N	Y	Y	Y	Y	Y
HEPA filter	Y	N	Y	Y	Y	Y	Y
Simple mask	Y	N	Y	Y	Y	Y	Y
No mask	Y	Y	Y	Y	Y	Y	Y
Organisational measures	Y	Y	Y	N	Y	Y	Y
No organisational measures	Y	Y	Y	Y	Y	Y	Y
General dilution ventilation	N	Y	N	Y	N	Y	Y
No general ventilation	Y	Y	Y	Y	Y	Y	Y
Source: Section 3, based on data collected for this study							

5.3.4 Effectiveness of RMMs

Every RMM has a different level of effectiveness in reducing the workers exposure to formaldehyde. The percentage reduction in exposure due to each type of RMM used in the analysis is shown in Table 5-7.

Table 5-7: Percentage reduction in exposure achieved with RMM	
Type of RMM	**% reduction in exposure**
Discontinuation & Substitution	100%
Rework	50%
Full enclosure	99.5%
Partial enclosure	90%
Open hood	80%
No LEV	0%
Pressurised or sealed	99.5%
Simple enclosed cab	80%
No enclosure	0%
Breathing apparatus	99.5%
HEPA filter	95%
Simple mask	60%
No mask	0%
Organisational measures	30%
No organisational measures	0%
General dilution ventilation	30%
No general ventilation	0%
Source: RPA and manufacturers of RMMs	

5.3.5 Marginal abatement cost curves

Three different costs, all present values for 60 years, are calculated: TOTAL (CAPEX + OPEX), CAPEX, and OPEX. These are shown for each target OEL (i.e. reference point, see Section 2.3) by enterprise size in Table 5-8. Figure 5-1 shows the TOTAL cost in graphical form.

Estimated costs

Table 5-8: Formaldehyde: estimated CAPEX, OPEX and TOTAL costs as present value over 60 years in € million by target OELV by size of enterprise			
Enterprise size/ Target OELV	**0.15 mg/m³**	**0.37 mg/m³**	**0.6 mg/m³**
All sectors			
Small CAPEX	€ 943	€ 21	€ 11
Small OPEX	€ 186	€ -8	€ -16
Small TOTAL	**€ 1,129**	**€ 13**	**€ -5**
Medium CAPEX	€ 1,006	€ 257	€ 14
Medium OPEX	€ 463	€ -81	€ -16
Medium TOTAL	**€ 1,469**	**€ 176**	**€ -2**

Table 5-8: Formaldehyde: estimated CAPEX, OPEX and TOTAL costs as present value over 60 years in € million by target OELV by size of enterprise			
Enterprise size/ Target OELV	**0.15 mg/m³**	**0.37 mg/m³**	**0.6 mg/m³**
Large CAPEX	€ 4,442	€ 1,903	€ 111
Large OPEX	€ 3,303	€ -373	€ -39
Large TOTAL	**€ 7,745**	**€ 1,530**	**€ 72**
Source: Derived by the study team.			

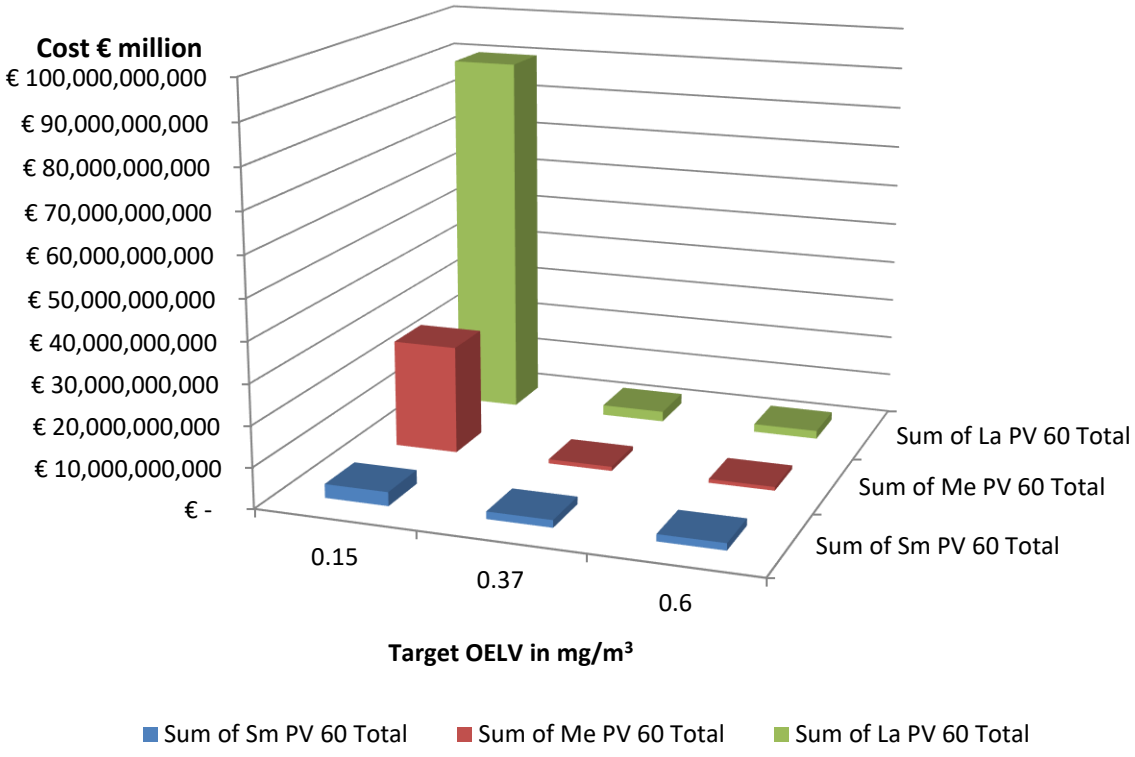


Figure 5-1: Share of PV at 60 years split between small, medium and large enterprises for different target OELVs
Source: Derived by the study team.

5.3.6 Sector/use-specific cost curves

The TOTAL, CAPEX and OPEX (all present values for 60 years) are shown for a range of target OELVs for all 24 sectors in Tables 5-9 to 5-11. Figure 5.2 shows the TOTAL cost in Table 5-9 for each sector in graphical form.

Estimated costs

Table 5-9: Formaldehyde: estimated TOTAL costs (present value for 60 years) in € by target by sector			
Sector/ Target OELV	**0.15 mg/m³**	**0.37 mg/m³**	**0.6 mg/m³**
A	€ -	€ -	€ -
C10	€ -	€ -	€ -
C13	€ 120,895,045	€ -	€ -
C15	€ 30,855,745	€ -	€ -
C16	€ 13,272,839	€ -	€ -
C17	€ 831,761,517	€ -	€ -
C20	€ 54,311,864	-€ 15,847,236	€ -
C21	€ -	€ -	€ -
C22	€ 33,105,085	€ -	€ -
C25	€ -	€ -	€ -
C27	€ -	€ -	€ -
C28	€ -	€ -	€ -
C29	€ -	€ -	€ -
C30.3	€ 379,789,854	€ 220,905,190	€ 62,057,076
C31	€ 1,665,164,312	€ -	€ -
E36	€ -	€ -	€ -
E38	€ -	€ -	€ -
F41	€ -	€ -	€ -
M72	€ 36,447,252	€ -	€ -
M74.2	€ -	€ -	€ -
M75	€ 42,558,743	€ 3,521,739	€ 3,457,499
P85.4	€ 277,571,777	€ 152,919,681	€ 28,103,898
Q86	€ 6,587,132,254	€ 1,244,629,459	€ -
S96.0.3	€ 269,708,364	€ 113,262,613	-€ 27,392,348
ALL	€ 10,342,574,651	€ 1,719,391,446	€ 66,226,125

Source: Derived by the study team.

Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities.

Table 5-10: Formaldehyde: estimated CAPEX costs (present value for 60 years) in € by target by sector			
Sector/ Target OELV	0.15 mg/m³	0.37 mg/m³	0.6 mg/m³
A	€ -	€ -	€ -
C10	€ -	€ -	€ -
C13	€ 152,113,391	€ -	€ -
C15	€ 38,714,135	€ -	€ -
C16	€ 20,623,472	€ -	€ -
C17	€ 490,239,996	€ -	€ -
C20	€ 37,266,405	€ 10,484,975	€ -
C21	€ -	€ -	€ -
C22	€ 37,353,672	€ -	€ -
C25	€ -	€ -	€ -
C27	€ -	€ -	€ -
C28	€ -	€ -	€ -
C29	€ -	€ -	€ -
C30.3	€ 184,979,396	€ 122,139,136	€ 64,960,063
C31	€ 1,259,282,627	€ -	€ -
E36	€ -	€ -	€ -
E38	€ -	€ -	€ -
F41	€ -	€ -	€ -
M72	€ 21,893,944	€ -	€ -
M74.2	€ -	€ -	€ -
M75	€ 23,513,163	€ 8,056,305	€ 8,357,982
P85.4	€ 136,535,531	€ 88,510,617	€ 41,999,124
Q86	€ 3,850,560,606	€ 1,876,763,854	€ -
S96.0.3	€ 137,471,584	€ 75,939,533	€ 21,565,446
ALL	€ 6,390,547,922	€ 2,181,894,420	€ 136,882,615

Source: Derived by the study team.

Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities.

Table 5-11: Formaldehyde: estimated OPEX costs (present value for 60 years) in € by target by sector			
Sector/ Target OELV	0.15 mg/m³	0.37 mg/m³	0.6 mg/m³
A	€ -	€ -	€ -
C10	€ -	€ -	€ -
C13	-€ 31,218,346	€ -	€ -
C15	-€ 7,858,390	€ -	€ -
C16	-€ 7,350,634	€ -	€ -
C17	€ 341,521,521	€ -	€ -
C20	€ 17,045,458	-€ 26,332,211	€ -
C21	€ -	€ -	€ -
C22	-€ 4,248,587	€ -	€ -
C25	€ -	€ -	€ -
C27	€ -	€ -	€ -
C28	€ -	€ -	€ -
C29	€ -	€ -	€ -
C30.3	€ 194,810,458	€ 98,766,055	-€ 2,902,986
C31	€ 405,881,685	€ -	€ -
E36	€ -	€ -	€ -
E38	€ -	€ -	€ -
F41	€ -	€ -	€ -
M72	€ 14,553,309	€ -	€ -
M74.2	€ -	€ -	€ -
M75	€ 19,045,581	-€ 4,534,566	-€ 4,900,483
P85.4	€ 141,036,247	€ 64,409,064	-€ 13,895,226
Q86	€ 2,736,571,648	-€ 632,134,395	€ -
S96.0.3	€ 132,236,780	€ 37,323,081	-€ 48,957,793
ALL	€ 3,952,026,730	-€ 462,502,972	-€ 70,656,488

Source: Derived by the study team.

Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities.

The TOTAL cost (present value for 60 years), is shown for a range of target OELVs in Figure 5-2, for each of the 24 relevant sectors. This is based upon the numbers in Table 5-9 above.

Estimated costs

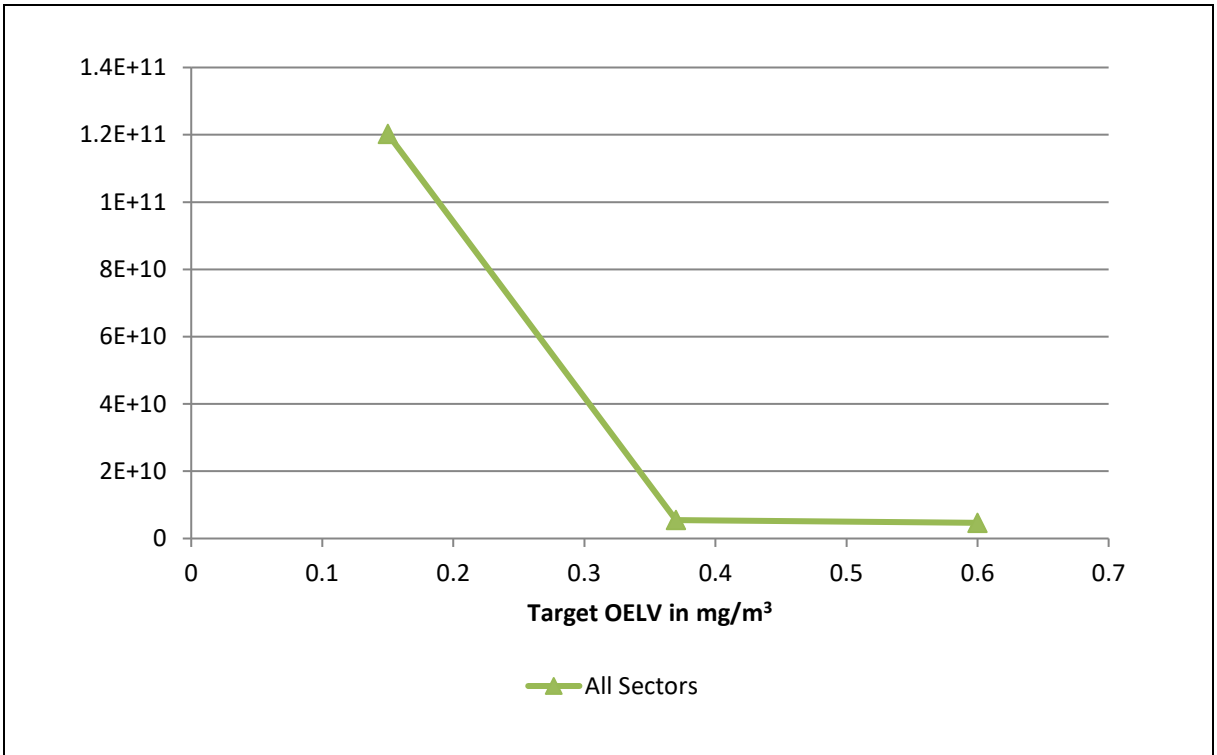


Figure 5-2: Estimated TOTAL costs (present value for 60 years) in € million against target OELVs
Source: Derived by the study team.

5.4 OELVs – indirect costs for companies

Indirect costs could include possible ripple effects through the value chain and the potential for costs to be passed on to users further down the value chain or to consumers.

Examples of indirect costs that could be incurred by economic actors as a result of achieving compliance with new limits include:

- Availability of products; and
- Choice of products.

FIgure 5-3 below sets out a range of potential scenarios covering likely indirect impacts along the supply chain resulting from the introduction of harmonised OELs. In the most severe case (in the event that a number of companies using formaldehyde are forced to close as a result of being unable to meet with the OEL requirements), there may be limitations on the availability of certain products/services being supplied by EU companies, further resulting in potential shortages down the supply chain. These shortages could then possibly lead to price rises for consumers where demand outstrips supply. Whilst modelling for this study has predicted that no companies will be forced to discontinue operations, some may in fact do so due to an inability to raise the funds required to carry out capital investments when OELs are introduced.

Key sectors where there are limited or no substitutes for formaldehyde are more likely to fall under this category, resulting in limited choices for consumers. In the case of funeral services for example, which use formaldehyde during the embalming process, there could also be significant non-financial costs to bereaved relatives resulting from a loss of the ability to preserve bodies in a particular state.

In cases where it is likely that downstream companies would be able to obtain supplies of components/products from outside the EU (where the EU OEL restrictions would not apply), under this scenario jobs and profits may be lost to the EU (where other compliant EU producers are not able to expand their capacity), being taken up by workers and competitors in third countries.

In the event that EU based companies continue production using formaldehyde by meeting OELs requirements, prices of intermediate and final products and components would potentially rise as companies using formaldehyde pass on the additional costs of meeting the OELs to their customers. For certain final products which comprise components manufactured using formaldehyde involving large numbers of exposed workers and a high percentage of the workforce in a particular sector (and which might therefore be expected to incur the greatest costs to meet the stipulated OELs), the indirect impact on prices might be expected to be higher. Possible examples include those which involve plated/finished metal, products used in automotive applications; furniture constructed using glue resins and health services involving operations where formaldehyde exposure occurs in operating rooms and pathology laboratories.

Where the contribution of formaldehyde to the final product is likely to be a very small part of the overall price composition, it is unlikely that there would be any significant indirect effect on prices, if at all. However, in other products, the price of the component requiring the use of formaldehyde is likely to be more significant, and in such circumstances, there would more likely be an indirect impact on prices resulting from the introduction of OELs as cost increases are passed down the supply chain, although given the relatively small share of increased costs as a percentage of turnover, such increases are likely to be small.

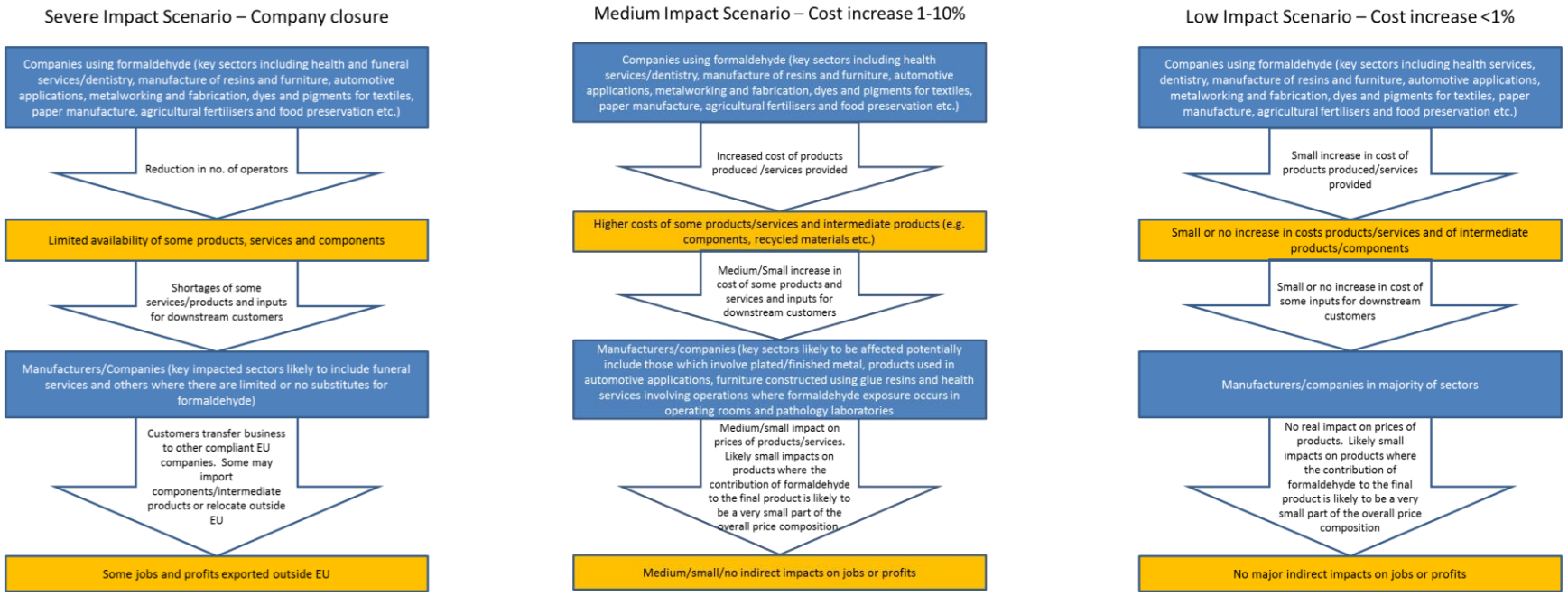


Figure 5-3: Indirect Impacts under different scenarios

5.5 STELs – direct and indirect costs for companies

The exposure data collected for this study suggests that, generally speaking, compliance with an OELV may also result in compliance with a STEL at 200% of the OELV. Quantifying the direct and indirect costs for companies resulting from the introduction of a harmonized STEL would thus entail double-counting since it is expected that a STEL under the CMD would not be introduced in isolation from an OELV.

