



National Institute for Public Health  
and the Environment  
*Ministry of Health, Welfare and Sport*

## **Occupational Exposure Limits and classification of 25 carcinogens**

RIVM Letter Report 320002001/2012  
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RIVM Letter report 320002001/2012

## Colofon

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## Abstract

### **Occupational Exposure Limits and classification of 25 carcinogens**

Occupational Exposure Limits (OELs) help to control exposure to dangerous substances in the workplace by setting the maximum amount of (air) concentration of a substance that can safely be allowed. These OELs can be laid down at a European level, national level or by industry. The regulations and interpretations of data for determining an OEL may vary between agencies, allowing the existence of multiple values for one substance within Europe. Besides the determination of OELs, substances are classified in a hazard class (classification). Also for classification different systems and different criteria exist within Europe.

This letter report summarizes the OELs and carcinogenicity classification of 25 carcinogens. The data are obtained from the evaluations of the European Commission, the Scientific Committee on Occupational Exposure Limits (SCOEL), the International Agency for Research on Cancer (IARC), REACH<sup>1</sup> registrants, the Netherlands, Germany and France. In addition, the Institute of Medicine (IOM) has estimated the impact of introducing an OEL on public health, health costs, the economy, society and the environment in Europe. The conclusions of the IOM are included in the overview.

For each substance an overview of the current available data on OELs and carcinogenicity classes is given which allows a direct comparison between values or classifications.

Keywords: carcinogens, occupational exposure levels, classification, Europe

<sup>1</sup> REACH is the European Community Regulation on chemicals and their safe use (EC 1907/2006). It deals with the Registration, Evaluation, Authorisation and Restriction of Chemical substances.

## Rapport in het kort

### **Grenswaarden en classificatie van 25 kankerverwekkende stoffen**

Grenswaarden voor beroepsmatige blootstelling aan stoffen helpen de blootstelling aan gevaarlijke stoffen op de werkplek te beheersen door de maximale concentratie van een stof (in de lucht) vast te stellen die nog veilig wordt geacht. Deze grenswaarden kunnen worden vastgelegd op Europees niveau, op nationaal niveau of door bedrijven. De regelgeving en interpretaties van gegevens voor het bepalen van een grenswaarde kunnen verschillen tussen instanties, waardoor er voor één stof meerdere grenswaarden kunnen bestaan binnen Europa. Naast het bepalen van grenswaarden kunnen stoffen worden ingedeeld in categorieën op basis van hun mogelijk kankerverwekkende eigenschappen (classificatie met betrekking tot carcinogeniteit). Ook voor deze classificatie bestaan er binnen Europa verschillende systemen en verschillende criteria om een stof in te delen.

Dit briefrapport bevat een overzicht van de grenswaarden voor beroepsmatige blootstelling en de classificatie met betrekking tot de carcinogeniteit van 25 kankerverwekkende stoffen. De gegevens zijn overgenomen van de beoordelingen van de Europese Commissie, het Wetenschappelijk Comité inzake grenswaarden voor beroepsmatige blootstelling (SCOEL), het Internationaal Agentschap voor Kankeronderzoek (IARC), REACH<sup>2</sup> registranten, Nederland, Duitsland en Frankrijk. Daarnaast is door het 'Institute of Medicine' (IOM) een schatting gemaakt van de impact die de invoering van een grenswaarde heeft op de publieke gezondheid, de gezondheidskosten, de economie, de samenleving en het milieu in Europa. De conclusies van het IOM zijn meegenomen in het overzicht.

De overzichten met grenswaarden en classificaties geven voor elke stof de huidige beschikbare gegevens weer en maken het mogelijk om een directe vergelijking te maken tussen grenswaarden of classificaties.

Trefwoorden: kankerverwekkende stoffen, grenswaarden, classificatie, Europa

<sup>2</sup> REACH is de Europese communautaire verordening over chemische stoffen en het veilige gebruik ervan (EG 1907/2006). Het gaat over de registratie, evaluatie, toelating en beperkingen ten aanzien van chemische stoffen.

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## 1 Introduction

Occupational Exposure Limits (OELs) can be derived by different methods, which may result in a variety of OELs. This also accounts for the classification of carcinogens, which can be based on various classification systems with their own requirements to be met. To compare OELs and classification for carcinogens the Ministry of Social Affairs and Employment requested an overview of the current OELs and classification of 25 selected carcinogens. Data were obtained from IARC, EU, SCOEL, three EU member states (the Netherlands, Germany and France) and REACH registrant dossiers. Additionally, the possible impact of introducing an OEL on health, costs, society and the environment in the EU was obtained from IOM research reports.

The different classification systems and methods for derivation of an OEL are briefly explained in the methods section. Furthermore, it includes information about the consulted sources and the selection of data. In the results section the classifications and OELs are presented in tables, one for each substance. No further conclusions were drawn based on the presented data.

## 2 Methods

### 2.1 Classification for carcinogenicity

#### 2.1.1 IARC

The International Agency for Research on Cancer (IARC) is an intergovernmental agency forming part of the World Health Organisation of the United Nations. It maintains a series of monographs on the carcinogenic risks to humans posed by substances. The IARC distinguishes 5 classes for carcinogenicity:

- Group 1: Carcinogenic to humans
- Group 2A: Probably carcinogenic to humans
- Group 2B: Possibly carcinogenic to humans
- Group 3: Not classifiable as to its carcinogenicity to humans
- Group 4: Probably not carcinogenic to humans

Up-to-date classifications (last update at 17 June 2011) and the corresponding monographs presented in this document were obtained from the IARC list of classified agents (IARC, website).

#### 2.1.2 EU

The classifications of substances that have been harmonized at Community level and presented in this document are listed in Annex VI to CLP (EC, 2008). These classifications are legally binding within the European Union. Three classes are distinguished:

- CLP class 1A: known carcinogenic potential for humans
- CLP class 1B: presumed carcinogenic potential for humans
- CLP class 2: suspected human carcinogens.

According to EU classification several substances can be assigned a specific Note. The Notes observed for the substances evaluated in this document were Note A, D, E, R and U. Except for Note R, these notes are of an administrative type (correct labelling) and they are not included in the results tables. Note R refers to the definition of fibres and is included when it was assigned.

#### 2.1.3 SCOEL

The Scientific Committee on Occupational Exposure Limits (SCOEL) is an EU commission consisting of independent scientific experts. The SCOEL advises the European Commission on occupational exposure limits for chemicals in the workplace. To facilitate the setting of an OEL for mutagens and carcinogens, the SCOEL distinguishes four main groups of mutagens and carcinogens (SCOEL, 2009a):

- Group A: Non-threshold genotoxic carcinogens
- Group B: Genotoxic carcinogens, for which the existence of a threshold cannot be sufficiently supported
- Group C: Genotoxic carcinogens for which a practical threshold is supported
- Group D: Non-genotoxic carcinogens and non-DNA-reactive carcinogens, for which a true threshold is associated with a clearly funded NOAEL.

When a substance was explicitly classified into a SCOEL carcinogen group this was included in the results tables.



#### 2.1.4 REACH

REACH is the European Community Regulation on chemicals and their safe use (EC 1907/2006). It deals with the Registration, Evaluation, Authorisation and restriction of CHEMical substances. The law entered into force on 1 June 2007 to streamline and improve the former legislative framework for chemicals of the EU. The classification system as described for EU (CLP) applies also to classification by REACH registrants.

The publicly available information of REACH dossiers that are submitted by manufacturers and/or importers were used for the overview in this document and were obtained from the European Chemicals Agency (ECHA, website).

## 2.2 Occupational Exposure Limits (OELs)

An OEL is the maximum allowed concentration of a given substance in the air in the workplace. The OELs considered in this document are time-weighted averages measured over an 8-hour period (8h TWA); short-term exposure limits for a 15 min period are not included. The derivation of OELs by SCOEL, the Netherlands, Germany and France are described below. In the REACH legislation another system is utilized, describing the derivation of so-called DNELs and DMELs instead of an OEL. Finally, the involvement of the IOM is described. OELs that were expressed only in ppm were converted by the author using Chemiekaarten (Chemiekaarten, online), unless a conversion factor was given.

#### 2.2.1 SCOEL

The SCOEL can recommend two types of OELs (SCOEL, 2009a):

- 1). Health-based OELs, which are based on a clear threshold. This OEL is derived from a No Observed Adverse Effect Level (NOAEL) or a Lowest Observed Adverse Effect Level (LOAEL) and applied to carcinogens classified in group C or D (see above). The recommend OEL is clearly presented.
- 2). Risk-based OELs, which are based on effects without a threshold (i.e. genotoxicity) and which carry some finite risk. A risk-based OEL is applied to carcinogens that are classified in group A or B. It requires carcinogenic risk assessment in which a linear non-threshold model is used. The examined concentrations and the associated risks are presented, but no specific recommendation about the acceptability of a specific risk level is given.

#### 2.2.2 The Netherlands (NL)

Dutch OELs are recommended by the Dutch Health Council (GR). In principle, all OELs are health-based OELs, with the exception of OELs for carcinogenic and mutagenic substances for which no safe health-based OEL can be established. For these substances a risk level is applied. Two risk levels are used: a prohibitive risk level that prohibits an additional risk of cancer higher than  $10^{-4}$  per year ( $4 \cdot 10^{-3}$  during a 40-year working life) and a target risk level of an additional risk of  $10^{-6}$  per year ( $4 \cdot 10^{-5}$  during a 40-year working life), below which no additional protective measures need to be taken.

Risk-based limit values were obtained from the corresponding reports of the Dutch Health Council (GR). The current statutory OELs, as presented in this document, were obtained from the Social and Economic Council of the Netherlands (SER, website). The OEL currently in force is underlined.

### 2.2.3 *Germany (DE)*

Since 1-1-2005 a new system concerning OELs for carcinogenic substances is in force. This system involves the derivation of health-based OELs for substances for which a threshold effect is in effect. For carcinogens without a threshold currently no legally binding OELs exist. For these substances the risk-based target values will come into place. The following target levels for occupational exposure-related lifetime cancer risks were adopted (referring to a working lifetime of 40 years):

- Acceptable risk:
  - o  $4 \cdot 10^{-4}$  as interim limit,
  - o  $4 \cdot 10^{-5}$  as soon as possible but not later than 2018.

Above these limits a risk will be tolerated if the measures specified in the catalogue of measures are complied with.

- Tolerable risk:  $4 \cdot 10^{-3}$ , which may not be exceeded

The risk-based values should be taken into account by employers when performing a risk assessment, however, during the introductory phase they are not legally binding yet (legal basis expected to be established in 2015). OELs and risk-based concentrations presented in this document are obtained from the GESTIS database of international OELs (IFA, GESTIS) and from Announcement 910 "Risk figures and exposure-risk relationships in activities involving carcinogenic hazardous substances" (BAuA, 2011).

### 2.2.4 *France (FR)*

French OELs are derived for substances with and without a threshold. For carcinogens without a threshold, the derived OEL does not give an absolute protection against carcinogenic risks, but represents a low risk (i.e. an excess risk of developing cancer of  $10^{-4}$ ,  $10^{-5}$  or  $10^{-6}$ ) or is based on a technical feasibility when quantitative assessment is not possible (pragmatic OEL). The French OELs presented in this document were obtained from the list of OELs published by the French national institute for research and safety (INRS, 2008). The list does not indicate if the OEL is threshold-based or risk-based and also no risk levels are given.

### 2.2.5 *REACH*

Two types of effect levels can be derived by REACH registrants: derived no-effect levels (DNELs) for carcinogens with a threshold and derived minimal effect levels (DMELs) for carcinogens without a threshold. There is no EU legislation setting the 'tolerable' risk level for carcinogens, however, cancer risk levels of  $10^{-5}$  and  $10^{-6}$  could be seen as indicative tolerable risks levels when setting DMELs for workers. If it is not possible to identify a DNEL/DMEL, this shall be clearly stated and fully justified. DNELs or DMELs shall always be made public by the lead registrant (REACH regulation, Article 119). However, the derivation of a DNEL or DMEL is only required for substances manufactured/imported/used in quantities from 10 tonnes per year onwards that are classified (ECHA, 2010). Additionally, the data on which DNELs and DMELs are based differ between the tonnage levels and the use (e.g., intermediates).

For this assessment, public REACH registration dossiers were consulted via ECHA (EC, 2006) to obtain information about derived effect levels. Only DNELs and DMELs derived for workers for long-term exposures are considered in our document. For long-term exposures two values can be derived by the registrant

(systemic effects and local effects); in this document only the value for systemic effects is presented (unless mentioned otherwise). Values for exposure via inhalation and via dermal uptake are both presented. Risk levels associated with the DMELs were not available from the public dossiers.