However, some exceptions have been identified in the data collected; these relate to the following sectors:

- C13 Manufacture of textiles;
- C15 Manufacture of leather and related products; and
- C17 Manufacture of paper and paper products.

For some processes in these sectors, companies would have to implement measures that are additional to those required for an OELV to ensure compliance with a STEL at 200% of the OELV. It is expected that this would most likely involve an increased use of PPE to deal with short-term peak exposures.

5.6 OELVs, STELs – costs for public authorities

The impacts on public authorities, mainly at the national level but in some Member States also at the regional level, are expected to relate to:

- The cost of adapting national legislation and procedures to the new OELV (where the Member State is above the OELV); and
- The enforcement of the new OEL.

It is not expected that there will be a significant cost to national authorities in the Member States which already have an OEL for formaldehyde.[28] Member States where OELs do not exist may incur a one-off cost for changing their legislation and a recurring cost associated with an increase in enforcement. Thus, although the specific OELV level will determine whether a Member State needs to revise legislation, the transposition and implementation costs are unlikely to depend on the specific values, so there will only be a cost difference between the baseline scenario and scenarios where a new OEL is introduced in a Member State.

In addition, the cost of legislative change will only be incurred once, regardless of whether one or several chemical agents are covered, and whether an OELV or also a STEL and/or skin notation is introduced.

5.6.1 Cost of transposition

EU Member States could incur costs arising from the need to transpose the relevant changes into national legislation. In practice, the exact costs would 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 are therefore likely to vary significantly between Member States (for example, Sweden is obliged to

[28] Some Member States may carry out Impact Assessments on the transposition of EU legislation but this cost is not considered here.

carry out an impact assessment on new EU legislation; it is expected that this may not be the case in some Member States).

Of the 28 EU Member States, research carried out for this study has confirmed that 23 have an OEL(s) for formaldehyde. There is no information with regard to formaldehyde OEL for the following Member States and it is therefore assumed that they do not have an OEL for formaldehyde: Belgium, Spain, Italy, Luxembourg and Malta. It is thus assumed that these five Member States would incur costs for transposing an OELV introduced under the CMD.

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)[29], 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 (e.g. preparing an impact assessment, drafting a substantial bill and presenting the legislation before government/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 CMD which already contains a number of OELVs, it appears more likely that the cost of transposing an additional OELV 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[30]), which suggests that the costs would likely 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.

Table 5-12: Transposition costs

Member States with no OEL	Transposition cost per Member State	Total cost across the EU
5 Member States: Belgium, Spain, Italy, Luxembourg and Malta	€50,000	€250,000
Source: Study team assumptions.		

It is assumed that for Member States that already have an OEL for formaldehyde, the change to a different value (in case the existing national OEL was higher than the OELV) would entail no significant costs.

5.6.2 Enforcement costs

Enforcement costs depend on the number of companies that will be covered by the OELV. In principle, national authorities are supposed to inspect companies already as they have the general obligation to protect workers and formaldehyde is currently classified as a Carc. Cat 1B. However, there could be

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

[30] RPA (2015): Study on the potential of impact assessments to support environmental goals in the context of the European Semester, available at http://ec.europa.eu/environment/integration/green_semester/pdf/J856.pdf

an additional cost due to the need to ensure compliance with the new OELV. Such enforcement costs depend on the inspection regime in each country and they are not estimated in this study.

5.7 Aggregated costs & sensitivity analysis

5.7.1 Aggregated costs

The total compliance costs over 60 years for all sectors are set out below.

Table 5-13: Sum of all compliance costs for the reference OELVs (PV CAPEX and OPEX over 60 years, relative to the baseline) in € million

Cost	0.15 mg/m³	0.37 mg/m³	0.6 mg/m³
CAPEX	6,391	2,181	137
OPEX	3,952	-463	-71
Total across all sectors	**10,343**	**1,718**	**66**

Source: Derived by the study team.

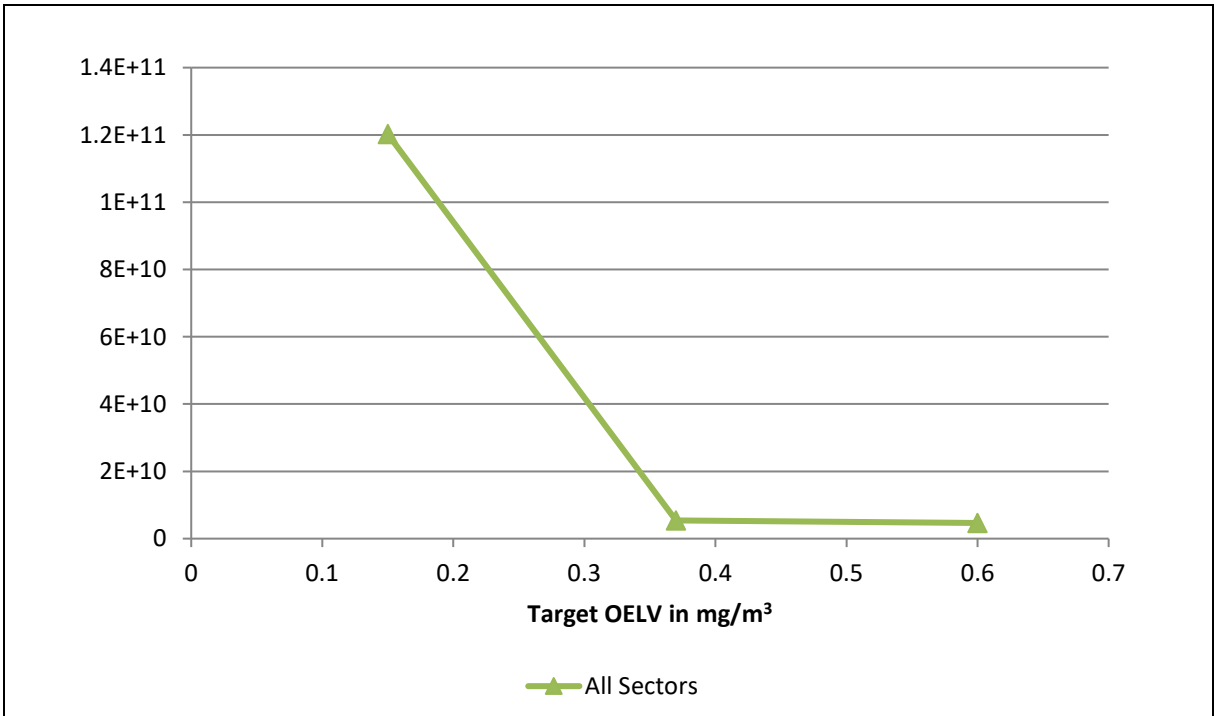


Figure 5-4: Estimated TOTAL costs (present value for 60 years) in € million against target OELVs
Source: Derived by the study team.

5.7.2 Sensitivity analysis

Similarly as in case of the assessment of benefits, the assessment of costs is sensitive to a number of uncertainties, including the exposure concentrations in the workplace (in particular in some Member States) and the impact that the aerospace (NACE C30.3), health (Q86) and veterinary sectors (M75) and embalmers (S96.0.3) have on the overall results.

The key scenarios that have been estimated under sensitivity analysis are:

- Scenario 1: Exposure concentrations: measured concentrations collected through consultation and desk research, AM/GM for the benefits, P95 for the costs;
- Scenario 3: Exposure concentrations: measured concentrations collected through desk research and consultation, P75, P90, or P95 for both the costs and the benefits;
- Scenario 4: Exposure concentrations: assumes that companies comply with 50% of the OEL or with an estimated GM; and
- Scenarios 2a, 2b, and 2c which mirror the scenarios above but without the aerospace (NACE C30.3), health (Q86) and veterinary (M75) and funeral services (S96.0.3) sectors.

The results for all scenarios are summarized in table overleaf. In addition, results under scenario 1[31] are presented in more detail in Annex 2.

[31] The methodology approach under this scenario corresponds to the ones used in the other substance impact assessment reports under this study.

Table 5-14: Formaldehyde – Additional assessment scenarios				
Scenario	Sub-scenario	Reference point (mg/m³)	Additional Costs PV 60y (€ billion)	Additional Costs PV 60y (€ billion) without C30.3, M75, Q96 and S96.0.3
S4/S2a Upper bound – OELs	50% OEL	0.6	11.38	5.9
		0.37	12.11	6.2
		0.15	39.08	20.4
	Est GM	0.6	11.94	5.9
		0.37	12.54	6.2
		0.15	39.8	20.4
S3/S2b Measured – percentiles – P95, P90, P75	P95	0.6	7.19	0.1
		0.37	9.35	1.5
		0.15	22.68	4.7
	P90	0.6	1.69	0.1
		0.37	8.3	1.2
		0.15	16.5	3.4
	P75	0.6	0.07	0.03
		0.37	1.72	0.12
		0.15	10.34	3.1
S1/S2c Measured – percentiles – P95	AM/GM	0.6	4.7	3
		0.37	5.4	3.5
		0.15	120	6.7
Note: C30.3 = Aerospace sector; M75 = Veterinary services; Q86 = Health activities and S96.0.3 = Funeral services Source: Derived by the study team.				

6 Market effects

This section comprises the following subsections:

- Section 6.1: Overall impact
- Section 6.2: Impact on research and innovation
- Section 6.3: Impact on the single market
- Section 6.4: Impact on competitiveness of EU business
- Section 6.5: Impact on employment

6.1 Overall impact

Overall, market impacts (in terms of the effect on R&D, the single market, competitiveness of EU businesses and employment) will be strongly influenced by the extent to which costs are incurred to comply with the OELs (as a result of taking measures to reduce exposure to formaldehyde or replacing its use altogether), and the extent to which any cost increases are a significant contributor to companies' overall costs and/or represent a significant proportion of turnover. In extreme cases, companies will be forced out of business if they are unable to meet the OELs and absorb these additional costs or pass them on to customers and/or consumers.

However, the model developed for this study estimates that businesses will not be likely to exit the market in any of the sectors identified as using formaldehyde, with businesses adopting appropriate risk management measures (RMMs) in order to ensure compliance at the different OELs. Given this conclusion, the key factor in determining the nature and scale of market effects is therefore likely to be the extent to which the costs of implementing the RMMs constitute a significant cost increase in relation to turnover for businesses' formaldehyde-related operations, leading to price rises for goods and services.

Table 6-1 below presents the average turnover per sector where companies are using formaldehyde. The following tables then provide estimates of the potential increases in costs for each sector and these costs as a % of the average turnover for small, medium and large companies. This information provides important input for the subsequent analysis of market impacts resulting from the introduction of OELs at different levels.

Table 6-1: Average turnover by sector and size of enterprise

Sector	Small			Medium			Large		
	Turnover /€m	No. firms	Ave. turnover/ €m	Turnover /€m	No. firms	Ave. turnover/ €m	Turnover /€m	No. firms	Ave. turnover/ €m
A	-	-	-	-	-	-	-	-	-
C10	104,030	238,017	0.4	366,842	25,464	14.4	490,000	2,400	204.2
C13	8,648	55,462	0.2	43,914	5,000	8.8	19,691	-	:
C15	6,035	32,685	0.2	25,011	4,109	6.1	17,248	168	102.7
C16	35,390	162,710	0.2	57,549	7,425	7.8	36,493	300	121.6
C17	10,330	14,737	0.7	73,740	4,063	18.1	102,610	480	213.8
C20	25,281	22,795	1.1	132,655	5,955	22.3	346,366	826	419.3
C21	-	2,509	:	33,131	1,215	27.3	230,936	473	488.2

Table 6-1: Average turnover by sector and size of enterprise									
Sector	Small			Medium			Large		
	Turnover /€m	No. firms	Ave. turnover/ €m	Turnover /€m	No. firms	Ave. turnover/ €m	Turnover /€m	No. firms	Ave. turnover/ €m
C22	29,300	49,000	0.6	143,995	12,264	11.7	-	1,020	:
C25	109,313	352,041	0.3	242,100	31,100	7.8	130,000	1,280	101.6
C27	16,886	39,598	0.4	23,647	6,430	3.7	209,000	940	222.3
C28	50,525	70,524	0.7	218,998	17,923	12.2	387,695	1,900	204.1
C29	5,688	14,156	0.4	69,677	4,053	17.2	952,917	1,287	740.4
C30.3	2,699	1,354	2.0	7,592	420	18.1	124,007	176	704.6
C31	23,539	7,555	3.1	45,851	6,729	6.8	32,091	422	76.0
E36	7,597	13,118	0.6	15,006	774	19.4	45,471	321	141.7
E38	31,313	41,341	0.8	70,645	6,292	11.2	54,792	496	110.5
F41	270,910	849,989	0.3	180,745	18,807	9.6	124,260	469	264.9
M72	10,608	12,000	0.9	23,502	3,062	7.7	47,532	330	144.0
M74.2	6,191	121,689	0.1	1,713	322	5.3	682	10	68.2
M75	10,207	76,474	0.1	1,138	924	1.2	-	-	-
P85.4	-	-	-	-	-	-	-	-	-
Q86	-	-	-	-	-	-	-	-	-
S96.0.3	-	-	-	-	-	-	-	-	-
Total		2,177,754			162,331			13,298	
Average			0.7			11.8			254.6
Source: Derived by the study team.									

Based on these figures, the model used to estimate the costs arising from the OELs utilised rounded average turnover figures as follows:

- Small - €500,000
- Medium - €10,000,000
- Large - €15,000,000

The figure of €15,000,000 has been assumed for large companies since it is likely that only a proportion of their business will be associated with the use of formaldehyde, and it is unlikely that large companies would have to close their entire business as a result of being unable to meet the stipulated OELs. These estimates are utilised to estimate the proportion of turnover represented by the envisaged increase in costs for meeting the OELs below.

Tables 6-2 to 6-4 provide estimates of the costs that will likely be incurred on a per company basis (discounted at 4% over 60 years) and Tables 6-5 to 6-7 then provide estimates of these costs as a % of the average turnover for small, medium and large companies.

Table 6-2: Costs per company for those continuing to trade - Small companies (€)			
Sector	OEL mg/m3		
	0.6	0.37	0.15
A	-	-	-
C10	-	-	-
C13	-	-	5,862

Table 6-2: Costs per company for those continuing to trade - Small companies (€)			
Sector	OEL mg/m3		
	0.6	0.37	0.15
C15	-	-	5,862
C16	-	-	4,283
C17	-	-	22,309
C20	-	-7,364	9,883
C21	-	-	-
C22	-	-	5,229
C25	-	-	-
C27	-	-	-
C28	-	-	-
C29	-	-	-
C30.3	5,073	23,433	43,044
C31	-	-	17,343
E36	-	-	-
E38	-	-	-
F41	-	-	-
M72	-	-	21,184
M74.2	-	-	-
M75	2,705	2,767	38,665
P85.4	-	-	-
Q86	-	-	-
S96.0.3	-7,011	10,333	33,944
Source: Derived by the study team.			

Table 6-3: Costs per company for those continuing to trade - Medium companies (€)			
Sector	OEL mg/m^3		
	0.6	0.37	0.15
A	-	-	-
C10	-	-	-
C13	-	-	115,140
C15	-	-	115,140
C16	-	-	88,106
C17	-	-	288,818
C20	-	-52,154	171,920
C21	-	-	-
C22	-	-	103,005
C25	-	-	-
C27	-	-	-
C28	-	-	-
C29	-	-	-
C30.3	101,623	307,753	519,868
C31	-	-	259,707
E36	-	-	-
E38	-	-	-
F41	-	-	-
M72	-	-	269,883
M74.2	-	-	-
M75	61,073	61,626	448,468
P85.4	-	-	-
Q86	-	61,073	250,948

Table 6-3: Costs per company for those continuing to trade - Medium companies (€)			
Sector	OEL mg/m³		
	0.6	0.37	0.15
S96.0.3	-46,416	179,494	440,569

Table 6-4: Costs per company for those continuing to trade - Large companies (€)			
Sector	OEL mg/m³		
	0.6	0.37	0.15
A	-	-	-
C10	-	-	-
C13	-	-	466,664
C15	-	-	466,664
C16	-	-	337,420
C17	-	-	1,338,866
C20	-	-193,810	954,959
C21	-	-	-
C22	-	-	405,073
C25	-	-	-
C27	-	-	-
C28	-	-	-
C29	-	-	-
C30.3	402,042	1,441,930	2,478,786
C31	-	-	1,034,195
E36	-	-	-
E38	-	-	-
F41	-	-	-
M72	-	-	1,235,802
M74.2	-	-	-
M75	208,177	209,390	2,056,087
P85.4	208,177	1,132,738	2,056,087
Q86	-	208,177	1,132,738
S96.0.3	-167,234	996,184	2,205,808
Source: Derived by the study team.			

Table 6-5: Costs per company as a % of turnover - Small companies			
Sector	OEL mg/m³		
	0.6	0.37	0.15
A	-	-	-
C10	-	-	-
C13	-	-	0.05%
C15	-	-	0.05%
C16	-	-	0.04%
C17	-	-	0.19%
C20	-	-0.06%	0.08%
C21	-	-	-
C22	-	-	0.04%
C25	-	-	-
C27	-	-	-
C28	-	-	-
C29	-	-	-
C30.3	0.04%	0.20%	0.37%

Table 6-5: Costs per company as a % of turnover - Small companies			
Sector	OEL mg/m³		
	0.6	0.37	0.15
C31	-	-	0.15%
E36	-	-	-
E38	-	-	-
F41	-	-	-
M72	-	-	0.18%
M74.2	-	-	-
M75	0.02%	0.02%	0.33%
P85.4	-	-	-
Q86	-	-	-
S96.0.3	-0.06%	0.09%	0.29%
Source: Derived by the study team.			

Table 6-6: Costs per company as a % of turnover - Medium companies			
Sector	OEL mg/m³		
	0.6	0.37	0.15
A	-	-	-
C10	-	-	-
C13	-	-	0.05%
C15	-	-	0.05%
C16	-	-	0.04%
C17	-	-	0.12%
C20	-	-0.02%	0.07%
C21	-	-	-
C22	-	-	0.04%
C25	-	-	-
C27	-	-	-
C28	-	-	-
C29	-	-	-
C30.3	0.04%	0.13%	0.22%
C31	-	-	0.11%
E36	-	-	-
E38	-	-	-
F41	-	-	-
M72	-	-	0.11%
M74.2	-	-	-
M75	0.03%	0.03%	0.19%
P85.4	-	-	-
Q86	-	0.03%	0.11%
S96.0.3	-0.02%	0.08%	0.19%
Source: Derived by the study team.			

Table 6-7: Costs per company as a % of turnover - Large companies			
Sector	OEL mg/m³		
	0.6	0.37	0.15
A	-	-	-
C10	-	-	-
C13	-	-	0.13%
C15	-	-	0.13%

Table 6-7: Costs per company as a % of turnover - Large companies			
Sector	OEL mg/m³		
	0.6	0.37	0.15
C16	-	-	0.10%
C17	-	-	0.38%
C20	-	-0.05%	0.27%
C21	-	-	-
C22	-	-	0.11%
C25	-	-	-
C27	-	-	-
C28	-	-	-
C29	-	-	-
C30.3	0.11%	0.41%	0.70%
C31	-	-	0.29%
E36	-	-	-
E38	-	-	-
F41	-	-	-
M72	-	-	0.35%
M74.2	-	-	-
M75	0.06%	0.06%	0.58%
P85.4	0.06%	0.32%	0.58%
Q86	-	0.06%	0.32%
S96.0.3	-0.05%	0.28%	0.63%
Source: Derived by the study team.			

The report estimates that approximately 155,000 businesses in the EU have some workers potentially exposed to formaldehyde across the different sectors and the market effects of the introduction of OELVs at different levels will need to be considered across these companies.

The above information provides important input for the subsequent analysis of market impacts resulting from the introduction of OELs at different levels in the following sub-sections.

6.2 Research and innovation

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

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

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

Table 6-8 below provides examples of sector-wide R&D expenditures in 2015 in a selection of MS in some of the sectors using formaldehyde.

Table 6-8: R&D Expenditure at national level per sector involving use of Formaldehyde (in € million)					
Member State	M72	C29	C28	C21	C20
CZ	331	260	142	41	43
DE	2,170	21,466	5,549	3,956	3,786
IT	899	1,698	1,509	539	418
PL	240	165	74	91	61
UK	7,324	3,250	1,197	535	430
Source: Eurostat					

R&D expenditures in sectors such as M72: Scientific research and development, C29: Motor vehicles, trailer and semi-trailers and C28: Machinery and equipment n.e.c. is significant (although it is noted that these figures cover the entire sector and not just R&D in production using formaldehyde).

Better Regulation Tool #21 indicates that "All compliance costs divert resources from other purposes, potentially including research and innovation." Whilst the estimates of costs arising from the implementation of the different OELs represent a relatively small percentage of overall turnover for all sizes of companies, they still represent an increase in costs compared to the current situation, and R&D expenditures may be put under pressure as a result.

This pressure on R&D expenditures may be exacerbated by the fact that the regulatory environment would be becoming stricter, and companies may be doubtful about the future of formaldehyde as an input in their production process. Even if the final OELV implemented were at the higher (less strict) end of the range, the perception could well emerge that other more stricter limits might be imposed in the future, 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.

On the other hand, regulatory pressure on a substance can encourage R&D into alternatives, and businesses may increase investment into developing such alternatives in order to maintain operations in the longer term.

6.3 Single market

6.3.1 Competition

Table 6-9 below includes the initial screening of impacts on competition in order to focus the analysis on those impacts likely to be the most significant. The most significant impacts are further explored in the following paragraphs.

Table 6-9: Screening of Competition Impacts		
Impacts	Key questions	Yes/No
Existing firms	Additional costs?	Yes. Costs of RMMs to meet OELs (some capital, some on-going (e.g. PPE, energy supply for LEVs)
	Scale of costs significant?	Potentially, in some cases under stricter OELs. Capital costs may be more significant for SMEs. Capital and on-going (see costs as % of turnover in Tables 6-6 to 6-8 above, broken down by firm size)
	Old firms affected more than new?	Unlikely, although some older businesses may have older, more inefficient RMM equipment, requiring more significant investment to meet OELs
	Location influences?	Yes.

Table 6-9: Screening of Competition Impacts		
Impacts	**Key questions**	**Yes/No**
		Existing OELs vary across MS. Harmonisation will bring differences closer together, affecting businesses in MS with higher current OELs to a greater extent, but also levelling the playing field
	Some firms will exit the market?	No
	Are competitors limited in growth potential?	No, assuming they can meet the OELs
	Increased collusion likely?	Unknown, but introducing OELs in itself is unlikely to provide an added incentive to collude
New entrants	Restrict entry?	Possibly. High capital cost to meet OELs.
Prices	Increased prices for consumers	Yes. Increased production costs.
Non-price impacts	Product quality/variety affected?	No.
	Impact on innovation	Yes. Potentially as result of increases in costs leading to fewer resources available for R&D (See Section on R&D above)
Upstream and downstream market	Will OELs affect vertically integrated companies more or less than non-integrated ones?	No
	Will OELs encourage greater integration and market barriers?	No, other than entry costs.
	Will OELs affect bargaining power of buyers or suppliers?	No, since no businesses are anticipated to leave the market.

As indicated previously, approximately 155,000 businesses with workers potentially exposed to formaldehyde are operating in the EU. However, the vast majority of these businesses are already operating at exposure levels below the proposed 0.6 mg/m^3 OEL as indicated in Table 6-10 below. In fact, there are estimated to be only 4 sectors where exposure is higher than 0.6 mg/m:

- C30.3: Manufacture of air and space craft and related machinery;
- M75: Professional, Scientific and Technical Activities – Veterinary activities;
- P85.4: Education (NACE Code P85- P85.4. Higher Education); and
- S96.0.3: Funeral and related activities

Consequently, the majority of businesses across all sectors will not be required to implement any additional RMMs in order to be compliant with an OEL of 0.6 mg/m^3, with no implications for competition within the sectors in which these companies operate (although some may voluntarily choose to do so in order to ensure they continue to remain compliance if they are currently operating at levels close to the 0.6 mg/m^3 level).

In the four sectors where it is estimated that RMM costs will be incurred in order to become complaint, the "Funeral and related activities" sector indicates the highest level of current non-compliance with the 0.6 mg/m^3 OEL, with all of the businesses operating in the sector estimated to be operating at exposure levels higher than this. However, all businesses operating in the sector will be affected in the same way and are expected to be able to meet the OEL, with none being forced to leave the market. As a result, no significant impacts on competition are envisaged.

As regards the "Manufacture of air and space craft and related machinery", "Professional, Scientific and Technical Activities – Veterinary activities" and "Education (NACE Code P85- P85.4 Higher Education) sectors, whilst a significant number of companies are currently above the 0.6 mg/m3 OEL (more than half in most sectors), again, no businesses are expected to leave the market, leaving the total numbers of businesses operating in these sectors the same. Costs will increase for businesses that are required to implement RMMs in order to reach compliance, but as indicated in Tables 6-5 to 6-7, the envisaged costs represent a small percentage of businesses turnover, so again, no significant impacts on competition are envisaged.

Table 6-10: Number of businesses compliant and non-compliant with an OELV of 0.6 mg/m^3						
Sector	Already compliant			Non-compliant		
	Small	Medium	Large	Small	Medium	Large
A	16,375	351	81	0	0	0
C10	7,319	408	202	0	0	0
C13	6,733	372	88	0	0	0
C15	1,694	87	23	0	0	0
C16	1,282	46	11	0	0	0
C17	7,198	807	339	0	0	0
C20	1,227	151	103	0	0	0
C21	294	70	117	0	0	0
C22	1,145	111	40	0	0	0
C25	1,119	48	11	0	0	0
C27	6,590	657	567	0	0	0
C28	343	32	18	0	0	0
C29	3,193	501	1,360	0	0	0
C30.3	66	18	31	160	44	141
C31	48,098	1,907	348	0	0	0
E36	167	15	15	0	0	0
E38	687	43	20	0	0	0
F41	22,798	380	85	0	0	0
M72	434	27	18	0	0	0
M74.2	7,002	21	4	0	0	0
M75	1,347	0	0	885	14	1
P85.4	0	0	169	0	0	135
Q86	0	2,276	5,311	0	0	0
S96.0.3	0	0	0	1,125	150	75
Source: Derived by the study team.						

When it comes to the lower OELs, the number of sectors and businesses in these sectors that are not currently compliant increases, as expected. Tables 6-11 and 6-12 provide figures for the numbers of businesses that are already compliant and those that are not currently compliant with the 0.37 mg/m^3 and 0.15 mg/m^3 OELs.

As can be seen from Table 6-11, in addition to the 4 sectors likely to be affected at the 0.6 mg/m^3 OEL, only the following additional sectors would likely be affected at the 0.37 mg/m^3 OEL:

- C20: Manufacture of chemicals and chemical products;
- C22: Manufacture of rubber and plastic products; and
- Q86: Human health and social work activities: Human health activities.

A further 6 sectors (making a total of 13 sectors in all out of the 24 sectors identified as having workers potentially exposed to formaldehyde in the EU) would likely be affected at the 0.15 mg/m^3 OEL, implying that all businesses in the remaining 11 sectors would remain fully compliant even at the strictest OEL level without being required to implement any additional RMMs.

Modelling of the potential impacts of the introduction of harmonised OELs has indicated that no businesses are likely to exit the market in the sectors identified as using formaldehyde, and consequently, it is not expected that there would be any significant impacts on competition in these broad markets. This is reinforced by the fact that for those that would be required to implement additional RMMs (even at the strictest OEL), the cost of such RMMs is estimated to represent only a small percentage to average turnover in the respective sectors where they would be required (<1% in all cases, for small, medium and large businesses.)

Table 6-11: Number of businesses compliant and non-compliant with an OELV of 0.37 mg/m^3

Sector	Already compliant			Non-compliant		
	Small	Medium	Large	Small	Medium	Large
A	16,375	351	81	0	0	0
C10	7,319	408	202	0	0	0
C13	6,733	372	88	0	0	0
C15	1,694	87	23	0	0	0
C16	1,282	46	11	0	0	0
C17	7,198	807	339	0	0	0
C20	561	78	66	666	73	37
C21	294	70	117	0	0	0
C22	1,119	108	40	26	3	-
C25	1,119	48	11	0	0	0
C27	6,590	657	567	0	0	0
C28	343	32	18	0	0	0
C29	3,193	501	1,360	0	0	0
C30.3	66	18	31	160	44	141
C31	48,098	1,907	348	0	0	0
E36	167	15	15	0	0	0
E38	687	43	20	0	0	0
F41	22,798	380	85	0	0	0
M72	434	27	18	0	0	0
M74.2	7,002	21	4	0	0	0
M75	1,347	0	0	885	14	1
P85.4	0	0	169	0	0	135
Q86	0	0	0	0	2,276	5,311
S96.0.3	0	0	0	1,125	150	75
Source: Derived by the study team.						

Table 6-12: Number of businesses compliant and non-compliant with an OELV of 0.15 mg/m^3

Sector	Already compliant			Non-compliant		
	Small	Medium	Large	Small	Medium	Large
A	16,375	351	81	0	0	0
C10	7,319	408	202	0	0	0
C13	154	7	2	6,579	365	86
C15	5	0	0	1,689	87	23
C16	7	1	0	1,275	45	11
C17	147	24	4	7,051	783	335
C20	561	78	66	666	73	37

Table 6-12: Number of businesses compliant and non-compliant with an OELV of 0.15 mg/m³						
Sector	Already compliant			Non-compliant		
	Small	Medium	Large	Small	Medium	Large
C21	294	70	117	0	0	0
C22	26	3	0	1,119	108	40
C25	1,119	48	11	0	0	0
C27	6,590	657	567	0	0	0
C28	343	32	18	0	0	0
C29	3,193	501	1,360	0	0	0
C30.3	66	18	31	160	44	141
C31	1,011	20	1	47,087	1,887	347
E36	167	15	15	0	0	0
E38	687	43	20	0	0	0
F41	22,798	380	85	0	0	0
M72	31	2	1	403	25	17
M74.2	7,002	21	4	0	0	0
M75	1,347	0	0	885	14	1
P85.4	0	0	169	0	0	135
Q86	0	0	0	0	2,276	5,311
S96.0.3	0	0	0	1,125	150	75
Source: Derived by the study team.						

Figure 6-1 provides a graphical summary of the sectors and numbers of businesses expected to be affected by having to implement RMMs in order to be compliant with the different OELs.

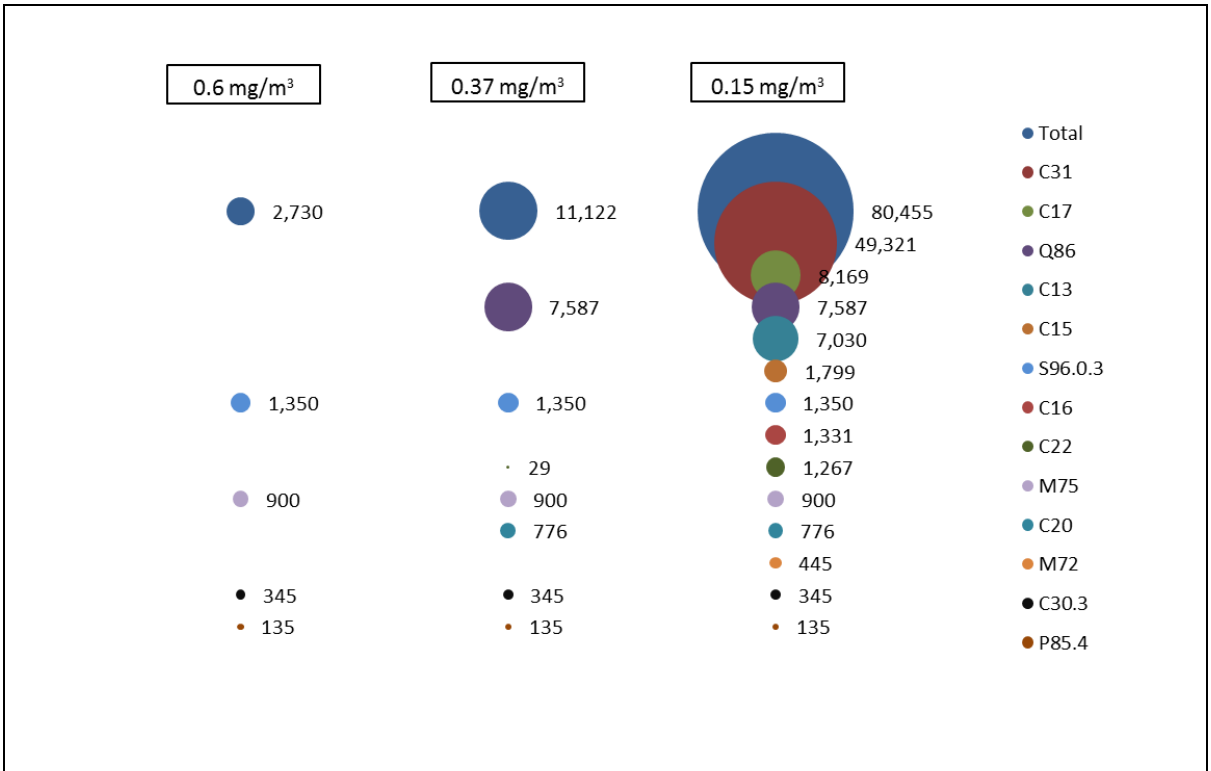


Figure 6-1: Sectors and businesses affected at different OELs Source: Derived by the study team.

It is noted that the figures used to generate estimates of the proportion of turnover that increased costs resulting from expenditure on RMMs to meet the different OELs represent are based on both capital (CAPEX) and operational (OPEX) expenditures at different levels over the 60-year assessment

period. In order to be permitted to continue operation, some businesses will need to invest significant sums in equipment (capital expenditure) upfront to reduce exposure levels to the stipulated OEL. Whilst the percentage of a company's turnover that the total (CAPEX plus OPEX) costs indicated above represent a relatively small amount of a company's turnover spread over 60 years, significant CAPEX expenditures in year 1 would represent a significant proportion of a business's turnover, especially for small companies. This high initial outlay requirement may result in some businesses being unable to continue operations, particularly where they are unable to secure finance for the investment (e.g. for necessary LEV equipment). This aspect may be particularly relevant for older businesses which have outdated and/or inefficient RMM equipment which needs to be replaced in order to meet the required OELs.

Given the levels of capital expenditure required to provide adequate protection of workers and meet the OELs required, it may be more difficult for new businesses to enter the market.

In the event that some businesses do exit the market, the impact on competition will be dependent to a degree on which specific companies (in terms of location) end up going out of business. In MS where there are limited numbers of companies operating in a particular sector, even a limited number of companies exiting the market could lead to a reduction in competition on the local market. Moreover, it is likely to be the case that greater pressure on costs will be felt in those MS which currently have the highest national OELs, requiring a greater shift in exposure levels where businesses are operating at levels close to these. Section 8.5 below provides greater detail on the potential impacts at different OELs and identifies Bulgaria, Croatia, Cyprus, Greece, Romania, Slovenia and UK as potentially having the highest (or no) national OELs and where businesses might therefore be operating currently at higher levels.

Formacare[32] estimates that annual sales of formaldehyde based chemicals in the EU are approximately €9.5 billion and based on 2009 data, that 22 MS manufacture formaldehyde. It is noted by IHS Markit that *"formaldehyde is usually produced close to the point of consumption since it is fairly easy to make, but it is costly to transport and can develop problems associated with stability during transport. As a result, world trade in formaldehyde is minimal."* Consequently, any regulatory measures that would impact on the demand for formaldehyde from downstream users would have significant implications for formaldehyde producers as they would have difficulty in selling their products outside of the EU. However, as indicated above, whilst some of the businesses across the different sectors using formaldehyde are likely to incur costs arising from having to implement RMMs in order to be compliant with the different OELs, none are expected to go out of business, ensuring continued demand for formaldehyde within the EU. As a result, upstream formaldehyde suppliers are unlikely to be significantly affected by the introduction of harmonised OELs.

6.3.2 Consumers

The information presented above suggests that very few companies across all sectors using formaldehyde may be forced to exit the market at the strictest OEL of 0.15 mg/m^3, implying that no monopolistic markets are likely to emerge as a result. Those companies continuing operation will incur additional capital and operating costs, and this may likely to lead to some increase in overall prices paid by consumers, although it is not possible to determine the extent of such increases due to data limitations. However, the fact that the cost increases resulting from the requirement to implement additional RMMs for some businesses are likely to be less than 1% of average turnover in

[32] Formacare is the formaldehyde sector group of the European Chemical Industry Council (Cefic) representing key European producers of formaldehyde, aminoplast glues and polyols, and is made up of representatives from large chemical and manufacturing companies across Europe,

all cases (and significantly less in the majority of cases) would suggest that any such increases in prices would be minimal.