*IOM*

The Institute of Occupational Medicine (IOM) performed a socioeconomic, health and economic assessment at EU level for 25 occupational carcinogens (SHEcan project, unpublished data), based on an OEL that was found typical in Europe. The OEL on which the assessment was based is presented in the results table and the conclusions of the impact assessment, obtained from the individual reports, are summarized in a corresponding footnote. The overall conclusions were obtained from the IOM summary report (IOM, 2011x). Costs are presented in millions (m) or billions (bn) euro.

### 3 Results

The 25 selected carcinogens for which an overview is given are listed below. The tables are presented from page 12 onward.

<b>Table #</b>	<b>Substance name</b>	<b>CAS #</b>
1	acrylamide	79-06-1
2	benzo[a]pyrene	50-32-8
3	beryllium	7440-41-7
4	1,3-butadiene	106-99-0
5	(refractory) ceramic fibres	-
6	chromium VI compounds	
7	1,2-dibromoethane	106-93-4
8	1,2-dichloroethane	107-06-2
9	diesel engine exhaust emissions:	-
10	epichlorohydrin	106-89-8
11	ethylene oxide	75-21-8
12	hexachlorobenzene	118-74-1
13	hydrazine	302-01-2
14	4,4'-methylene bis 2-choloraniline (MOCA)	101-14-4
15	4,4-methylenedianiline (MDA)	101-77-9
16	mineral oils	-
17	2-nitropropane	79-46-9
18	propylene oxide	75-56-9
19	respirable crystalline silica:	
	- quartz	14808-60-7
	- cristobalite	14464-46-1
	- tridymite	15468-32-3
20	rubber process fumes and dust	-
21	o-toluidine	95-53-4
22	trichloroethylene	79-01-6
23	vinyl bromide	593-60-2
24	vinyl chloride monomer	75-01-4
25	(hard)wood dust	-

Table 1. Acrylamide (CAS No. 79-06-1)						
Evaluation	Carcinogenicity	Occupational Exposure Limits				Reference
		4·10 <sup>-3</sup> (mg/m <sup>3</sup> )	4·10 <sup>-4</sup> (mg/m <sup>3</sup> )	4·10 <sup>-5</sup> (mg/m <sup>3</sup> )	Other (mg/m <sup>3</sup> )	
IARC/WHO	2A					IARC, 1994
EU	1B					EC, 2008
SCOEL	Group B				Not assigned <sup>a</sup>	SCOEL, 2009b (SUM/139)
NL	1B <sup>b</sup>	0.16 <sup>c</sup>		0.0016		SER, website; GR, 2006a (2006/05OSH); GR, 2002 (2002/02OSH)
DE		- <sup>d</sup>	0.07			BAuA, 2011
FR					0.3	INRS, 2008
IOM					0.03 <sup>e</sup>	IOM, 2011i
REACH	1B <sup>f</sup>				Inhalation: DMEL = 0.07 mg/m <sup>3</sup> ; Dermal: DMEL = 0.1 mg/kg bw/day	ECHA, website

<sup>a</sup> The SCOEL reports (in a draft report) that 'a reasonable quantitative cancer risk assessment for humans is not feasible for acrylamide, because of two reasons: (1) Human cancer studies do not provide reliable figures as a basis of a risk quantitation. (2) The cancers observed in rats (testicular mesotheliomas, mammary tumours, glial cell tumours, thyroid tumours, adrenal phaeochromocytomas) are significantly influenced by species-specific factors, which make meaningful quantitative extrapolations to humans almost impossible.'

<sup>b</sup> Classification by the Dutch Health Council according to report 2002/02OSH. The original classification as described in the report (class 2, according to Directive 67/548/EEC) was translated according to Annex VII of the CLP regulation (EC 1272/2008) in 1B. Acrylamide is considered genotoxic.

<sup>c</sup> Risk-based levels obtained from report 2006/05OSH. Acrylamide is listed on the work programme of the Health Council of the Netherlands.

<sup>d</sup> The OEL of 0.7 mg/m<sup>3</sup> (4·10<sup>-3</sup> risk level) is not established, since toxic effects other than carcinogenicity cannot be ruled out at this concentration (threshold value for neurotoxicity is 0.15 mg/m<sup>3</sup>).

<sup>e</sup> IOM conclusion based on OEL = 0.03 mg/m<sup>3</sup>: i. No expected additional health benefits, ii. Minimal economic costs given that exposure is already largely controlled, iii. No social, macroeconomic or environmental impacts expected. Overall IOM conclusion: no strong case for introducing an OEL (no/limited health impact).

<sup>f</sup> Acrylamide is on the Candidate List of Substances of Very High Concern for authorisation under REACH.

Evaluation	Carcinogenicity	Occupational Exposure Limits				Reference
		$4 \cdot 10^{-3}$ (mg/m <sup>3</sup> )	$4 \cdot 10^{-4}$ (mg/m <sup>3</sup> )	$4 \cdot 10^{-5}$ (mg/m <sup>3</sup> )	Other (mg/m <sup>3</sup> )	
<b>IARC/WHO</b>	1					IARC, 2012
<b>EU</b>	1B					EC, 2008
<b>SCOEL</b>	-				-	SCOEL, 2011d
<b>NL</b>		<u>0.00055</u> <sup>a</sup>		0.0000057		SER, website; GR, 2006b (2006/01OSH)
<b>DE</b>		0.0007 <sup>b</sup>	0.00007 <sup>b</sup>			BAuA, 2011
<b>FR</b>					-	INRS, 2008
<b>IOM</b>					0.002 <sup>c</sup>	IOM, 2011j
<b>REACH</b>	-				-	ECHA, website

<sup>a</sup> At the SER website this OEL is described as a private OEL. However, from the background documents it is made clear that this OEL is public. The OEL subcommittee of the Social and Economic Council of the Netherlands (SER) has planned (in 2011) to decrease the current OEL to 0.0002 mg/m<sup>3</sup> B[a]P (8-hour TWA) or as low as possible based on measurements, going into effect on July 1 2012.

<sup>b</sup> Benzo[a]pyrene as key component in defined PAH mixtures.

<sup>c</sup> IOM conclusion based on OEL = 0.002 mg/m<sup>3</sup>: i. No predicted health benefits, ii. No important costs, iii. No social or macro-economic costs. Overall IOM conclusion: there is a case for introducing an OEL.