6.3.3 Internal market

It has not been possible to identify the extent of intra-EU trading in products produced using formaldehyde. Similarly, due to the methodological approach adopted for estimating the numbers of businesses using formaldehyde in different MS, it has not been possible to identify the specific numbers of businesses that are operating in more than one EU MS. However, it is likely that some companies will actually have facilities in more than one MS (e.g. due to the fact that large businesses are operating in significant numbers in a number of the sectors analysed) and this will require these businesses to adhere to a range of regulatory requirements under the baseline scenario.

Time and resources will be required to research and regularly update information on different OELs in force in different MS and where these differ for a business operating in more than one MS, production processes/operations may need to be adapted in order to be compliant. Harmonised OELs across all MS would remove the need to carry out this research and construct facilities in different ways, using different processes and equipment in order to ensure regulatory compliance in each MS. This would consequently represent a cost saving for businesses.

6.4 Competitiveness of EU businesses

IHS Markit[33] indicates that the production of urea-, phenol-, and melamine-formaldehyde resins accounted for approximately 70% of world consumption of formaldehyde in 2017. Construction/remodelling activity, vehicle and furniture production, and original equipment manufacture (OEM) are identified as major sectors consuming formaldehyde worldwide. Overall, demand for formaldehyde is closely related to economic activity and Figure 6-2 below provides detail on the share of world consumption in 2017.

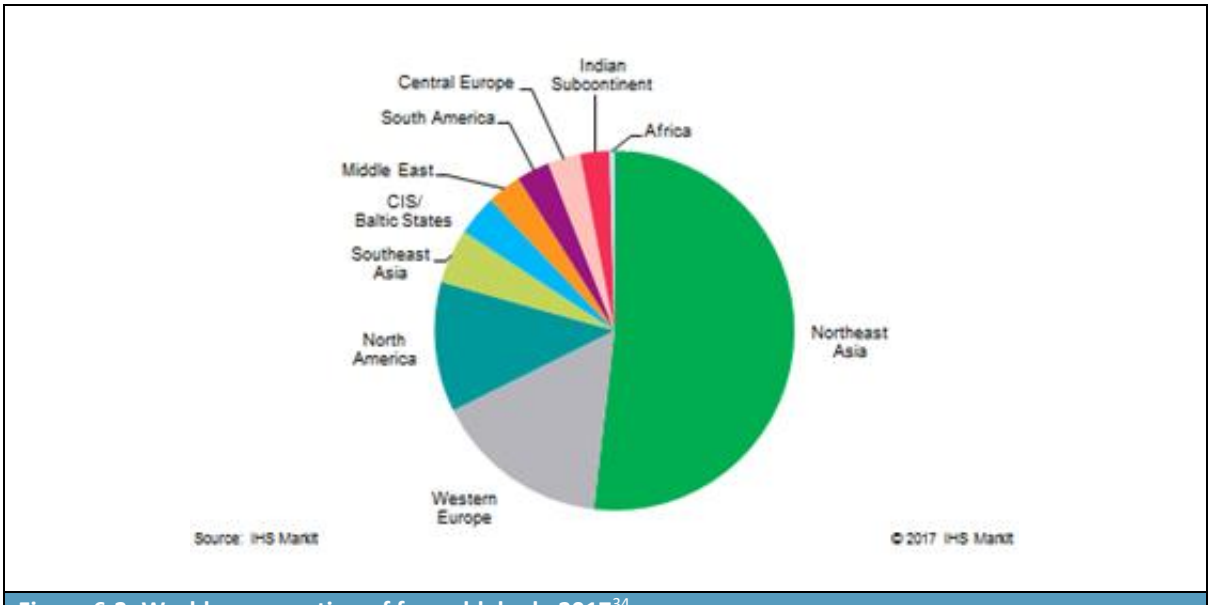


Figure 6-2: World consumption of formaldehyde 2017[34]

[33] https://ihsmarkit.com/products/formaldehyde-chemical-economics-handbook.html

[34] ibid

However, since it is estimated that no businesses are likely to cease trading under any of the proposed OELs, and that costs associated with ensuring that they operate in compliance with proposed levels are anticipated to be a small percentage of turnover in all sectors, no significant impacts on the competitive position of EU businesses are foreseen.

It is noted, however, that under the 0.15 mg/m^3 OEL, a significant number of companies (almost 50,000) in the C31: Manufacture of furniture sector, which is indicated as being one of the highest users of formaldehyde, would be required to implement RMMs due to the fact that they are currently operating in excess of the 0.15 mg/m^3 OEL. This represents almost 98% of companies anticipated to be using formaldehyde.

In the event that regulations are less stringent outside the EU, some businesses may elect to transfer operations to countries where they would not have to incur the costs associated with RMMs in order to achieve compliance with the proposed OELs. This might be a particular option for larger companies with multiple sites using formaldehyde and already operating in those countries.

However, as can be seen from Table 6-13 below (data extracted from Table 3-1 above), the indicative or established OELs in the vast majority of countries where data has been identified are already below the proposed harmonised OELs. In any event, it has been estimated that the costs of implementing RMMs in order to achieve compliance with the harmonised OELs represents only a small percentage of annual turnover of businesses in all sectors, and the costs associated with establishing operations in other countries are likely to exceed these, particularly for businesses that do not already have operations in those countries. For some sectors, such as P85.4: Education (NACE Code P85- P85.4. Higher Education), Q86: Human health and social work activities: Human health activities and S96.0.3: Funeral and related activities, it is highly likely that it would simply not be feasible to transfer activities to other countries and still serve their same customers within the EU.

Table 6-13: OELs in selected non-EU countries

Country	Value/mg/m³
Australia	0.22
Brazil	-
Canada, Ontario	0.005
Canada, Québec	0.22
China	-
India	-
Japan, JSOH	0.005
South Korea	0.11
USA; ACGIH	0.11
USA, OSHA	-
USA, NIOSH	0.003

- Not assigned, not established
Source: see Table 3-1

6.5 Employment

As estimated previously, no businesses are expected to cease operating. As a result, no employees working in these businesses would lose their jobs and consequently, no social costs of unemployment are envisaged.

7 Environmental impacts

This section comprises the following subsections:

- Section 7.1: PBT screening
- Section 7.2: Current environmental levels in relation to hazard data
- Section 7.3: Current environmental exposure – sources and impact
- Section 7.4: Humans via the environment
- Section 7.5: Conclusion

7.1 PBT screening

Formaldehyde is **not classified for environmental hazards** and is **not classified as a PBT** (Persistent, bioaccumulative and toxic[35]). The aquatic and terrestrial PNEC[36] (Predicted No-Effect Concentration) have been derived at 440 µg/L (by sensitivity distribution) and 200 µg/kg soil dry weight (equilibrium partitioning method), respectively (ECHA, 2017a). The sensitivity distribution approach allows for lower assessment factors compared to the "classical approach" starting with the most sensitive species, which would lead to a $PNEC_{aquatic}$ of 5.8 µg/L (OECD, 2002).

Formaldehyde is rapidly removed from air *via* the photodegradation by OH radicals with a half-life in air of 1.7 days, and by direct photolysis, with a half-life of 4.1 hours. Transport and distribution modelling has indicated water to be the main target compartment (99 %) for formaldehyde. Formaldehyde is also biodegradable in water and soil in a relatively short time and also does not accumulate in organisms (WHO, 1989).

7.2 Current environmental levels in relation to hazard data

Formaldehyde is formed primarily by the combustion of organic materials and by a variety of natural and anthropogenic activities. Secondary formation of formaldehyde occurs in the atmosphere through photochemical oxidation and incomplete combustion of natural and anthropogenic volatile organic compounds (VOCs) in the air. Formaldehyde is also emitted by bacteria, algae, plankton, and vegetation. Whilst there are no reliable estimates for releases from natural sources and for secondary formation, these may be expected to be much larger than direct emissions from anthropogenic activities and secondary formation may contribute up to 70–90% of the total atmospheric formaldehyde (OECD, 2002 and WHO, 1989).

The concentrations of formaldehyde in air near the ground in coastal, mountain or oceanic areas in different parts of the world are in good agreement and rang from 0.05 to 14.7 µg/m³. Measurements conducted in Germany, which areconsidered to be representative for the air in the rural areas of Central Europe ranged from 0.1 to 4.5 µg/m³, with a mean value of about 1.5 µg/m³. Measurements

[35] Persistent Definition: Attribute of a substance that describes the length of time that the substance remains in a particular environment before it is physically removed or chemically or biologically transformed. Bioaccumulative: Progressive increase in the amount of a substance in an organism or part of an organism which occurs because the rate of intake exceeds the organism's ability to remove the substance from the body. Source: IUPAC Glossary of Terms Used in Toxicology, 2nd Edition (2007), available at https://sis.nlm.nih.gov/enviro/iupacglossary/frontmatter.html

[36] Concentration that is expected to cause no adverse effect to any naturally occurring population in an environment at risk from exposure to a given substance. Source: IUPAC Glossary of Terms Used in Toxicology, 2nd Edition (2007), available at https://sis.nlm.nih.gov/enviro/iupacglossary/frontmatter.html

in a highly industrialised area with also heavy traffic undertaken in Germany (1979 –1984) gave annual mean values of 7 – 12 µg/m³. Additional measurements conducted in recent years in different locations indicate mean outdoor concentrations ranging from 2.5 µg/m³ to 15.7 µg/m³ (OECD, 2002; WHO, 2002).

Formaldehyde is biodegraded in water and soil in a relatively short time and does not accumulate in organisms. Concentrations in surface waters of Canada ranged from < detection limit of 1 µg/L up to maximum values of 9 µg/l (WHO, 2002). Compared to the PNEC of 440 µg/L, these values are by a factor of at least 50 lower.

Formaldehyde is also not expected to significantly sorb to suspended solids and sediments from water. Biotic and abiotic degradation are expected to be significant processes affecting the fate of formaldehyde in sediment. Soil concentrations were only detectable at contaminated sites, with for example a mean of 76 mg/kg at a plywood plant, but below the detection limit of 0.1 mg/kg at non-industrial areas (WHO, 2002).

7.3 Current environmental exposure – sources and impact

From the direct use of the substance as for example as a biocide it can be assumed that a very high amount is released into the environment. With an amount of 75000 to 90000 t/a worldwide this is a significant pollution source. In addition, reported use of formaldehyde in fish farming and animal husbandry may lead to significant environmental exposure (OECD, 2002; WHO, 2002). However, because of limited stability, on a regional or global scale, formaldehyde emissions do not significantly contribute to the overall environmental burden.

7.4 Humans via the environment

There is no indication of relevant contamination of food, air or drinking water by formaldehyde *via* the environment.

7.5 Conclusion

In conclusion, the environmental impact of formaldehyde is regarded as “low” due to the following factors:

- The non PBT properties of formaldehyde;
- The low environmental exposure/PNEC ratio;
- The low contribution of industrial air emissions to the total emission; and
- A negligible human exposure via the environment.

This characterisation is independent from an additional potential environmental impact from changes of the OEL. However, quantitative calculation of an environmental impact due to OEL changes is not feasible (see the methodology section). Qualitatively, it is expected that this impact is minor and does not modify the overall assessment result for formaldehyde.

8 Distribution of the impacts

The impacts identified under the previous tasks are broken down here by stakeholder type and a systematic analysis of who will bear the costs and accrue the benefits is 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

Businesses using formaldehyde and not already compliant with the introduced OEL will be required to implement a range of protective and preventative measures (involving both capital and operational expenditures) in order to meet OEL requirements. In order to meet the OELs, the number and cost of measures required will be higher the stricter the OEL.

Table 8-1 below sets out the estimated total costs under the P75 scenario (PV over 60 years, discounted at 4%) to businesses arising from the implementation of measures required to meet each of the OELs considered in this study. These costs would be offset by a small benefit to businesses resulting from avoided losses in productivity resulting from nasopharyngeal cancer deaths. This amount, due to the small number of cancer cases (6.9 over 60 years) is estimated to be €30,000 (PV, discounted at 4% over the 60 year assessment period).

Table 8-1: Estimated costs to businesses (P75 scenario) under OELs

	OEL (mg/m^3)		
	0.6	**0.37**	**0.15**
Estimated cost to businesses/€	0.07 billion	1.72 billion	10.34 billion
Source: Derived by the study team.			

Currently, businesses using formaldehyde face different OELs in different MS, with the ratio of the highest OEL to the lowest OEL being 20:1. In the event that an OEL of 0.6 mg/m3 is introduced, that ratio would reduce to 4:1 (NL has the lowest OEL for formaldehyde of 0.15 mg/m3), to approximately 2:1 under an OEL of 0.37 mg/m3 and under an OEL of 0.15 mg/m3, there would be no difference between MS.

The introduction of harmonised OELs will therefore benefit businesses by helping to ensure a level playing field across MS with the 0.15 mg/m3 OEL meaning that all businesses would be required to meet the same standards in all MS which will promote competition. Even under the higher OELs, the disparity between MS regulations would be significantly reduced.

Greater harmonisation will also benefit those businesses which already, or might wish to, operate in multiple MS. If OELs are the same across MS (or at least the disparity is significantly reduced), businesses will be able to design operations in multiple MS in ways that do not have to accommodate

large differences in the OELs they are required to adhere to. This can enable common design of facilities, bulk purchasing of RMM and other equipment, thereby reducing costs. It may also reduce R&D costs associated with having to comply with multiple regulations across MS.

8.1.1 SMEs

The numbers of small, medium and large enterprises likely to have workers exposed to formaldehyde and that will be affected by the introduction of the strictest OEL (i.e. the maximum number of businesses that could be affected) in the EU is estimated in Table 8-2 below. As the table shows, SMEs represent a large proportion of businesses estimated to have workers exposed to formaldehyde, and consequently will be most affected by the introduction of OELs.

Table 8-2: Enterprises in EU28 with workers exposed to formaldehyde, by size category

Sector	Small	Medium	Large
A	16,375	351	81
C10	7,319	408	202
C13	6,733	372	88
C15	1,694	87	23
C16	1,282	46	11
C17	7,198	807	339
C20	1,227	151	103
C21	294	70	117
C22	1,145	111	40
C25	1,119	48	11
C27	6,590	657	567
C28	343	32	18
C29	3,193	501	1,360
C30.3	226	62	172
C31	48,098	1,907	348
E36	167	15	15
E38	687	43	20
F41	22,798	380	85
M72	434	27	18
M74.2	7,002	21	4
M75	2,232	14	1
P85.4	0	0	304
Q86	0	2,276	5,311
S96.0.3	1,125	150	75
Total	**137,281**	**8,536**	**9,313**

Source: Eurostat

The total costs of implementing measures to comply with the different OELs are presented above in Table 8-1. These figures (PV, discounted at 4%) are broken down by size of business in the following table which also differentiates between capital and operational expenses over a 60 year assessment period. As indicated in Tables 6-5 to 6-7 above in Section 6, the compliance costs associated with meeting even the strictest OELs represent less than 1% of SMEs' average total turnover in the different sectors that would be affected.

Table 8-3: Overview of costs to businesses, broken down by business size							
Reference OELV	Cost type	SMALL Businesses		MEDIUM Businesses		LARGE Businesses	
		CAPEX PV 60y €m	OPEX PV 60y €m	CAPEX PV 60y €m	OPEX PV 60y €m	CAPEX PV 60y €m	OPEX PV 60y €m
0.6 mg/m3	Direct	11	-16	14	-16	111	-39
0.37 mg/m3	Direct	21	-8	257	-81	1,903	-373
0.15 mg/m3	Direct	941	186	1,006	463	4,442	3,303
Source: Derived by the 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."* Given the regulatory climate surrounding formaldehyde, the long-term future of businesses using it may be perceived by finance companies as being inherently more risky than other investment opportunities, thereby increasing the difficulty that SME's 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 OELVs require significant capital expenditure, putting SMEs at a disadvantage due to the likely higher cost of finance, if they can secure it.

Furthermore, when it comes to business decisions regarding investment in the different measures required in order to ensure compliance with the proposed OELs, larger businesses will be able to make those decisions in relation to total turnover figures, and not necessarily only in relation to the smaller amounts represented solely by activities relating to formaldehyde.

Finally, it is unlikely that SMEs would be exempted from the OLEV requirements given the potential impacts on health and safety of workers from doing so.

8.1.2 Impacts on Competition and Competitiveness

Available information suggests that no businesses across all sectors using formaldehyde would be forced to exit the market, even at the strictest OEL of 0.15 mg/m^3, implying that no monopolistic markets are likely to emerge from the implementation of OELs. As a result, no impacts on competition are envisaged to arise from the introduction of harmonised OELs.

The introduction OELs will lead to some cost increases for EU businesses, but these are believed to be relatively small when compared with their overall turnover. Consequently, no significant impacts have been identified on the competiveness of EU businesses.

8.2 Workers

The introduction of OELs is intended to result in benefits to workers in terms of avoided work-related cancer cases and sensory irritation resulting from exposure to formaldehyde.

Figure 8-1 below illustrates the current distribution of workers estimated to be exposed to formaldehyde based on different national OELs. The figure suggests that 60% of workers are exposed where national OELs are 0.6 mg/m^3 and below and 50% are exposed where national OELs are 0.37 mg/m^3 and below. However, only 3% of workers are exposed where national OELs are below 0.15

mg/m^3. It is expected that actual exposures will be below these national OELs as part of businesses implementing measures to demonstrate compliance with the different national requirements.

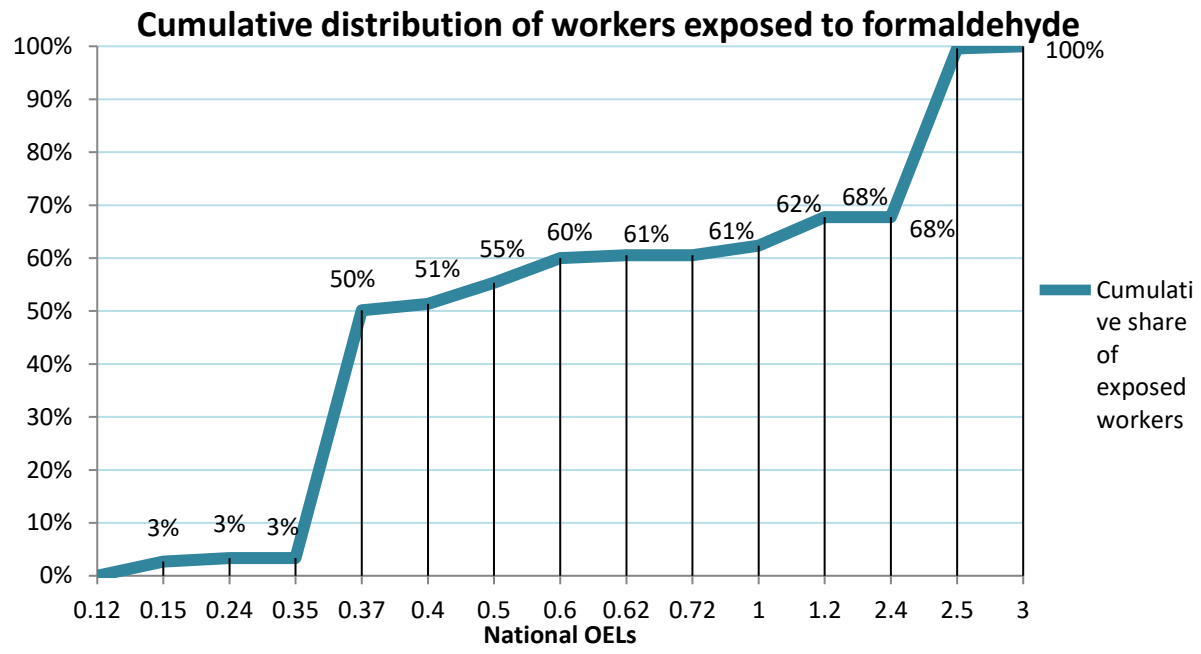


Figure 8-1: Cumulative distribution of workers exposed to formaldehyde
Source: Derived by the study team.

Introducing harmonised OELs will lead to benefits in terms of reduced numbers of cancers and sensory irritation arising from workers no longer being exposed to formaldehyde at higher levels.

It is estimated that 6.9 cases of cancer and approximately 19,200 cases of sensory irritation will be avoided under each of the three proposed OELs, based on the P75 scenario. Consequently, monetised benefits to workers arising from avoiding these cases will be the same under each OEL.

Table 8-4 below provides the monetised estimates over a 60 year period (PV, discounted at 4%) of the benefits to workers from these avoided cases.

Table 8-4: Benefits to workers and their families	
	Benefits to workers & families
Reduction in ill health (nasopharyngeal cancer)	€3.5-2.8 million
Reduction in ill health (sensory irritation)	€950-5,023 million
Total	**€954-5,026 million**
Note: Ranges are developed using two methods of calculation, with Method 1 based on WTP values for morbidity and Method 2 based on monetised DALYs Source: Derived by the study team.	

No businesses are anticipated to cease trading under any of the OELs proposed for formaldehyde, with all of them taking appropriate RMMs in order to be compliant with the OELs. As previously indicated, the increase in costs to businesses as a result of having to implement a range of RMMs

represents a relatively small percentage of businesses' overall turnover, even for SMEs. Consequently, workers are overall unlikely to lose their jobs as a result of the introduction of any of the OELs.

8.3 Consumers

Available information suggests that no businesses across all sectors using formaldehyde would be forced to exit the market, even at the strictest OEL of 0.15 mg/m^3, implying that no monopolistic markets (and consequent price rises for consumers as a result) are likely to emerge from the implementation of OELs.

Those businesses continuing operation and currently operating at OELs above the proposed OELs will incur additional capital and operating costs and this may lead to some increase in overall prices paid by consumers, although it is not possible to determine the extent of such increases due to data limitations. However, it is noted that cost increases are expected to be limited in comparison to businesses' overall turnover, suggesting that businesses may be able absorb these cost increases without significant impacts on prices.

8.4 Taxpayers/public authorities

Member State authorities would be required to transpose and enforce legislation to implement the OEL selected, incurring legal and enforcement costs in the process. It is noted however that MS will already have enforcement systems in place to ensure compliance with their own OELs and consequently, these costs may be expected to be limited.

Transposition costs will be higher at stricter OELs due to the fact that more MS will have existing OELs which will need to be revised and consequently, higher total transposition costs will arise across the EU. Based on an estimate of €50,000 to transpose legislation, it is estimated that these costs would amount to:

At the 0.6 mg/m3 OEL - €600,000

At the 0.37 mg/m3 OEL - €950,000

At the 0.15 mg/m3 level - €1.35 million

As no businesses are expected to cease trading under any of the OELs being considered, there are unlikely to be any significant impacts on MS authority tax revenues.

In terms of benefits, MS authorities will incur lower costs for the provision of healthcare resulting from avoided cases of cancer and sensory irritation. In addition, under the baseline, where workers are sick (or in worst case, die as a result of cancer), workers will earn less wages and as a result, public authorities will receive less tax revenue. The introduction of OELs would subsequently mean that workers earn higher salaries as a result of not having to take time off sick, leading to higher tax revenues for governments.

With an estimated 6.9 cases of nasopharyngeal cancer and 19,200 cases of sensory irritation avoided over the 60 year period under the P75 scenario under all OELs, public healthcare costs and losses in tax revenue would be reduced against the baseline by an amount of approximately €181 million.

8.5 Specific Member States/regions

MS national limits

OELs already exist in different MS but these differ MS to MS. Table 3-1 in Section 3 of this report sets out the OELs in force in the MS[37] and it can be seen that a number of MS would already have equivalent or lower OELs in place than those being proposed. Table 8-5 below summarises the information on national OELs for formaldehyde and lists those MS at each proposed OEL that currently have a higher limit, indicating which MS would be impacted by the introduction of each specific OEL.

Table 8-5: MS with OELs higher than proposed levels		
OEL mg/m³	**Member States where current limits are higher**	**Notes regarding national limits**
0.15	AT, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, HU, IE, LV, LT, PL, PT, RO, SK, SI, SE, UK	
0.37	BG, HR, CY, CZ, DK, EE, FR, EL, HU, LV, LT, PL, RO, SI, UK	FR: Intended change to 0.35 PL: intended change to 0.37
0.6	BG, HR, CY, EL, RO, SI, UK	
Source: Derived by the study team.		

Numbers of businesses affected in different MS

Estimates have been made in Section 3 of this report of the number of businesses operating with formaldehyde across the EU28 MS (Table 3-47). MS with the highest numbers of businesses working with formaldehyde in each sector are likely to experience the greatest impacts (in terms of both costs and benefits) from the introduction of harmonised OELs across the EU and Table 8-6 provides details on the MS with the highest number of businesses broken down by each sector.

Table 8-6: The 5 MS with the highest numbers of businesses working with formaldehyde, by sector		
Sector	**Code**	**Top 5 MS**
Agriculture, forestry, fishing	A	PL, RO, IT, ES, EL
Manufacturing of food products	C10	DE, IT, FR, ES, PL
Manufacture of textiles	C13	IT, DE, ES, UK, FR
Manufacture of leather and related products	C15	IT, PT, ES, RO, PL
Manufacture of wood and products of wood and cork; except furniture	C16	RO, DE, CZ, UK, IT
Manufacture of paper and paper products	C17	IT, FR, PL, ES, DE,
Manufacture of chemicals and chemical products	C20	IT, DE, UK, ES, FR
Manufacture of basic pharmaceutical products and pharmaceutical preparations	C21	DE, FR, IT, UK, ES
Manufacture of rubber and plastic products	C22	DE, IT, UK, PL, FR
Manufacture of fabricated metals, except machinery and equipment	C25	DE, IT, UK, FR, ES
Manufacture of electrical equipment	C27	IT, DE, CZ, FR, UK
Manufacture of machinery and equipment	C28	IT, DE, UK, FR, ES
Manufacture of motor vehicles, trailers and semi-trailers	C29	DE, UK, IT, FR, ES
Manufacture of air and spacecraft and related machinery	C30.3	UK, FR, ES, IT, CZ
Manufacture of furniture	C31	IT, PL, ES, DE, FR
Water collection, treatment and supply	E36	UK, DE, PL, ES, FR
Waste collection, treatment and disposal activities; materials recovery	E38	UK, IT, FR, DE, PL
Construction of buildings	F41	ES, IT, UK, DE, PL
Professional, Scientific and Technical Activities: Scientific research, development	M72	DE, UK, FR, ES, IT
Professional, Scientific and Technical Activities: Photographic activities	M74.2	DE, FR, IT ES, UK

[37] Where these are known. The study team has been unable to identify values for BE, IT, LU, MT, ES. Note that NL does not appear as it already has an OEL of 0.15

Table 8-6: The 5 MS with the highest numbers of businesses working with formaldehyde, by sector		
Sector	**Code**	**Top 5 MS**
Professional, Scientific and Technical Activities: Veterinary activities	M75	DE, UK, FR, ES, IT
Education (NACE Code P85- P85.4. Higher Education)	P85.4	IT, DE, ES, FR, PL
Human health and social work activities: Human health activities	Q86	DE, FR, IT, PL, ES
Funeral and related activities	S96.0.3	UK
Source: Derived by the study team.		

8.6 Different timeframes for costs and benefits

Following the introduction of harmonised OELs, those businesses not already operating at OELs at or below the introduced levels will need to immediately take risk management measures in order to comply with the legislation. As such, the majority of costs calculated over the 60 year period will be incurred at the beginning of the period. This is particularly the case for the capital expenditures required, whereas the operational ones would be spread more evenly over the 60 years.

When it comes to the benefits, the cancer cases avoided would be expected to come to light later in the period due to the fact that there is a latency period for symptoms to occur and a condition to be then diagnosed. This means that a large amount of the benefits calculated above will be set to arise towards the end of the 60 year assessment period.

This difference in the timing of the occurrence of the costs and benefits is problematic as the benefits (occurring towards the end of the period) will be discounted more heavily than the costs (which largely occur towards the beginning of the period. This has been partially addressed by assuming a very conservative latency period of 10 years in the benefits calculations, although this does not deal completely with the issue.

9 Conclusions

This section comprises the following subsections:

- Cost-benefit analysis (CBA); and
- Multi-criteria analysis (MCA).

9.1 Cost-benefit assessment (CBA)

The costs and benefits are summarised below for the following reference OELVs:

- OELV A: 0.6 mg/m^3;
- OELV B: 0.37 mg/m^3; and
- OELV C: 0.15 mg/m^3.

A number of scenarios have been developed for this study, reflecting a range of assumptions about methods of compliance with the OELs and the exposure concentrations that are used to estimate the ill health effects of formaldehyde exposure. The results presented in this section are based on Scenario S3 (P75) which relies on measured exposure data converted to values which reflect the 75th percentile of the samples taken. An overview of the other scenarios that have been estimated is provided in the sensitivity analysis section.

9.1.1 Overview of the costs and benefits of the reference OELVs

Reference OELV A: 0.6 mg/m^3

The benefits and the costs for reference OELV A (0.6 mg/m^3) are summarised in Table 9-1 and Table 9-2. For the purposes of this report, all benefits that accrue from reduced ill health are treated as direct benefits.

Table 9-1: Overview of the benefits (reference OELV A: 0.6 mg/m^3)		
Description	**Amount for 60 year with a static discount rate (PV)**	**Comments**
Direct benefits		
Total	€1-5.1 billion	Healthcare, informal care, productivity loss, lost wages, employers, intangible benefits
Reduction in ill health (nasopharyngeal cancer)	€0.004 billion	
Reduction in ill health (sensory irritation)	€1-5.1 billion	
Indirect benefits		
None quantified		
Source: Derived by the study team.		

Table 9-2: Overview of the costs (reference OELV A 0.6 mg/m³)							
Reference OELV	Cost type	Workers		Businesses		Administrations	
		CAPEX PV 60y €m	OPEX PV 60y €m	CAPEX PV 60y €m	OPEX PV 60y €m	CAPEX PV 60y €m	OPEX PV 60y €m
0.6 mg/m³	Direct	0	0	137	-71	0.6	-
	Indirect	-	-	-	-	-	-
Source: Derived by the study team.							

Reference OELV B: 0.37 mg/m³

The benefits and the costs for reference OELV B (0.37 mg/m³) are summarised in Table 9-3 and 9-4. For the purposes of this report, all benefits that accrue from reduced ill health are treated as direct benefits.

Table 9-3: Overview of the benefits (reference OELV B: 0.37 mg/m³)		
Description	Amount for 60 year with a static discount rate (PV)	Comments
Direct benefits		
Reduction in ill health (nasopharyngeal cancer)	€0.004 billion	Healthcare, informal care, productivity loss, lost wages, employers, intangible benefits
Reduction in ill health (sensory irritation)	€1-5.1 billion	
Indirect benefits		
None quantified		
Source: Derived by the study team.		

Table 9-4: Overview of the costs (reference OELV B 0.37 mg/m³)							
Reference OELV	Cost type	Workers		Businesses		Administrations	
		CAPEX PV 60y €m	OPEX PV 60y €m	CAPEX PV 60y €m	OPEX PV 60y €m	CAPEX PV 60y €m	OPEX PV 60y €m
0.37 mg/m3	Direct	0	0	2,181	-463	0.95	-
	Indirect	-	-	-	-	-	-
Source: Derived by the study team.							

Reference OELV C: 0.15 mg/m³

The benefits and the costs for reference OELV C (0.15 mg/m³) are summarised in Table 9-5 and Table 9-6. For the purposes of this report, all benefits that accrue from reduced ill health are treated as direct benefits.

Table 9-5: Overview of the benefits (reference OELV C: 0.15 mg/m³)		
Description	Amount for 60 year with a static discount rate (PV)	Comments
Direct benefits		
Reduction in ill health (nasopharyngeal cancer)	€0.004 billion	Healthcare, informal care, productivity loss, lost wages, employers, intangible benefits
Reduction in ill health (sensory irritation)	€1-5.1 billion	

Table 9-5: Overview of the benefits (reference OELV C: 0.15 mg/m³)		
Description	**Amount for 60 year with a static discount rate (PV)**	**Comments**
Indirect benefits		
None quantified		

Table 9-6: Overview of the costs (reference OELV C 0.15 mg/m³)							
Reference OELV	**Cost type**	**Workers**		**Businesses**		**Administrations**	
		CAPEX PV 60y €m	**OPEX PV 60y €m**	**CAPEX PV 60y €m**	**OPEX PV 60y €m**	**CAPEX PV 60y €m**	**OPEX PV 60y €m**
0.15 mg/m3	Direct	0	0	6,391	3,952	1.35	-
	Indirect	-	-	-	-	-	-
Source: Derived by the study team.							

9.1.2 CBA for the reference OELVs

The overall costs and benefits of establishing an OELV at the three different reference levels are shown in Table 9-7 and Figure 9-1.

Table 9-7: Summary of monetised costs and benefits		
Reference OELV	**PV benefits over 60 years (€2017)**	**PV costs over 60 years (€2017)**
A: 0.6 mg/m3	€1-5.1 billion	€0.07 billion
B: 0.37 mg/m3	€1-5.1 billion	€1.72 billion
C: 0.15 mg/m3	€1-5.1 billion	€10.34 billion
Monetised costs and benefits	Avoided NFC Avoided sensory irritation	RMMs Discontinuation of business Transposition costs
Significant non-monetised costs and benefits	Simplification of rules for companies operating in several Member States	None
Source: Derived by the study team.		

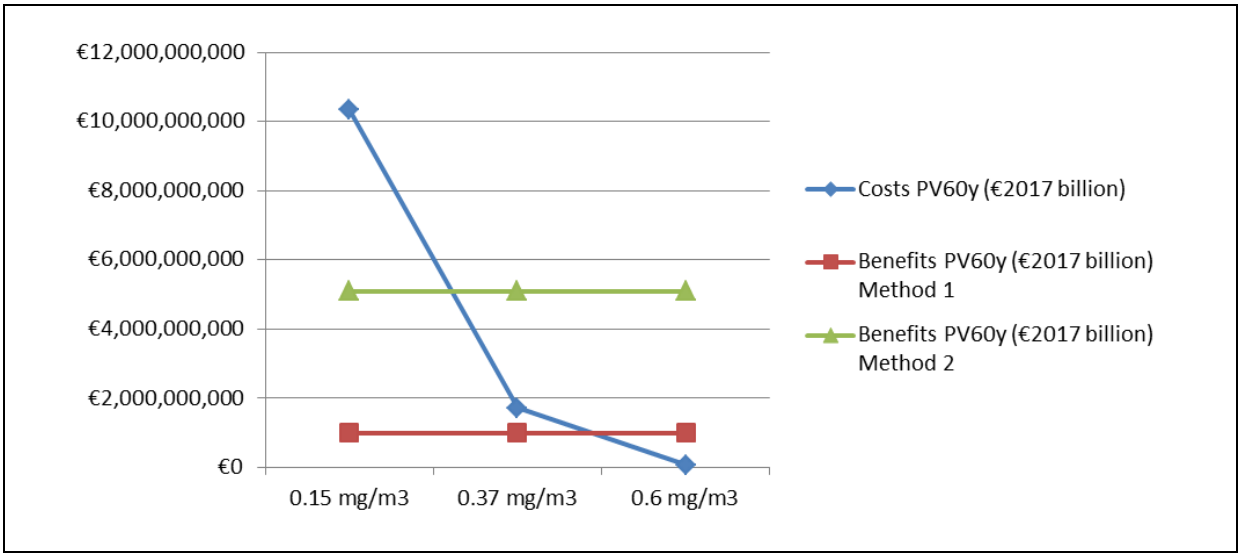


Figure 9-1: Costs vs Benefits: Scenario 3 (measured concentrations) P75
Source: Derived by the study team.

9.2 Multi-criteria analysis (MCA)

The table below summarises both the monetised impacts as well as those that are assessed qualitatively in this report.

Table 9-8: Multi-criteria analysis (formaldehyde OELV, all costs PV 60 years)

Impact	Stakeholders affected	0.15 mg/m3	0.37 mg/m3	0.6 mg/m3
Economic impacts				
Compliance costs	Companies	€10.34 billion	€1.72 billion	€0.07 billion
Transposition costs	Public sector	€1.35 million	€0.95 million	€0.55 million
Benefits from reduced ill health	Reduction in cases (nasopharyngeal cancer)	*7 (over 60 years)*	*7 (over 60 years)*	*7 (over 60 years)*
	Reduction in cases (sensory irritation)	*19,234 (*on any given day)	*19,234 (*on any given day)	*19,234 (*on any given day)
	Reduction in DALYs	*115,510*	*115,510*	*115,510*
	Employers (avoided costs)	€0.03 million	€0.03 million	€0.03 million
	Public sector (avoided costs)	€181 million	€181 million	€181 million
Single market: competition	No. of company closures	*0*	*0*	*0*
Single-market: consumers	Consumers	***No impacts identified***	***No impacts identified***	***No impacts identified***
Single market: internal market	Companies	***Significant positive impact*** Reduction of highest OEL/lowest OEL ratio from 20:1 to 'no difference'	***Significant positive impact*** Reduction of highest OEL/lowest OEL ratio from 20:1 to 2:1	***Positive impact*** Reduction of highest OEL/lowest OEL ratio from 20:1 to 4:1
International competitiveness	Companies	Limited impact	Limited impact	Limited impact
Specific MSs/regions	MSs	All except NL	MSs impacted: BE, BG, HR, CY, CZ, DK, EL, EE, HU, IT, LV, LT, LU, MT, PL, RO, SI, ES, UK	MSs impacted: BE, BG, HR, CY, EL, IT, LU, MT, RO, ES, UK
Social impacts				
Ill health avoided (incl. intangible costs)	Workers & families	€1 billion (Method 1), €5 billion (Method 2)		

Table 9-8: Multi-criteria analysis (formaldehyde OELV, all costs PV 60 years)				
Impact	**Stakeholders affected**	**0.15 mg/m3**	**0.37 mg/m3**	**0.6 mg/m3**
Employment	Jobs lost	No impacts identified		
	Social cost	No impacts identified		
Environmental impacts				
Environmental releases	Environment	Limited impacts under all options		
Recycling – loss of business	Recycling companies	Limited impacts under all options		
Notes: All costs/benefits are relative to the baseline (PV over 60 years). Source: Derived by the study team.				