Evaluation	Carcinogenicity	Occupational Exposure Limits				Reference
		4·10 <sup>-3</sup> (mg/m <sup>3</sup> )	4·10 <sup>-4</sup> (mg/m <sup>3</sup> )	4·10 <sup>-5</sup> (mg/m <sup>3</sup> )	Other (mg/m <sup>3</sup> )	
<b>IARC/WHO</b>	1					IARC, 2011
<b>EU</b>	1B					EC, 2008
<b>SCOEL</b>	-				-	SCOEL, 2011d
<b>NL</b>					- <sup>a</sup>	SER, website
<b>DE</b>					- (evaluation is planned/ongoing)	IFA, GESTIS
<b>FR</b>					0.002 <sup>b</sup>	INRS, 2008
<b>IOM</b>					0.002 <sup>c</sup>	IOM, 2011k
<b>REACH</b>	2 <sup>d</sup>				No DNEL/DMEL	ECHA, website

<sup>a</sup> Beryllium is listed on the work programme of the Health Council of the Netherlands.

<sup>b</sup> Unknown if OEL is threshold-based or risk level based. The OEL was re-evaluated by Affset in 2010 and an OEL of 0.01 µg/m<sup>3</sup> was recommended, based on a LOAEC for sensitization. Further evaluation of introducing this OEL is ongoing (ANSES, website).

<sup>c</sup> IOM conclusions based on OEL = 0.002 mg/m<sup>3</sup>: i. The total net health benefits are estimated to be between €11m and €30m, ii. Total costs over the period 2010-2069 (Net Present Value) are estimated to be between €5bn and €34bn, iii. The costs of compliance with the OEL will disproportionately affect small and medium sized enterprises and closure or cease of the use of beryllium-containing components is possible. There are no significant environmental impacts foreseen. Overall IOM conclusion: no strong case for introducing an OEL (no/limited health impact).

<sup>d</sup> Based on self-classification, differs from EU classification. The registrant remarks that, based on the results of the data generated to comply with the REACH requirements and all available data which are relevant for the hazard assessment of beryllium, the Substance Information Exchange Forum (SIEF) of beryllium concluded that the classification of beryllium (REACH legislation, Annex VI) has to be changed.

<b>Table 4. 1,3-butadiene (= vinyl ethylene) (CAS No. 106-99-0)</b>						
<b>Evaluation</b>	<b>Carcinogenicity</b>	<b>Occupational Exposure Limits</b>				<b>Reference</b>
		<b>4·10<sup>-3</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-4</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-5</sup> (mg/m<sup>3</sup>)</b>	<b>Other (mg/m<sup>3</sup>)</b>	
<b>IARC/WHO</b>	1					IARC, 2012
<b>EU</b>	1A					EC, 2008
<b>SCOEL</b>					No recommended OEL <sup>a</sup>	SCOEL, 2007 (SUM/75)
<b>NL</b>		47.4		0.47	Current OEL = <u>46.2</u> <sup>b,c</sup>	SER, website; GR, 1990 (RA 5/90)
<b>DE</b>		5	0.5			IFA, GESTIS
<b>FR</b>					-	INRS, 2008
<b>IOM</b>					[1.1, 2.3 or 11.3] <sup>d</sup>	IOM, 2011e
<b>REACH</b>	1A				Inhalation: DMEL = 2.21 mg/m <sup>3</sup> ; Dermal: no data available, testing technically not feasible	ECHA, website

<sup>a</sup> Non-threshold based mechanism. SCOEL agrees with IARC that 1,3-butadiene should be treated as a possible human carcinogen, operating via a genotoxic mechanism. The excess risk entailed in exposure during a working life to 0.2, 0.5, 1.1, 2.3, 4.5 11.3 and 22.5 mg/m<sup>3</sup> (original values of 0.1, 0.2, 0.5, 1, 2, 5 and 10 ppm converted by author) of butadiene was calculated, resulting in 0 – 7.64 (0.2, 0.5, 1.1 mg/m<sup>3</sup>), 0 – 10.78 (2.3 mg/m<sup>3</sup>), 0 – 9.88 (4.5 mg/m<sup>3</sup>), 0 – 11.67 (11.3 mg/m<sup>3</sup>) and 1.73 – 21.45 (22.5 mg/m<sup>3</sup>) excess leukaemia deaths for a population of 1000 adult males.

<sup>b</sup> 1,3-Butadiene is listed on the work programme of the Health Council of the Netherlands.

<sup>c</sup> The current OEL, obtained from the SER, differs from the original OEL of 47.4 as published in report RA 5/90. This is probably due to the conversion from mg/m<sup>3</sup> to ppm and from ppm to mg/m<sup>3</sup> back again.

<sup>d</sup> IOM conclusions based on OEL = 1.1, 2.3 or 11.3 mg/m<sup>3</sup> (original values of 0.5, 1 and 5 ppm converted by author): i. There are no net health benefits, ii. The total compliance costs aggregated over the period 2010 to 2069 range from between €2m to €7m for an OEL of 11.3 mg/m<sup>3</sup> to €27 to €100m for an OEL of 1.1 mg/m<sup>3</sup>. No plant closures are foreseen as a consequence of introducing an OEL, iii. No macro-economic impacts and no increased environmental harm is assumed. Overall IOM conclusion: no strong case for introducing an OEL (no/limited health impact).



<b>Table 5. (refractory) Ceramic fibres (= aluminosilicate fibres)</b>						
<b>Evaluation</b>	<b>Carcinogenicity</b>	<b>Occupational Exposure Limits</b>				<b>Reference</b>
		<b>4·10<sup>-3</sup></b>	<b>4·10<sup>-4</sup></b>	<b>4·10<sup>-5</sup></b>	<b>Other</b>	
<b>IARC/WHO</b>	2B					IARC, 2002
<b>EU</b>	1B <sup>a</sup>					EC, 2008
<b>SCOEL</b>	D				0.3 fibres/ml <sup>b</sup>	SCOEL, 2010d (SUM/165)
<b>NL</b>	1B <sup>c</sup>	5.6 fibres/cm <sup>3</sup>		0.056 fibres/cm <sup>3</sup>	Current OEL: <u>0.5</u> fibres/cm <sup>3</sup> <sup>d</sup>	SER, website; GR, 1995 (1995/02 WGD); GR, 2011c (2011/29)
<b>DE</b>		0.1 fibres/cm <sup>3</sup> <sup>e</sup>	0.01 fibres/cm <sup>3</sup> <sup>e</sup>		-	BAuA, 2011
<b>FR</b>					0.1 fibres/cm <sup>3</sup> <sup>f</sup>	INRS, 2008
<b>IOM</b>					0.1 or 1 fibres/ml <sup>g</sup>	IOM, 2011u
<b>REACH</b>	- <sup>h</sup>				-	ECHA, website

<sup>a</sup> Assigned Note R: the classification as a carcinogen need not apply to fibres with a length weighted geometric mean diameter less two standard geometric errors greater than 6 µm.

<sup>b</sup> Threshold-based OEL. The OEL was derived from NOAELs from a human study.

<sup>c</sup> Classification by the Dutch Health Council, according to regulation 1272/2008 of the European Union (CLP classification). Carcinogenic effect is considered threshold-based (critical effect is the induction of chronic inflammation) (report 2011/29).

<sup>d</sup> Current OEL, as decided by SER, is based on the former assumption of a genotoxic mechanism (linear relationship, OEL based on risk levels) and on feasibility of the recommended risk-based OELs described in report 1995/02 WGD.

<sup>e</sup> Aluminosilicate (ceramic) fibres.

<sup>f</sup> Risk-based OEL, related to an excess risk of lung cancer of 5·10<sup>-4</sup> per year (ANSES, website).

<sup>g</sup> IOM conclusions based on OEL = 0.1 or 1 fibres/ml: i. Health benefits are expected to be minimal for both OELs, ii. Compliance costs for OEL = 0.1 fibres/ml are expected to be €60 to €140 million for controlling and €2.5 billion for substitution with alternatives, iii. No expected important social, macro-economic or environmental impacts with an OEL at 1.0 fibres/ml. Introduction of OEL = 0.1 fibres/ml could lead to some relocation of activities to outside the EU, with associated loss of employment. Overall IOM conclusion: no strong case for introducing an OEL (no/limited health impact).

<sup>h</sup> A sub-set of refractory ceramic fibres is on the Candidate List of Substances of Very High Concern for authorisation under REACH (<http://echa.europa.eu/web/guest/candidate-list-table>).

Table 6. Chromium VI compounds (= hexavalent chromium) <sup>a</sup>						
Evaluation	Carcinogenicity	Occupational Exposure Limits				Reference
		4·10 <sup>-3</sup> (mg/m <sup>3</sup> )	4·10 <sup>-4</sup> (mg/m <sup>3</sup> )	4·10 <sup>-5</sup> (mg/m <sup>3</sup> )	Other (mg/m <sup>3</sup> )	
IARC/WHO	1					IARC, 2011
EU	1A / 1B <sup>b</sup>					EC, 2008
SCOEL	-				Not assigned <sup>c</sup>	SCOEL, 2004c (SUM/86)
NL		0.002		0.00002	Current OEL: <u>0.025</u> <sup>d</sup>	SER, website; GR, 1998a (1998/01 WGD(R))
DE					- (evaluation ongoing)	IFA, GESTIS
FR					0.05 <sup>e</sup>	INRS, 2008
IOM					0.025, 0.05 or 0.1 <sup>f</sup>	IOM, 2011q
REACH	1A / 1B <sup>g,h</sup>				Inhalation: DMEL <sub>local effects</sub> = 0.5 µg/m <sup>3</sup> , 6 µg/m <sup>3</sup> and 0.01 mg/m <sup>3</sup> <sup>i</sup>	ECHA, website

<sup>a</sup> Hexavalent chromium encompasses various chromium-containing substances. An indicative list of these specific substances is presented in IARC monograph 100C (2011). Hexavalent chromium was evaluated as a group, unless mentioned otherwise.

<sup>b</sup> Classification of chromium trioxide, zinc chromates and zinc potassium chromates: Carc. 1A. Classification of chromium (VI) compounds, with the exception of barium chromate and of compounds specified elsewhere in Annex VI: Carc. 1B

<sup>c</sup> Risk-based approach. Hexavalent chromium is considered a genotoxic carcinogen without a threshold. A pragmatic approach may be appropriate; adequate protection may be provided at a working lifetime exposure limit of 0.01, 0.025 or 0.05 mg/m<sup>3</sup> with corresponding excess lung cancers of 1-6, 2-14 and 5-28 in a population of 1000 male workers. Lead chromate was evaluated separately and described in SCOEL report SUM 117 (SCOEL, 2004b). It was concluded that the risk for lead chromate-induced lung tumours must be distinctly lower than that calculated for other chromates in general. An OEL of 100 µg Pb/m<sup>3</sup> ambient air for lead chromate was recommended, based on the derived OEL for inorganic lead compounds in general.

<sup>d</sup> The recommended risk-based values of 0.002 and 0.00002 mg/m<sup>3</sup> are obtained from report 1998/01 WGD(R). The current OEL of 0.025 mg/m<sup>3</sup> is based on feasibility, as decided by SER (an OEL of 0.002 was considered not feasible).

<sup>e</sup> An OEL of 0.001 mg/m<sup>3</sup> will come into force in 2012, update expected in February 2012 (personal communication with ANSES).

<sup>f</sup> IOM conclusions based on OEL = 0.025, 0.05 or 0.1 mg/m<sup>3</sup>: i. Expected reduction of cancer registrations for all OELs. The total health benefits are €157m - €445m (OEL of 0.1 mg/m<sup>3</sup>), €339m - €966m (OEL of 0.05 mg/m<sup>3</sup>) and €453m - €1,294m (OEL of 0.025 mg/m<sup>3</sup>) ii. The proportion of enterprises that requires additional control measures to meet the OELs of 0.025, 0.05 and 0.1 mg/m<sup>3</sup> is expected to be 27, 16 and 9 %

respectively, with compliance costs over 50 years that are estimated to be € 30 bn - € 115 bn, € 18bn - € 67bn and € 7bn - € 37 bn respectively, iii. Small firms are expected to be disproportionately affected, possibly leading to closure or ceasing to use hexavalent chromium containing components. There are no significant environmental impacts foreseen. Overall IOM conclusion: strong case for introducing an OEL.

<sup>g</sup> Chromium VI compounds were registered per compound:

- Carc 1A: chromium trioxide and zinc potassium chromate. Strontium chromate was classified as 1A, wrongly referring to the EU CLP regulation.

- Carc 1B: ammonium dichromate, lead sulfochromate yellow (lead chromate), lead chromate molybdate sulfate red (molybdenum orange), potassium chromate, potassium dichromate, sodium chromate, sodium dichromate

<sup>h</sup> The chromium VI compounds ammonium dichromate, chromium trioxide, potassium chromate, potassium dichromate, sodium chromate, sodium dichromate and acids generated from chromium trioxide and their oligomers are on the Candidate List of Substances of Very High Concern for authorisation under REACH and are included in the third Annex XIV recommendation of ECHA of 20 December 2011 for inclusion of substances in the Authorisation List (EC 1907/2006, Annex XIV).