10 Limitations and sensitivity analysis

10.1 Sensitivity analysis

The costs and benefits estimated in this report for the different reference OELVs for all alternative scenarios are summarised in tables overleaf and the difference between estimated benefits and costs (i.e. by how much are the benefits expected to exceed costs) for each of the scenarios and reference points is depicted in Figures 10-1, 10-2 and 10-3 below.

The key scenarios that have been estimated under sensitivity analysis are:

- Scenario 1: Exposure concentrations: measured concentrations collected through consultation and desk research, AM/GM for the benefits, P95 for the costs;
- Scenario 3: Exposure concentrations: measured concentrations collected through desk research and consultation, P75, P90, or P95 for both the costs and the benefits;
- Scenario 4: Exposure concentrations: assumes that companies comply with 50% of the OEL or with an estimated GM; and
- Scenarios 2a, 2b, and 2c which mirror the scenarios above but without the aerospace (NACE C30.3), health (Q86) and veterinary (M75) and funeral services (S96.0.3) sectors.

Table 10-1: Formaldehyde – Additional assessment scenarios for ALL sectors								
Scenario	Sub-scenario	Reference point (mg/m³)	Cases (40 years)		Additional Benefits PV 60y (€ billion)			Additional Costs PV 60y (€ billion)
			Can	Sen Irr	Can	Sen Irr	Total	Total
S4 Upper bound – OELs	50% OEL	Baseline	**21**	**105,414**				
		0.6	0	0	0.02	5.2-28	5.2-28	11.38
		0.37	0	0	0.02	5.2-28	5.2-28	12.11
		0.15	0	0	0.02	5.2-28	5.2-28	39.08
	Est GM	Baseline	**4**	**16,270**				
		0.6	0	0	0.003	0.9-4.3	0.9-4.3	11.94
		0.37	0	0	0.003	0.9-4.3	0.9-4.3	12.54
		0.15	0	0	0.003	0.9-4.3	0.9-4.3	39.8
S3 Measured – percentiles – P95, P90, P75	P95	Baseline	**34**	**152,000**				
		0.6	13	66,197	0.01	4.6-22.8	4.7-22.8	7.19
		0.37	0	0	0.02	8.2-40.4	8.2-40.4	9.35
		0.15	0	0	0.02	8.2-40.4	8.2-40.4	22.68
	P90	Baseline	**16**	**77,136**				
		0.6	0	0	0.01	4.2-20.5	4.2-20.5	1.69
		0.37	0	0	0.01	4.2-20.5	4.2-20.5	8.3
		0.15	0	0	0.01	4.2-20.5	4.2-20.5	16.5
	P75	Baseline	**4**	**19,234**				
		0.6	0	0	0.004	1-5.1	1-5.1	0.07
		0.37	0	0	0.004	1-5.1	1-5.1	1.72
		0.15	0	0	0.004	1-5.1	1-5.1	10.34
S1 Measured – percentiles – AM/GM/ for benefits; P95 for costs	AM/GM/P95	Baseline	**0.52**	**2,406**				
		0.6	0	0	0	0	0	4.7
		0.37	0	0	0.0005	0.045-1.15	0.046-1.16	5.4
		0.15	0	0	0.0005	0.045-1.15	0.046-1.16	120
Source: Derived by the study team.								

Table 10-2: Formaldehyde – alternative scenarios without Aerospace sector (C30.3), Veterinary services (M75), Health activities (Q86) and Funeral services (S96.0.3)								
Scenario	Sub-scenario	Reference point (mg/m³)	Cases (40 years)		Additional Benefits PV 60y (€ billion)			Additional Costs PV 60y (€ billion)
			Can	Sen Irr	Can	Sen Irr	Total	Total
S2a Upper bound – OELs	50% OEL	Baseline	**14**	**71,411**				
		0.6	0	0	0.01	3.9-19	3.9-19	5.9
		0.37	0	0	0.01	3.9-19	3.9-19	6.2
		0.15	0	0	0.01	3.9-19	3.9-19	20.4
	Est GM	Baseline	**2**	**10,770**				
		0.6	0	**0**	0.002	0.6-2.9	0.6-2.9	5.9
		0.37	0	0	0.002	0.6-2.9	0.6-2.9	6.2
		0.15	0	0	0.002	0.6-2.9	0.6-2.9	20.4
S2b Measured – percentiles – P95, P90, P75	P95	Baseline	**12**	**60,268**				
		0.6	8	42,335	0.004	1-4.8	1-4.8	0.1
		0.37	0	0	0.01	3.3-16	3.3-16	1.5
		0.15	0	0	0.01	3.3-16	3.3-16	4.7
	P90	Baseline	**5**	**24,682**				
		0.6	4	18,243	0.001	0.4-1.7	0.4-1.7	0.1
		0.37	0	0	0.005	1.3-6.6	1.3-6.6	1.2
		0.15	0	0	0.005	1.3-6.6	1.3-6.6	3.4
	P75	Baseline	**1**	**4,447**				
		0.6	1	2,847	0.0005	0.1-0.4	0.1-0.4	0.03
		0.37	0	0	0.001	0.2-1.2	0.2-1.2	0.12
		0.15	0	0	0.001	0.2-1.2	0.2-1.2	3.1
S2c Measured – percentiles – AM/GM/ for benefits; P95 for costs	AM/GM/P95	Baseline	**0.52**	**2,406**				
		0.6	0	0	0.001	0.1-0.6	0.1-0.6	3
		0.37	0	0	0.001	0.1-0.6	0.1-0.6	3.5
		0.15	0	0	0.001	0.1-0.6	0.1-0.6	6.7
Source: Derived by the study team.								

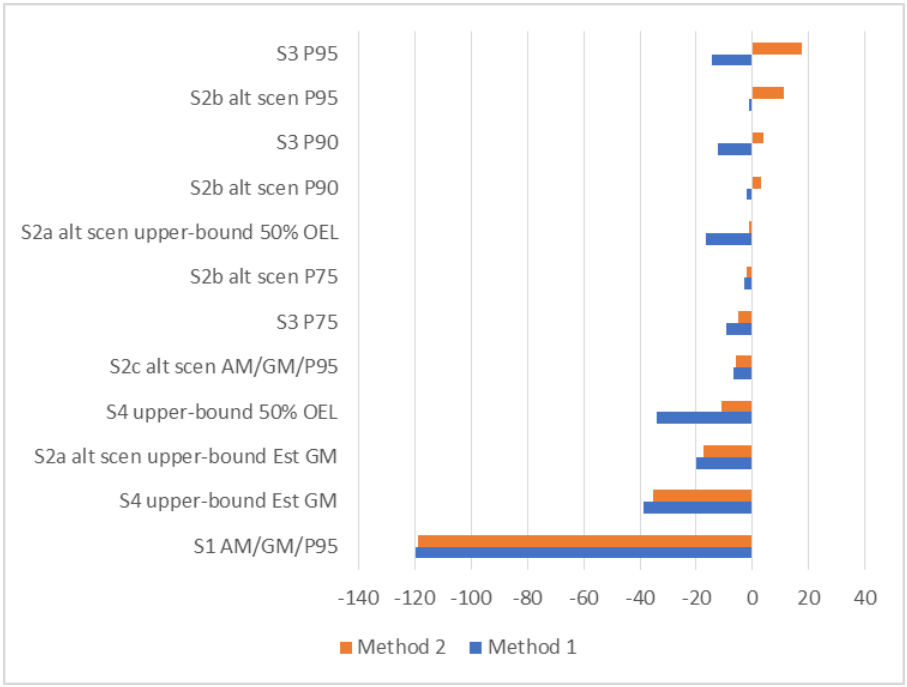


Figure 10-1: Sensitivity analysis (Benefits-Costs): alternative scenarios for reference point 0.15 mg/m³ (€ billion)

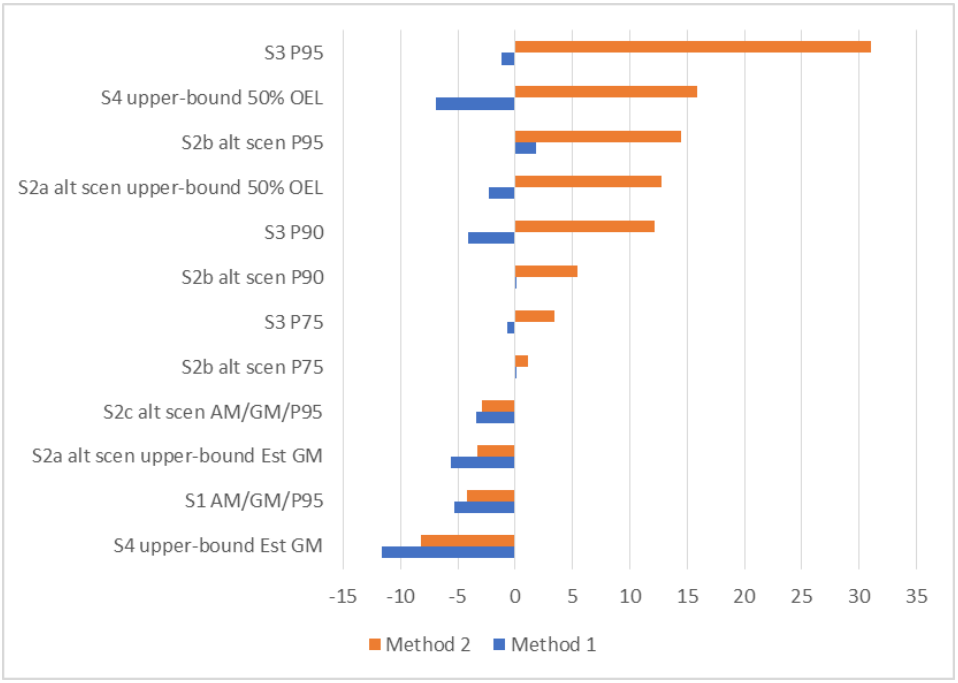


Figure 10-2: Sensitivity analysis (Benefits-Costs): alternative scenarios for reference point 0.37 mg/m³ (€ billion)

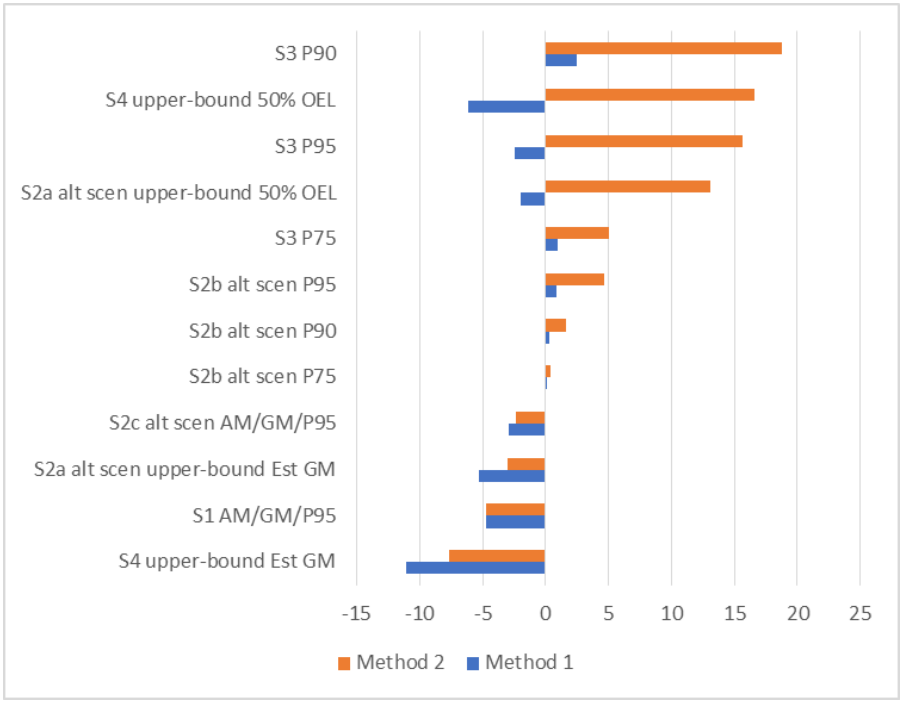


Figure 10-3: Sensitivity analysis (Benefits-Costs): alternative scenarios for reference point 0.6 mg/m³ (€ billion)

10.2 Limitations

10.2.1 Overview of limitations and uncertainties

This section sets out the key limitations and uncertainties and considers their potential impact on the conclusions. Whilst some of these uncertainities have been internalised into the assessment by means of the different cost and benefit scenarios, significant uncertainities remain. These are summarised below and their significance for the results of this study is assessed. A more detailed assessment of some of these limitations and uncertainities is provided in the second part of this section.

Table 10-3: Overview of the key limitations/uncertainties and their significance

Limitation or uncertainty	Explanation	Estimates in this study are U (underestimates) or O (overestimates)	
		Costs	Benefits
Additional health endpoints	A number of health endpoints could not be quantified due to insufficient information.	Not relevant	U
Slope of ERRs/DRRs	There are uncertainities in the evidence available to develop the ERR and DRR.	Not relevant	Could be either U or O
The latency period for cancer	In order to avoid underestimating the benefits from an OELV, an extremely conservative latency period of 10 years has been used for the estimation of future cancer cases.	Not relevant	O
Future trends	Exposed workforce and concentrations are assumed to remain unchanged.	O	O
Discount rate	The estimates in this report have all been modelled using a static discount rate. A declining discount rate would reduce both the costs and the benefits.	U	U
PPE in exposure data	Some of the input data have been corrected for PPE use. However, there is insufficient information to determine which data precisely have been corrected. Should PPE currently be worn, then both the costs and benefits would be overestimated.	O	O
'Positive bias' in reported data	It is possible that there has been some self-selection among companies that provided the data collected through consultation for this study, with worse-performing companies less likely to report their exposure concentrations.	U	U
Assessment period	The reference period of 60 years for this study was selected both to be consistent with previous Commission IAs but also to ensure that the long latency period for cancer does not mean that the benefits are not counted. The cumulative nature of cancer risk and the fact workers can develop sensory irritation every day mean that the impact of extending the assessment period would most likely to be significant.	U	U

10.2.2 Key limitations and uncertainties

The key uncertainities are summarised below.

Additional health endpoints and slope of ERRs/DRRs

Costs and benefits of alternative OELs for formaldehyde depend on the toxicological parameters (ERR, DRR, threshold), as derived in Section 2. However, those parameters include some uncertainties, because of the completeness of endpoints, for example are all relevant tumour locations addressed and are all relevant non-cancer endpoints covered and because of the respective selected slope of the ERR or DRR (the effects and severity in higher doses compared to lower doses).

Generally, only the most sensitive tumour site (highest associated risk at low level exposures as agreed by SCOEL) has been selected. For formaldehyde, nasopharyngeal cancer has been chosen as critical tumour site. However, as formaldehyde has been classified as Carc. Cat. 1B according to CLP regulation, further cancer sites observed in animal studies may be relevant. These are according to IARC (2012) (reliability of the studies and human relevance of tumours not analysed for the purpose of this listing)[38]:

- Haematopoetic tissue (p=0.0056) or lymphohaematopoetic tumours (p< 0.01, trend);
- Testicular interstitial-cell adomomas (p<0.01);
- Small intestine leiomyosarcoma (p<0.01);
- Adenosarcoma of the pylorus (stomach gatekeeper; p<0.05) or fore-stomach squamous-cell papillomas (p<0.01);
- Nasal cavity tumours (many studies, some of them significant); and
- Lung tumours (p<0.01) or tracheal tumours (p<0.05)

In addition, several tumour sites have been observed in human case-control or cohort studies with occupational exposure to formaldehyde. IARC (2012)[39] assumes that there is sufficient evidence for nasopharyngeal cancer and leukaemia. On the other hand, RAC (2012) concluded that the epidemiology data do not show consistent findings across studies for leukaemia rates. The inconsistent findings across job types and exposure groupings, and the lack of biological plausibility argue against formaldehyde as the cause of the increased rates. Results based on cohort and case-control studies do not suggest an association between formaldehyde exposure and leukaemia[40]. IARC also finds a positive association between sinonasal cancer and occupational exposure to formaldehyde. Because of those uncertainties no conclusions in the shift of the slope for the ERR (all cancer sites vs. most significant cancer site) can be provided in this sensitivity analysis. Moreover, there exists no adequate methodology to discriminate the occurrence of multiple cancers in identical persons or the additive occurrence of cancers in different persons (hence, additional cancer cases, if more cancer sites are considered). Therefore a quantitative sensitivity analysis is not feasible, but it may be concluded that the reference to only nasopharyngeal cancers tends to underestimate the total number of cancer cases to be expected after occupational exposure to formaldehyde.

Regarding non-cancer effects, sensory irritation has been assessed as the most critical effect with qualified data to describe the DRR (at least in the low concentration range). However, other respiratory effects have been observed in humans, which may or may not be secondary to sensory

[38] At least one study with significantly elevated additional risk, according to IARC, International Agency for Research on Cancer (2012) Formaldehyde

[39] In: IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Vol. 100F. A Review of Human Carcinogens. Chemical Agents and Related Occupations, WHO, World Health Organization, Lyon, France, 401-430

[40] RAC (Committee for Risk Assessment) (2012) Opinion proposing harmonised classification and labelling at EU level of Formaldehyde. CLH-O-0000003155-80-01/F

irritation. In addition, human experience indicates possible neurological effects[41] and asthma[42] and animal studies demonstrate further possible organ toxicity. It is well known that formaldehyde is a skin sensitiser from dermal exposure. As these non-cancer endpoints have not been selected for OEL derivation by SCOEL because the studies often do not provide a dose response relationship validated for the occupational exposure scenario and because those studies are not equally analysed for reliability, a quantitative sensitivity analysis is not feasible. For the reasons mentioned, the reference to sensory irritation only tends to underestimate the total number of non-cancer cases to be expected after occupational exposure to formaldehyde.

Two health endpoints have been able to be quantified for formaldehyde; these are nasopharyngeal cancer (cancer endpoint) and sensory irritation (non-cancer endpoint). There are a number of other endpoints for formaldehyde; however these could not be quantified and be used for the cost benefit calculations due to the reasons discussed in the following table.