<sup>i</sup> Chromium VI compounds were registered per compound:

- Strontium chromate and zinc potassium chromate: DMEL (local effects) = 0.5 µg/m<sup>3</sup>

- Lead sulfochromate yellow (lead chromate) and lead chromate molybdate sulfate red (molybdenum orange): DMEL = 6 µg/m<sup>3</sup>

- Chromium trioxide, potassium chromate, potassium dichromate, sodium chromate and sodium dichromate: DMEL (local effects) = 0.01 mg/m<sup>3</sup>

<b>Table 7. 1,2-dibromoethane (= ethylene dibromide) (CAS No. 106-93-4)</b>						
<b>Evaluation</b>	<b>Carcinogenicity</b>	<b>Occupational Exposure Limits</b>				<b>Reference</b>
		<b>4·10<sup>-3</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-4</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-5</sup> (mg/m<sup>3</sup>)</b>	<b>Other (mg/m<sup>3</sup>)</b>	
<b>IARC/WHO</b>	2A					IARC, 1999
<b>EU</b>	1B					EC, 2008
<b>SCOEL</b>	Group A				Not assigned <sup>a</sup>	SCOEL, 2011a (SUM/166)
<b>NL</b>		0.2		<u>0.002</u>		SER, website; GR, 1999a (1999/07OSH)
<b>DE</b>					-	IFA, GESTIS
<b>FR</b>					-	INRS, 2008
<b>IOM</b>					0.8 <sup>b</sup>	IOM, 2011b
<b>REACH</b>	1B				Inhalation: DMEL = 0.0005 mg/m <sup>3</sup> ; Dermal: DMEL = 0.01 mg/kg bw/day	ECHA, website

<sup>a</sup> Risk-based approach. The quantitative data on carcinogenicity and the present state of toxicokinetic interspecies modelling do not permit a reasonable and reliable quantitative cancer risk assessment for humans at the present time. It is therefore recommended that occupational contact with 1,2-dibromoethane should be avoided. It is noted that experimentally the carcinogenicity is already clear-cut at airborne concentrations of 77 mg/m<sup>3</sup> (original value of 10 ppm converted by author using conversion factor as mentioned in SCOEL document) and that lower concentrations have not been tested.

<sup>b</sup> IOM conclusions based on OEL = 0.8 mg/m<sup>3</sup>: i. There are no predicted health benefits, ii. The cost (over a period of 2010 to 2069) is judged to be between €0.086m and €0.29m, iii. There are no social or macro-economic costs or environmental impacts foreseen. Overall IOM conclusion: insufficient justification for introducing an OEL (uncertainty occupational cancer risk).

<b>Table 8. 1,2-dichloroethane (CAS No. 107-06-2)</b>						
<b>Evaluation</b>	<b>Carcinogenicity</b>	<b>Occupational Exposure Limits</b>				<b>Reference</b>
		<b>4·10<sup>-3</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-4</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-5</sup> (mg/m<sup>3</sup>)</b>	<b>Other (mg/m<sup>3</sup>)</b>	
<b>IARC/WHO</b>	2B					IARC, 1999
<b>EU</b>	1B					EC, 2008
<b>SCOEL</b>	-				-	SCOEL, 2011d
<b>NL</b>		Z <sup>a</sup>		0.07		SER, website; GR, 1997a (1997/01 WGD)
<b>DE</b>					- (evaluation is planned/ongoing)	IFA, GESTIS
<b>FR</b>					40	INRS, 2008
<b>IOM</b>					4 or 20 <sup>b</sup>	IOM, 2011c
<b>REACH</b>	1B <sup>c</sup>				Inhalation: DMEL = 6.6 mg/m <sup>3</sup> ; Dermal: DMEL = 62.4 mg/kg bw/day	ECHA, website

<sup>a</sup> 1,2-dichloroethane is listed on the work programme of the Health Council of the Netherlands.

<sup>b</sup> IOM conclusions based on OEL = 4 or 20 mg/m<sup>3</sup>: i. Not possible to undertake a health impact assessment (limited data), but also no important health risk expected, ii. Cost of compliance over 50 years with a limit of 4 mg/m<sup>3</sup> is judged to be between zero and €43m and for a limit of 20 mg/m<sup>3</sup> between zero and €13m, iii. No social, macro-economic costs or environmental impact associated with introducing an OEL. Overall IOM conclusion: insufficient justification for introducing an OEL (uncertainty occupational cancer risk).

<sup>c</sup> 1,2-Dichloroethane is on the Candidate List of Substances of Very High Concern for authorisation under REACH.

<b>Table 9. Diesel engine exhaust</b>						
<b>Evaluation</b>	<b>Carcinogenicity</b>	<b>Occupational Exposure Limits</b>				<b>Reference</b>
		<b>4·10<sup>-3</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-4</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-5</sup> (mg/m<sup>3</sup>)</b>	<b>Other (mg/m<sup>3</sup>)</b>	
<b>IARC/WHO</b>	2A					IARC, 1989
<b>EU</b>	-					EC, 2008
<b>SCOEL</b>	-				-	SCOEL, 2011d
<b>NL</b>					- <sup>a</sup>	SER, website
<b>DE</b>					- (evaluation ongoing)	IFA, GESTIS
<b>FR</b>					-	INRS, 2008
<b>IOM</b>					0.1 <sup>b</sup>	IOM, 2011m
<b>REACH</b>	-				-	ECHA, website

<sup>a</sup> Diesel engine exhaust is listed on the work programme of the Health Council of the Netherlands.

<sup>b</sup> IOM conclusions based on an OEL = 0.1 mg/m<sup>3</sup>: i. No predicted health benefits. To have impact, the OEL would need to be much lower than 0.1 mg/m<sup>3</sup>, ii. No predicted important costs, iii. No social, macro-economic or environmental impact expected. Overall IOM conclusion: there is a case for introducing an OEL, but this OEL would need to be lower than 0.1 mg/m<sup>3</sup>.

Evaluation	Carcinogenicity	Occupational Exposure Limits				Reference
		$4 \cdot 10^{-3}$ (mg/m <sup>3</sup> )	$4 \cdot 10^{-4}$ (mg/m <sup>3</sup> )	$4 \cdot 10^{-5}$ (mg/m <sup>3</sup> )	Other (mg/m <sup>3</sup> )	
<b>IARC/WHO</b>	2A					IARC, 1999
<b>EU</b>	1B					EC, 2008
<b>SCOEL</b>	Group A				Not assigned <sup>a</sup>	SCOEL, 2009c (SUM/169)
<b>NL</b>		19		<u>0.19</u> <sup>b</sup>		SER, website; GR, 2000c (2000/10OSH); Ministry of Social Affairs and Employment, 2010
<b>DE</b>					- (evaluation ongoing)	IFA, GESTIS
<b>FR</b>					-	INRS, 2008
<b>IOM</b>					1.9 <sup>c</sup>	IOM, 2011a
<b>REACH</b>	1B				Inhalation: DNEL = 1.52 mg/m <sup>3</sup> <sup>d</sup>	ECHA, website

<sup>a</sup> The SCOEL reports (in a draft report) that epichlorohydrin is categorized as a non-threshold carcinogen (group A) and accordingly the derivation of a health-based OEL is not possible. SCOEL strongly recommends avoiding any occupational exposure. A recommendation for biological monitoring cannot be given due to lack of data.

<sup>b</sup> The OEL was lowered from 1.9 mg/m<sup>3</sup> to 0.19 mg/m<sup>3</sup> since 1-1-2011 (Ministry of Social Affairs and Employment, 2010). The risk-based OELs were derived in report 2000/10OSH.

<sup>c</sup> IOM conclusions based on OEL = 1.9 mg/m<sup>3</sup>: i. No predicted health benefits, ii. No important costs associated with compliance with the suggested OEL, iii. No social or macro-economic costs or environmental impacts expected. General note: current exposures in the EU are judged to be already well below 1.9 mg/m<sup>3</sup>. Overall IOM conclusion: there is a limited case for introducing an OEL.

<sup>d</sup> The registrant has derived a DNEL for long-term exposure, which is threshold-based. According to SCOEL and NL, the OEL for epichlorohydrin is considered non-threshold based.

<b>Table 11. Ethylene oxide (CAS No. 75-21-8) (Synonym: epoxyethane)</b>						
<b>Evaluation</b>	<b>Carcinogenicity</b>	<b>Occupational Exposure Limits</b>				<b>Reference</b>
		<b>4·10<sup>-3</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-4</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-5</sup> (mg/m<sup>3</sup>)</b>	<b>Other (mg/m<sup>3</sup>)</b>	
<b>IARC/WHO</b>	1					IARC, 2012
<b>EU</b>	1B					EC, 2008
<b>SCOEL</b>	Group B				Not assigned <sup>a</sup>	SCOEL, 2011c (SUM/160)
<b>NL</b>		<u>0.84</u> <sup>b</sup>		0.008		SER, website; GR, 1989 (RA 6/89)
<b>DE</b>		2	0.2		-	BAuA, 2011
<b>FR</b>					[1.8] <sup>c</sup>	INRS, 2008
<b>IOM</b>					1.8 <sup>d</sup>	IOM, 2011n
<b>REACH</b>	1B				Inhalation: DMEL = 1.6 mg/m <sup>3</sup> ; Dermal: no-threshold effect and/or no dose-response information available	ECHA, website

<sup>a</sup> The SCOEL reports (in a draft report) that, although a non-linear dose-response relationship can reasonably be assumed based on arguments of mode of action, a definite no-effect level based on dose-response data cannot be defined. Quantitative cancer risk assessment is required (preferably based on biological monitoring). Six risk-based OELs (for a working lifetime) were calculated, including an extra risk for lymphoid cancer mortality of  $4 \times 10^{-3}$  for 39 mg/m<sup>3</sup> ethylene oxide,  $4 \times 10^{-4}$  for 5 mg/m<sup>3</sup> and  $4 \times 10^{-5}$  for 0.5 mg/m<sup>3</sup> (original values of 21.35, 2.77 and 0.268 ppm converted by author using conversion factor as mentioned in SCOEL document).

<sup>b</sup> Ethylene oxide is listed on the work programme of the Health Council of the Netherlands.

<sup>c</sup> Original value of 1 ppm converted by author.

<sup>d</sup> IOM conclusions based on OEL = 1.8 mg/m<sup>3</sup>: i. No health benefits expected, ii. No additional costs expected to comply with an OEL of 1.8 mg/m<sup>3</sup> (employers are already in full compliance with this limit), iii. No important social, macro-economic or environmental impacts expected. Overall IOM conclusion: no strong case for introducing an OEL (no/limited health impact).



<b>Table 12. Hexachlorobenzene (=perchlorobenzene) (CAS No. 118-74-1)</b>						
<b>Evaluation</b>	<b>Carcinogenicity</b>	<b>Occupational Exposure Limits</b>				<b>Reference</b>
		<b>4·10<sup>-3</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-4</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-5</sup> (mg/m<sup>3</sup>)</b>	<b>Other (mg/m<sup>3</sup>)</b>	
<b>IARC/WHO</b>	2B					IARC, 2001
<b>EU</b>	1B					EC, 2008
<b>SCOEL</b>	-				-	SCOEL, 2011d
<b>NL</b>	1B <sup>a</sup>				0.03 <sup>b</sup>	SER, website; GR, 1988 (RA 2/88); GR, 2011b (2011/35)
<b>DE</b>					-	IFA, GESTIS
<b>FR</b>					-	INRS, 2008
<b>IOM</b>					0.002 or 0.025 <sup>c</sup>	IOM, 2011p
<b>REACH</b>	-				-	ECHA, website

<sup>a</sup> Classification by the Dutch Health Council, according to regulation 1272/2008 of the European Union (CLP classification) (report 2011/35).

<sup>b</sup> The OEL of 0.03 mg/m<sup>3</sup> is threshold-based and derived based on a NOAEL in pigs where no increased porphyrin levels were observed. A private OEL of 0.006 mg/m<sup>3</sup> was derived in 2011 (report 2011/35). This OEL is threshold-based, based on the reproductive effects in a 90-days study with monkeys.