Table 10-4: Health endpoints for formaldehyde

Health endpoint	Endpoint Quantified/not quantified	Details
Cancer endpoints		
Nasopharyngeal cancer	Endpoint quantified in the report	Critical endpoint from SCOEL; tends to underestimate the total number of cancer cases to be expected after occupational exposure to formaldehyde
Haematopoetic tissue or lymphohaematopoetic tumours	Not quantified	May be relevant, observed in animal studies ($p=0.0056$ and $p<0.01$ respectively). Also no adequate methodology to discriminate the occurrence of multiple cancers in identical persons or the additive occurrence of cancers in different persons.
Testicular interstitial-cell adomomas	Not quantified	May be relevant, observed in animal studies ($p<0.01$). no adequate methodology to discriminate the occurrence of multiple cancers in identical persons or the additive occurrence of cancers in different persons
Small intestine leiomyosarcoma	Not quantified	May be relevant, observed in animal studies ($p<0.01$). No adequate methodology to discriminate the occurrence of multiple cancers in identical persons or the additive occurrence of cancers in different persons
Adenosarcoma of the pylorus (stomach gatekeeper; $p<0.05$) or fore-stomach squamous-cell papillomas ($p<0.01$	Not quantified	May be relevant, observed in animal studies ($p<0.01$ and $p<0.05$ respectively)
Nasal cavity tumours	Not quantified	Observed in animal studies. No adequate methodology to discriminate the occurrence of multiple cancers in identical persons or the additive occurrence of cancers in different persons

[41] ATSDR, Agency for Toxic Substances and Disease Registry (1999), Toxicological Profile for Formaldehyde, U.S. Department of Health and Human Services; Public Health Service

[42] At least one study with significantly elevated additional risk, according to IARC, International Agency for Research on Cancer (2012) Formaldehyde

Table 10-4: Health endpoints for formaldehyde		
Health endpoint	**Endpoint Quantified/not quantified**	**Details**
Lung tumours (p<0.01) or tracheal tumours (p<0.05)	Not quantified	Observed in animal studies (p<0.01 and p<0.05 respectively). no adequate methodology to discriminate the occurrence of multiple cancers in identical persons or the additive occurrence of cancers in different persons
Leukemia	Not quantified	Inconsistent findings across job types and exposure groupings, and the lack of biological plausibility argue against formaldehyde as the cause of the increased rates
Sinonasal	Not quantified	No adequate methodology to discriminate the occurrence of multiple cancers in identical persons or the additive occurrence of cancers in different persons
Non-cancer endpoints		
Sensory irritation	Quantified	Most critical effect with the most qualified data to derive a Dose Response Relationship (DRR). Tends to underestimate the total number of non-cancer cases to be expected after occupational exposure to formaldehyde using only sensory irritation
Possible neurological effects and asthma, animal studies demonstrate	Not quantified	Not selected by SCOEL for OEL derivation. The studies often do not provide a dose response relationship validated for the occupational exposure scenario and the studies are not equally analysed for reliability.
further possible organ toxicity	Not quantified	From animal studies. The studies often do not provide a dose response relationship validated for the occupational exposure scenario and the studies are not equally analysed for reliability.

Future trends

It should be noted that the industry is voluntarily working towards voluntary targets which involve a reduction of formaldehyde exposure (e.g. Formacare, wood-panel industry; see section 3.7). It is therefore likely that further reductions would take place even in the absence of an OELV being introduced under the CMD.

Discount rate

The estimates in the report have been modelled using a static discount rate of 4% over the 60 year period. A dynamic discount rate would increase both the value of the benefits and the costs but the value of the benefits would increase by a comparatively greater rate. The value of the benefits would increase by 12-13% for nasopharyngeal cancer and by 6% for sensory irritation. The value of the costs would increase by max 6%.

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Annex 1 Summary of Consultation Responses

Responses to consultation relevant to formaldehyde

Table A1-1: Number of responses relevant to formaldehyde	
Questionnaire responses	32
Interviews	30
Site visits	5
Total	**67**

There were a relatively larger number of questionnaires responses, interviews and site visits for formaldehyde due to its widespread use in a large number of sectors (e.g. paper products, pharmaceuticals, furniture, motor vehicles, electrical equipment, etc.).

Annex 2 Scenario 1 – detailed results

A2.1 Avoided cases of ill health (cancer and non-cancer)

The avoided cases of ill health at the reference OELV levels are summarised below.

Table A2-2: Cases of nasopharyngeal cancer and sensory irritation for each reference OELV				
Reference point (inhalable fraction)	nasopharyngeal cancer		sensory irritation	
	40 years	60 years	40 years	60 years
Baseline	0.51	0.87	2,406	4,800
0.15 mg/m^3	0	0	0	0
0.37 mg/m^3	0	0	0	0
0.60 mg/m^3	0.51	0.87	2,406	4,800
Source: Derived by the study team.				

A2.2 Benefits to workers & families

The benefits (avoided costs of ill health) for workers and their families are calculated using the two methods summarised below. These equal the cost of ill health under the baseline scenario, less the cost of ill health following the introduction of an OELV.

Table A2-3: 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*

The benefits of each reference OELV are summarised below. Method 1 relies on WTP values for morbidity, with the resulting estimates given in Table A2-4.

Table A2-4: METHOD 1: benefits € to WORKERS & FAMILIES (reference OELVs vs baseline)				
Reference (inhalable)	0.15 mg/m^3	0.37 mg /m^3	0.6 mg /m^3	Baseline
Constant workforce				
Nasopharyngeal cancer	450,000	450,000	0	0
Sensory irritation	33,966,000	33,966,000	0	0
Total	34,416,000	34,416,000	0	0
Source: Derived by the study team.				

Method 2 relies on monetised DALYs, with the estimates given in table A2-5.

Table A2-5: METHOD 2: benefits € to WORKERS & FAMILIES (reference OELVs vs baseline)				
Reference (inhalable)	0.15 mg/m^3	0.37 mg /m^3	0.6 mg /m^3	Baseline
Constant workforce				
Nasopharyngeal cancer	503,000	503,000	0	0
Sensory irritation	1,143,510,000	1,143,510,000	0	0
Total	1,144,012,000	1,144,012,000	0	0
Source: Derived by the study team.				

A2.3 Benefits to the public sector

The benefits (avoided costs of ill health) for the public sector are calculated using the method summarised below.

Table A2-6: 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)*[43]

The benefits of each reference OELV are summarised below.

Table A2-7: Benefits €to the PUBLIC SECTOR (reference OELVs vs baseline)				
Reference (inhalable)	**0.15 mg/m³**	**0.37 mg /m³**	**0.6 mg /m³**	**Baseline**
Constant workforce				
Nasopharyngeal cancer	8,000	8,000	0	0
Sensory irritation	12,454,000	12,454,000	0	0
Total	12,462,000	12,462,000	0	0
Source: Derived by the study team.				

A2.4 Benefits to employers

The benefits (avoided costs of ill health) accrued by employers are calculated using the method summarised below.

Table A2-8: Benefits € to EMPLOYERS (avoided cost of ill health)		
Stakeholder group	**Costs**	**Method of summation**
Employers	Ce, Cp	*CtotalEmployer=Ce+0.8*Cp*

The benefits of each reference OELV are summarised below.

Table A2-9: Benefits € to EMPLOYERS (reference OELVs vs baseline)				
Reference (inhalable)	**0.15 mg/m³**	**0.37 mg /m³**	**0.6 mg /m³**	**Baseline**
Constant workforce				
Nasopharyngeal cancer	3,000	3,000	0	0
Sensory irritation	0	0	0	0
Total	3,000	3,000	0	0
Source: Derived by the study team.				

[43] Assumes 20% tax.

A2.5 Aggregated benefits

Costs of ill health

The total costs of ill health (over 60 years) are summarised below for the baseline and each of the five reference OELVs.

Method 1 relies on WTP values for morbidity, with the results given in Table A2-10.

Table A2-10: METHOD 1: total cost € over 60 years of ill health (baseline line and reference OELVs)				
Reference (inhalable)	**0.15 mg/m³**	**0.37 mg /m³**	**0.6 mg /m³**	**Baseline**
Constant workforce				
Nasopharyngeal cancer	0	0	459,000	459,000
Sensory irritation	0	0	45,288,000	45,288,000
Total	0	0	45,746,000	45,746,000
Source: Derived by the study team.				

The results for Method 2, which relies on monetised DALYs, are given in Table A2-11.

Table A2-11: METHOD 2: total cost € over 60 years of ill health (baseline line and reference OELVs)				
Reference (inhalable)	**0.15 mg/m³**	**0.37 mg /m³**	**0.6 mg /m³**	**Baseline**
Constant workforce				
Nasopharyngeal cancer	0	0	511,000	511,000
Sensory irritation	0	0	1,154,832,000	1,154,832,000
Total	0	0	1,155,343,000	1,155,343,000
Source: Derived by the study team.				

Benefits – avoided ill health vis-à-vis the baseline

The benefits of each reference OELV are summarised below. These equal the cost of ill health under the baseline scenario minus the cost of ill health following the introduction of an OELV, i.e. they represent the net benefits from introducing an OELV.

Method 1 relies on WTP values for morbidity. The benefits calculated on the basis of Method 1 are given in Table A2-12 and depicted in Figure A2-1 below.

Table A2-12: METHOD 1: benefits € from avoided ill health (reference OELVs vs baseline)				
Reference (inhalable)	**0.15 mg/m³**	**0.37 mg /m³**	**0.6 mg /m³**	**Baseline**
Constant workforce				
Nasopharyngeal cancer	459,000	459,000	0	0
Sensory irritation	45,288,000	45,288,000	0	0
Total	45,746,000	45,746,000	0	0
Source: Derived by the study team.				

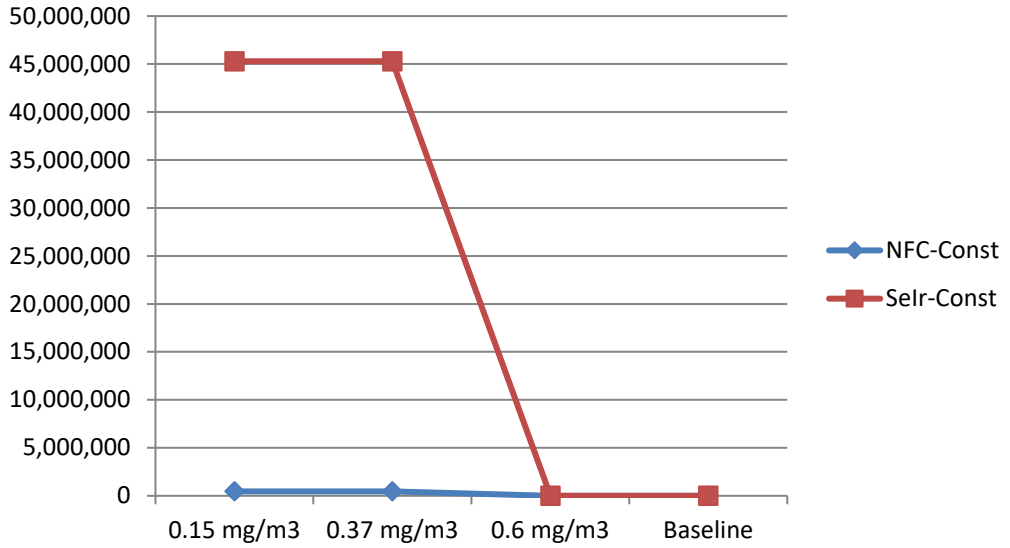

Figure A2-1: METHOD 1: benefits € from avoided ill health (reference OELVs vs baseline)
Source: Derived by the study team.

Method 2 relies on monetised DALYs, with the results presented in Table A2-13 below. The total net benefits calculated on the basis of Method 2 are depicted in Figure A2-2.

Table A2-13: METHOD 2: benefits € from avoided ill health (reference OELVs vs baseline)

Reference (inhalable)	0.15 mg/m³	0.37 mg /m³	0.6 mg /m³	Baseline
Constant workforce				
Nasopharyngeal cancer	511,000	511,000	0	0
Sensory irritation	1,154,832,000	1,154,832,000	0	0
Total	1,155,343,000	1,155,343,000	0	0
Source: Derived by the study team.				

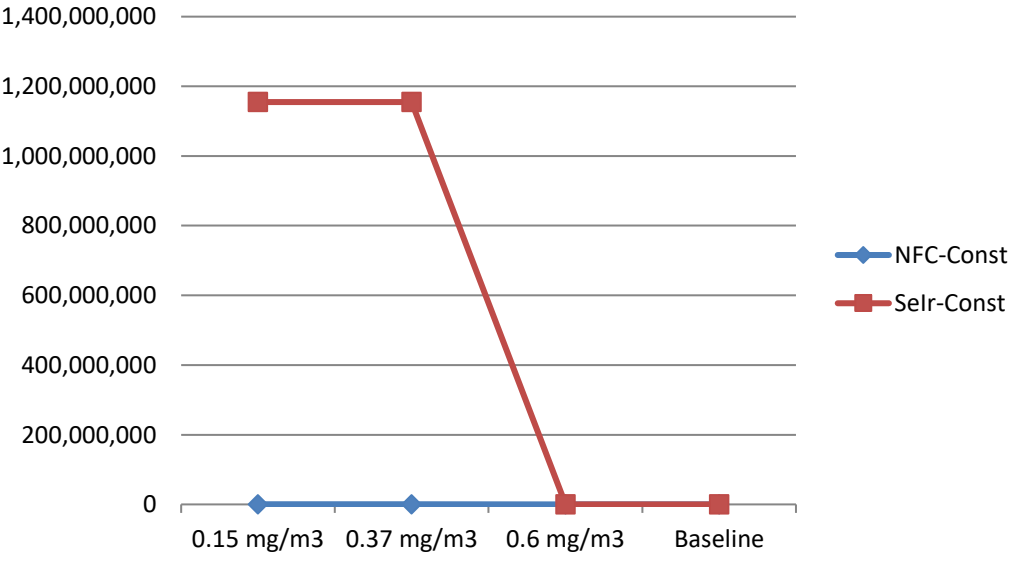

Figure A2-2: METHOD 2: benefits € from avoided ill health (reference OELVs vs baseline)
Source: Derived by the study team.

A2.6 OELVs – compliance and administrative costs for companies

A2.6.1 Current level of actual exposure in the companies

The exposure concentrations assumed to be occurring in the workplace by sector are shown in Table A2-14. As regards the exposure concentrations, the 95th percentile value has been estimated for each sector using the data reported in Section 3.5. The following approach has been applied:

- Data based on shoulder/waist apparatus are used in preference to fixed measurement data;
- The most recent data are preferred;
- A lognormal distribution hypothesisis is assumed;
- For each sector/use, an arithmetic mean or geometric mean, 75th, 90th and 95th percentile on a lognormal distribution have been calculated.
- For the calculation of costs, the P95 measurements were used (where 95th percentile value was not available, the 95th percentile has been estimated using a multiplier derived from the average difference for other processes within the same sector); and
- Where data for multiple processes were available, a weighted average of all 95th percentile values has been calculated (taking into account the relative importance of each process within the sector).

Table A2-14: Number of enterprises affected by formaldehyde at different exposure concentration by size of enterprise by sector

Sector	P95 (actual exposure mg/m^3(ppm))	Small enterprises	Medium enterprises	Large
A	<0.1(0.08)	16,375	352	81
C10	<0.1(0.08)	7,319	408	202
C13	1.31(1.1)	3,807	150	29
C15	1.31(1.1)	992	25	10
C16	0.5(0.42)	781	22	4
C17	1.31(1.1)	3,912	406	120
C20	0.98(0.82)	670	70	27
C21	0.03(0.025)	282	68	115
C22	0.2(0.17)	1,119	108	40
C25	0.29(0.24)	1,084	46	11
C27	0.2(0.17)	6,492	650	564
C28	0.15(0.12)	343	32	18
C29	0.11(0.09)	3,192	501	1,360
C30.3	0.11(0.09)	226	62	172
C31	0.6(0.5)	23,119	778	100
E36	<0.01	167	15	15
E38	<0.01	687	43	20
F41	0.7(0.58)	8,873	176	24
M72	1.45(1.22)	185	12	7
M74.2	<0.01	7,002	21	4
M75	3.85(3.2)	0	0	0
P85.4	0.85(0.7)	0	0	148
Q86	3.23(2.69)	0	213	496

Table A2-14: Number of enterprises affected by formaldehyde at different exposure concentration by size of enterprise by sector				
Sector	**P95 (actual exposure mg/m³(ppm))**	**Small enterprises**	**Medium enterprises**	**Large**
S96.0.3	4.8(4)	900	120	60
Source: Derived by the study team. Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities.				

A2.6.2 Estimated breakdown of RMMs used by enterprises, suitability and effectiveness of RMMs

These estimates are the same as those presented in Sections 5.3.2 and 5.3.3.

A2.6.3 Marginal abatement cost curves

Three different costs, all present values for 60 years, are calculated: TOTAL (CAPEX + OPEX), CAPEX, and OPEX. These are shown for each target OEL (i.e. reference point, see Section 2.3) by enterprise size in Table A2-15. Figure A2-3 shows the TOTAL cost in graphical form.

Estimated costs

Table A2--15: Formaldehyde: estimated CAPEX, OPEX and TOTAL costs as present value over 60 years in € by target OELV by size of enterprise			
Enterprise size/ Target OELV	**0.15 mg/m³**	**0.37 mg/m³**	**0.6 mg/m³**
All sectors			
Small CAPEX	€ 1,625,047,862	€ 1,009,803,632	€ 949,257,904
Small OPEX	€ 1,778,314,109	€ 820,367,841	€ 780,413,596
Small TOTAL	**€ 3,403,361,971**	**€ 1,830,171,473**	**€ 1,729,671,499**
Medium CAPEX	€ 25,892,576,261	€ 565,658,734	€ 511,490,478
Medium OPEX	€ 836,740,938	€ 475,811,683	€ 410,574,947
Medium TOTAL	**€ 26,729,317,198**	**€ 1,041,470,416**	**€ 922,065,425**
Large CAPEX	€ 88,876,156,972	€ 1,146,923,508	€ 1,012,630,585
Large OPEX	€ 1,212,450,766	€ 1,410,378,760	€ 991,028,420
Large TOTAL	**€ 90,088,607,738**	**€ 2,557,302,267**	**€ 2,003,659,004**

Source: Derived by the study team.

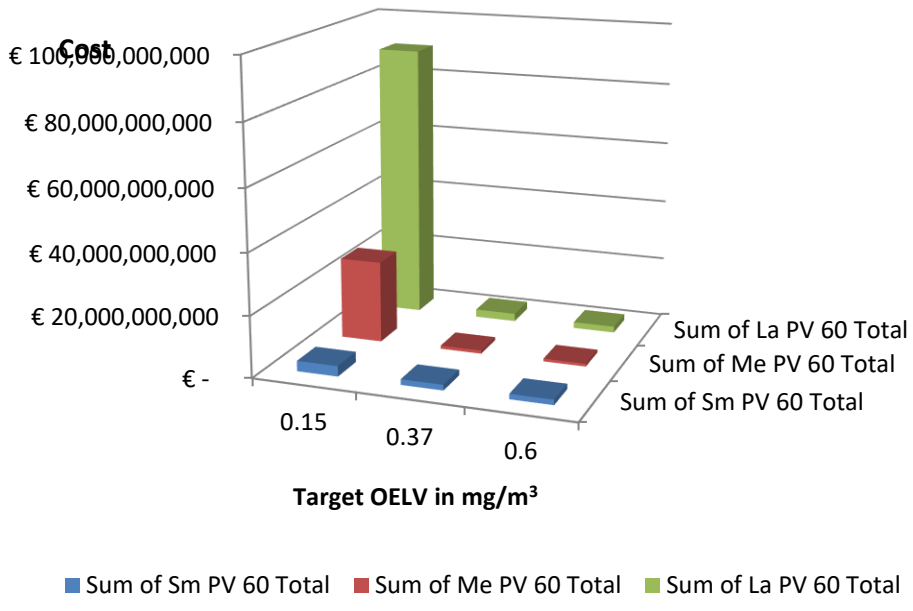

Figure A2-3: Share of PV at 60 years split between small, medium and large enterprises for different target OELVs
Source: Derived by the study team.

A2.6.4 Sector/use-specific cost curves

The TOTAL, CAPEX and OPEX (all present values for 60 years) are shown for a range of target OELVs for all 24 sectors in Tables A2-16 to A2-18. Figure A2-4 shows the TOTAL cost in Table A2-16 for all sectors in graphical form.

Estimated costs

Table A2-16: Formaldehyde: estimated TOTAL costs (present value for 60 years) in € by target by sector

Sector/ Target OELV	0.15 mg/m³	0.37 mg/m³	0.6 mg/m³
A	€ -	€ -	€ -
C10	€ -	€ -	€ -
C13	€ 508,079,047	€ 324,342,117	€ 280,173,367
C15	€ 128,662,427	€ 82,129,717	€ 71,242,217
C16	€ 44,371,810	€ 6,543,709	€ -
C17	€ 943,913,184	€ 543,723,101	€ 471,743,101
C20	€ 209,567,180	€ 104,048,695	-€ 14,974,098
C21	€ -	€ -	€ -
C22	€ 76,174,274	€ -	€ -
C25	€ 118,684,575	€ -	€ -
C27	€ 766,869,958	€ -	€ -

Table A2-16: Formaldehyde: estimated TOTAL costs (present value for 60 years) in € by target by sector			
Sector/ Target OELV	0.15 mg/m³	0.37 mg/m³	0.6 mg/m³
C28	€ 29,702,874	€ -	€ -
C29	€ -	€ -	€ -
C30.3	€ -	€ -	€ -
C31	€ 3,298,703,216	€ 2,132,775,709	€ 2,127,537,652
E36	€ -	€ -	€ -
E38	€ -	€ -	€ -
F41	€ 185,709,996	-€ 14,443,546	-€ 14,443,546
M72	€ 56,216,061	€ 28,491,089	€ 17,514,939
M74.2	€ -	€ -	€ -
M75	€ -	€ -	€ -
P85.4	€ 374,132,764	€ 332,369,539	€ 121,065,369
Q86	€ 113,014,045,883	€ 1,678,036,830	€ 1,400,737,080
S96.0.3	€ 466,453,658	€ 210,927,198	€ 194,799,849
ALL SECTORS	€ 120,221,286,907	€ 5,428,944,158	€ 4,655,395,930

Source: Derived by the study team.

Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities.

Table A2-17: Formaldehyde: estimated CAPEX costs (present value for 60 years) in € by target by sector			
Sector/ Target OELV	0.15 mg/m³	0.37 mg/m³	0.6 mg/m³
A	€ -	€ -	€ -
C10	€ -	€ -	€ -
C13	€ 257,060,097	€ 204,060,126	€ 159,891,376
C15	€ 64,971,148	€ 51,392,032	€ 40,504,532
C16	€ 32,638,080	€ 15,637,486	€ -
C17	€ 466,465,487	€ 372,429,944	€ 300,449,944
C20	€ 95,110,885	€ 59,265,563	€ 14,208,916
C21	€ -	€ -	€ -
C22	€ 68,321,775	€ -	€ -
C25	€ 63,585,169	€ -	€ -
C27	€ 619,480,815	€ -	€ -
C28	€ 25,711,864	€ -	€ -

Table A2-17: Formaldehyde: estimated CAPEX costs (present value for 60 years) in € by target by sector			
Sector/ Target OELV	0.15 mg/m³	0.37 mg/m³	0.6 mg/m³
C29	€ -	€ -	€ -
C30.3	€ -	€ -	€ -
C31	€ 1,353,773,818	€ 1,037,682,918	€ 1,064,729,892
E36	€ -	€ -	€ -
E38	€ -	€ -	€ -
F41	€ 120,058,890	€ 27,957,341	€ 27,957,341
M72	€ 24,728,712	€ 14,733,403	€ 9,166,100
M74.2	€ -	€ -	€ -
M75	€ -	€ -	€ -
P85.4	€ 178,764,671	€ 140,657,764	€ 83,908,385
Q86	€ 112,817,330,770	€ 697,250,597	€ 672,565,898
S96.0.3	€ 205,778,915	€ 101,318,698	€ 99,996,582
ALL SECTORS	€ 116,393,781,096	€ 2,722,385,872	€ 2,473,378,966

Source: Derived by the study team.

Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities.

Table A2-18: Formaldehyde: estimated OPEX costs (present value for 60 years) in € by target by sector			
Sector/ Target OELV	0.15 mg/m³	0.37 mg/m³	0.6 mg/m³
A	€ -	€ -	€ -
C10	€ -	€ -	€ -
C13	€ 251,018,950	€ 120,281,991	€ 120,281,991
C15	€ 63,691,279	€ 30,737,685	€ 30,737,685
C16	€ 11,733,731	-€ 9,093,777	€ -
C17	€ 477,447,697	€ 171,293,157	€ 171,293,157
C20	€ 114,456,295	€ 44,783,132	-€ 29,183,014
C21	€ -	€ -	€ -
C22	€ 7,852,499	€ -	€ -
C25	€ 55,099,406	€ -	€ -
C27	€ 147,389,143	€ -	€ -
C28	€ 3,991,010	€ -	€ -
C29	€ -	€ -	€ -

Table A2-18: Formaldehyde: estimated OPEX costs (present value for 60 years) in € by target by sector			
Sector/ Target OELV	**0.15 mg/m³**	**0.37 mg/m³**	**0.6 mg/m³**
C30.3	€ -	€ -	€ -
C31	€ 1,944,929,398	€ 1,095,092,790	€ 1,062,807,760
E36	€ -	€ -	€ -
E38	€ -	€ -	€ -
F41	€ 65,651,107	-€ 42,400,887	-€ 42,400,887
M72	€ 31,487,349	€ 13,757,686	€ 8,348,839
M74.2	€ -	€ -	€ -
M75	€ -	€ -	€ -
P85.4	€ 195,368,093	€ 191,711,775	€ 37,156,984
Q86	€ 196,715,113	€ 980,786,233	€ 728,171,182
S96.0.3	€ 260,674,744	€ 109,608,500	€ 94,803,267
ALL SECTORS	€ 3,827,505,814	€ 2,706,558,285	€ 2,182,016,964

Source: Derived by the study team.

Notes: A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities.

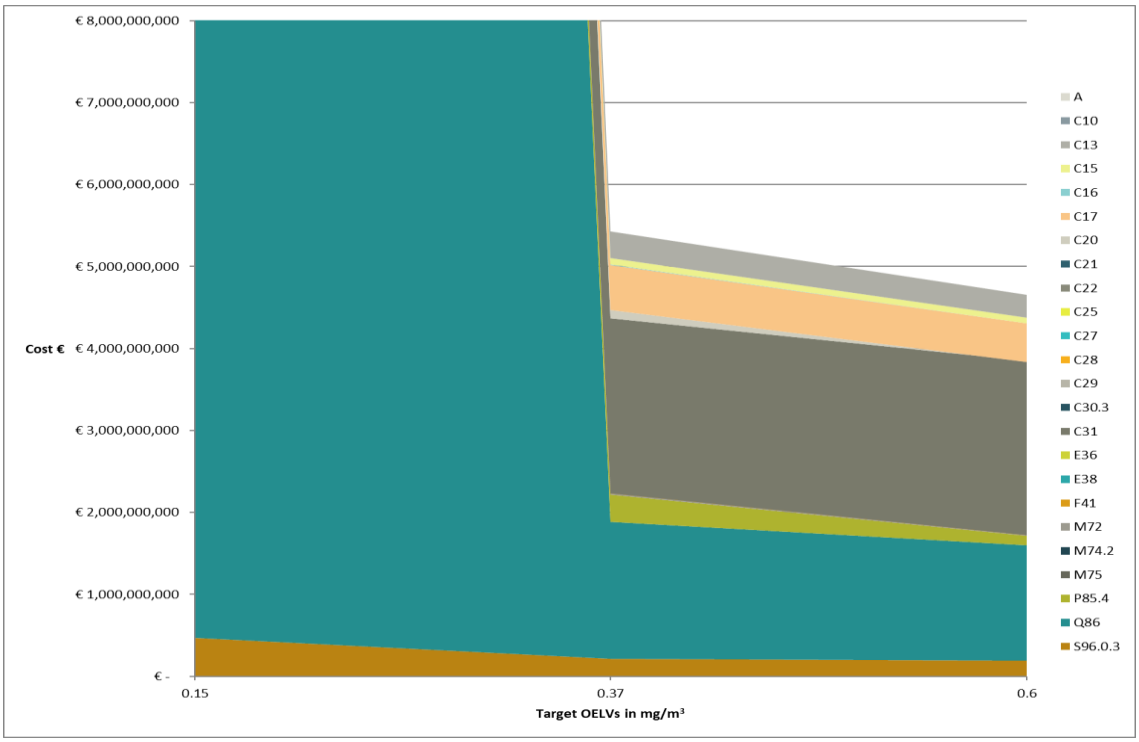

Figure A2-4: Share of TOTAL cost (present value at 60 years) in € split between sectors

Sectors:

A = Agriculture, Forestry and Fishing; C10 = Manufacturing of food products; C13 = Manufacture of textiles; C15 = Manufacture of leather and related products; C16 = Manufacture of wood and products of wood and cork - except furniture; C17 = Manufacture of paper and paper products; C20 = Manufacture of chemicals and chemical products; C21 = Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 = Manufacture of rubber and plastic products; C25 = Manufacture of fabricated metals, except machinery and equipment; C27 = Manufacture of electrical equipment; C28 = Manufacture of machinery and equipment; C29 = Manufacture of motor vehicles, trailers and semi-trailers; C30.3 = Manufacture of air and spacecraft and related machinery; C31 = Manufacture of furniture; E36 = Water collection, treatment and supply; E38 = Waste collection, treatment and disposal activities; materials recovery; F41 = Construction of buildings; M72 = Professional, Scientific and Technical Activities: Scientific research and development; M74.2 = Professional, Scientific and Technical Activities: Photographic activities; M75 = Professional, Scientific and Technical Activities: Veterinary activities; P85.4 = Higher education; Q86 = Human health and social work activities: Human health activities; S96.0.3 = Funeral and related activities.

Source: Derived by the study team.

A2.6.5 The total cost curve

The TOTAL cost (present value for 60 years), is shown for a range of target OELVs in Figure A2-5, for all 24 relevant sectors. This is based upon the numbers in Table A2-16 above.

Estimated costs

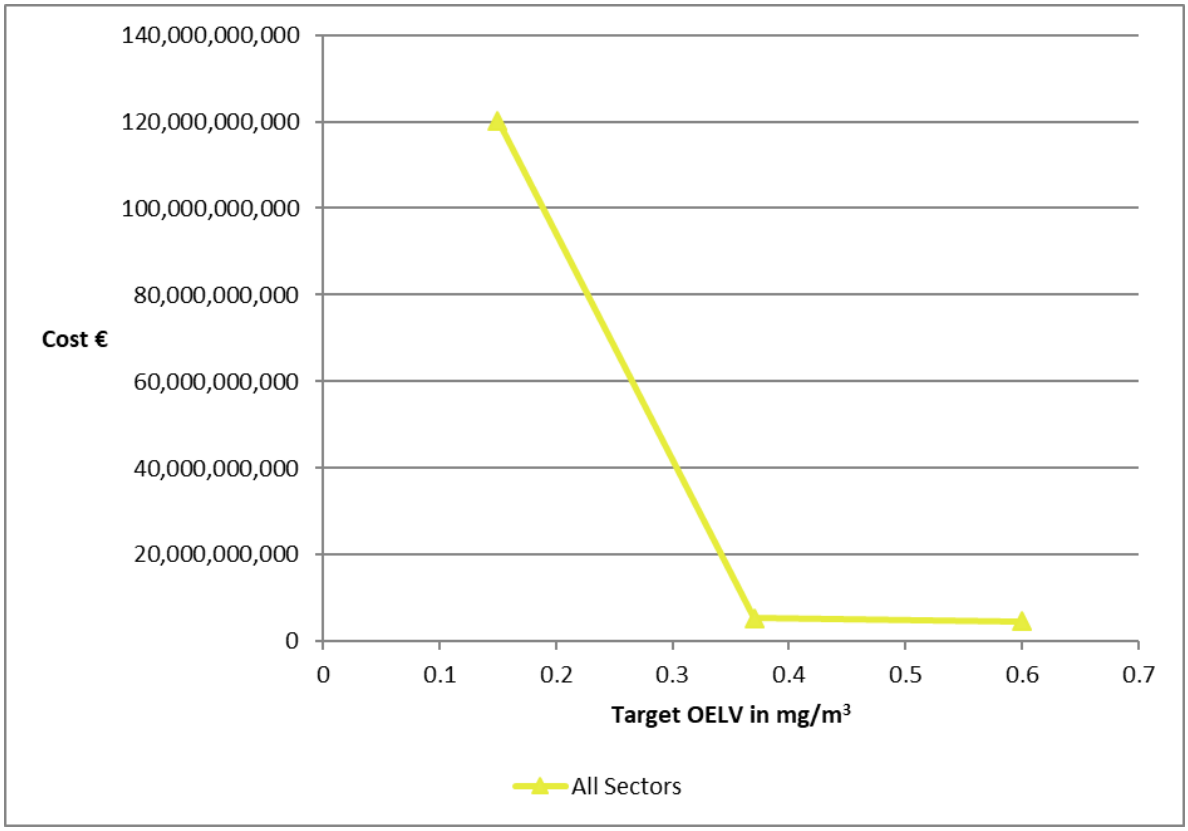

Figure A2-5: Estimated TOTAL costs (present value for 60 years) in € against target OELVs
Source: Derived by the study team.

A2.6.6 OELVs – indirect costs for companies

The assessment of indirect costs for companies is the same as the one presented in Section 5.4.

A2.6.7 OELVs – costs for public authorities and costs of transposition

The impacts on public authorities and costs arising from the need to transpose the relevant changes into national legislation are discussed in Sections 5.6.1 and 5.6.2.

A2.7 Summary of costs and benefits under Scenario 1

A2.7.1 Overview of the costs and benefits of the reference OELVs

The costs and benefits estimated in this report for the different reference OELVs are summarised in Table A2-19 and Table A2-20, respectively. For the purposes of this report, all benefits that accrue from reduced ill health are treated as direct benefits.

Table A2-19: Overview of the benefits		
Description	**Amount for 60 year with a static discount rate (PV)**	**Comments**
Direct benefits		
Direct benefits – NFC	0.6 mg/m3: €0 0.37 mg/m3: 459,000 0.15 mg/m3: 459,000	Healthcare, informal care, productivity loss, lost wages, employers, intangible benefits
Direct benefits – Sensory irritation	0.6 mg/m3: €0 0.37 mg/m3: 45,288,000 0.15 mg/m3: 45,288,000	
Indirect benefits		
None quantified		
Source: Derived by the study team.		

Table A2-20: Overview of the costs € (reference OELVs)							
Reference OELV	**Cost type**	**Workers**		**Businesses**		**Administrations**	
		CAPEX PV 60y €m	**OPEX PV 60y €m**	**CAPEX PV 60y €m**	**OPEX PV 60y €m**	**CAPEX PV 60y €m**	**OPEX PV 60y €m**
0.6 mg/m3	Direct	0	0	2,473	2,182	0.55	-
	Indirect	0	0	-	-	-	-
0.37 mg/m3	Direct	0	0	2,722	2,707	0.95	-
	Indirect	0	0	-	-	-	-
0.15 mg/m3	Direct	0	0	116,394	3,828	1.35	-
	Indirect	0	0	-	-	-	-

A2.7.2 CBA for the reference OELVs

The overall costs and benefits of establishing an OELV at the three different reference levels are shown in and Figure A2-.

Table A2-21: Summary of monetised costs and benefits (static discount rate)		
Reference OELV	**PV benefits over 60 years (€2017 million)**	**PV costs over 60 years (€2017 million)**
0.6 mg/m^3	0	4,655
0.37 mg/m^3	46	5,429
0.15 mg/m^3	46	120,221
Monetised costs and benefits	Avoided NFC and sensory irritation vis-à-vis the baseline	RMMs Discontinuation of business Transposition costs Measurements
Significant non-monetised costs and benefits	Simplification of rules for companies operating in several Member States	
Source: Derived by the study team.		

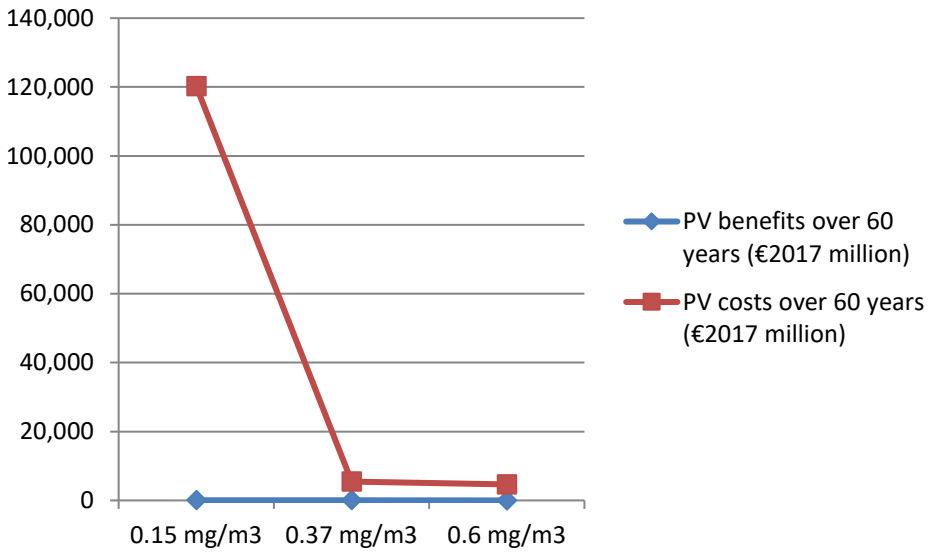

Figure A2-6: Costs/benefits of establishing an OELV for formaldehyde for all sectors in the EU. Present Value of all costs (CAPEX AND OPEX) vs the benefits over 60 years
Source: Derived by the study team.

The cost and benefit curves do not meet but significantly diverge at concentrations below 0.37mg/m^3 (0.3ppm).

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