<sup>c</sup> IOM conclusion based on 0.002 or 0.025 mg/m<sup>3</sup>: i. No health impact expected, ii. No additional costs due to compliance with the OELs, iii. No important social, macro-economic or environmental impacts expected. Note: it is currently unlikely that there are any workers in the EU exposed to hexachlorobenzene above the OELs of 0.002 and 0.025 mg/m<sup>3</sup>. Overall IOM conclusion: insufficient justification for introducing an OEL (uncertainty occupational cancer risk)

<b>Table 13. Hydrazine (CAS No. 302-01-2)</b>						
<b>Evaluation</b>	<b>Carcinogenicity</b>	<b>Occupational Exposure Limits</b>				<b>Reference</b>
		<b>4·10<sup>-3</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-4</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-5</sup> (mg/m<sup>3</sup>)</b>	<b>Other (mg/m<sup>3</sup>)</b>	
<b>IARC/WHO</b>	2B					IARC, 1999
<b>EU</b>	1B					EC, 2008
<b>SCOEL</b>	Group B				Not assigned <sup>a</sup>	SCOEL, 2010b (SUM/164)
<b>NL</b>					- <sup>b</sup>	SER, website
<b>DE</b>					- (evaluation ongoing)	IFA, GESTIS
<b>FR</b>					0.1	INRS, 2008
<b>IOM</b>					0.013 o 0.13 <sup>c</sup>	IOM, 2011r
<b>REACH</b>	1B <sup>d</sup>				Inhalation: Insufficient data available, testing proposed; Dermal: DNEL = 0.006 mg/kg bw/day	ECHA, website

<sup>a</sup> The SCOEL reports that the genotoxicity of hydrazine may be characterized by a threshold, however, specific mode-of-action data and toxicokinetic data about the critical target (respiratory tract) are lacking and there are considerable species differences. The derivation of a health-based OEL or a reasonable quantitative risk assessment is not possible at the present time. A recommendation for biological monitoring cannot be given.

<sup>b</sup> Hydrazine is listed on the work programme of the Health Council of the Netherlands.

<sup>c</sup> IOM conclusions based on 0.013 or 0.13 mg/m<sup>3</sup>: i. No or very small health benefits expected, ii. Costs of compliance with the higher suggested OEL range from €15m to €47m and for the lower OEL from €62 to €196m, iii. No important social, macro-economic or environmental impacts expected. Overall IOM conclusion: there is a limited case for introducing an OEL.

<sup>d</sup> Hydrazine is on the Candidate List of Substances of Very High Concern for authorisation under REACH.

<b>Table 14. 4,4'-Methylene bis 2-choloraniline (MOCA) (=2,2'-dichloro-4,4'-methylenedianiline) (CAS No. 101-14-4)</b>						
<b>Evaluation</b>	<b>Carcinogenicity</b>	<b>Occupational Exposure Limits</b>				<b>Reference</b>
		<b>4·10<sup>-3</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-4</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-5</sup> (mg/m<sup>3</sup>)</b>	<b>Other (mg/m<sup>3</sup>)</b>	
<b>IARC/WHO</b>	1					IARC, 2012
<b>EU</b>	1B					EC, 2008
<b>SCOEL</b>	Group A				not feasible to derive a health-based limit <sup>a</sup>	SCOEL, 2010a (SUM/174)
<b>NL</b>		2		<u>0.02</u>		SER, website; GR, 2000a (2000/09OSH)
<b>DE</b>					-	IFA, GESTIS
<b>FR</b>					0.22	INRS, 2008
<b>IOM</b>					5 or 15 µmol/mol <sup>b,c</sup>	IOM, 2011h
<b>REACH</b>	1B <sup>d</sup>				Inhalation: DMEL = 0.000776 mg/m <sup>3</sup> ; Dermal: DMEL = 0.00445 mg/kg bw/day	ECHA, website

<sup>a</sup> The SCOEL reports that MOCA is categorized as a genotoxic carcinogen to which a threshold cannot be assigned. Therefore, a health-based OEL cannot be assigned. Biological monitoring should be considered.

<sup>b</sup> It was suggested that a biological monitoring limit, rather than an OEL be used as relevant and "typical" limit as a practical tool to assess compliance and that the limit measured in urine samples should be either 5 or 15 µmol/mol (broadly equivalent to a an exposure limit of 0.1 mg/m<sup>3</sup>).

<sup>c</sup> IOM conclusions based on biological monitoring limit = 5 or 15 µmol/mol: i. Limited impact cancer incidence (current incidence already low). The health benefits over the period 2010 to 2069 are expected to be between €1m and €7m for the 15 µmol/mol limit and between €1m and €11m for the 5 µmol/mol limit, ii. Cost of compliance over 50 years is estimated as €564m - €1,129m for the higher limit and €1,482m - €2,964m for the lower limit, iii. No expected important social, macro-economic or environmental impacts. Overall IOM conclusion: no strong case for introducing an OEL (no/limited health impact).

<sup>d</sup> MOCA is on the Candidate List of Substances of Very High Concern for authorisation under REACH.

Evaluation	Carcinogenicity	Occupational Exposure Limits				Reference
		4·10 <sup>-3</sup> (mg/m <sup>3</sup> )	4·10 <sup>-4</sup> (mg/m <sup>3</sup> )	4·10 <sup>-5</sup> (mg/m <sup>3</sup> )	Other (mg/m <sup>3</sup> )	
<b>IARC/WHO</b>	2B					IARC, 1987a
<b>EU</b>	1B					EC, 2008
<b>SCOEL</b>					not feasible to derive a health-based limit <sup>a</sup>	SCOEL, 2004a (SUM/107)
<b>NL</b>		0.9		0.009 <sup>b</sup>		SER, website; GR, 2000b (2000/11OSH); Ministry of Social Affairs and Employment, 2010
<b>DE</b>		0.7	0.07			IFA, GESTIS
<b>FR</b>					-	INRS, 2008
<b>IOM</b>					0.08 and 0.8 <sup>c</sup>	IOM, 2011g
<b>REACH</b>	1B <sup>d</sup>				Inhalation: DMEL = 0.0148 mg/m <sup>3</sup> ; Dermal: DMEL = 0.0042 mg/kg bw/day	ECHA, website

<sup>a</sup> The SCOEL reports that there are no indications for a threshold effect. Based on the available data, quantitative assessment of the tumour risk for MDA in humans based on animal data is not possible. Biological monitoring should be considered.

<sup>b</sup> The OEL was lowered from 0.2 mg/m<sup>3</sup> to 0.009 mg/m<sup>3</sup> since 1-1-2011 (Ministry of Social Affairs and Employment, 2010).

<sup>c</sup> IOM conclusions based on OEL = 0.08 or 0.8 mg/m<sup>3</sup>: i. No health impact assessment was undertaken, because of the uncertainties surrounding the hazard in humans and the exposures in construction and sectors other than chemical manufacturing. Relatively low health benefit is expected, ii. No significant economic costs expected for an airborne OEL, iii. No social or macro-economic costs or environmental impact expected. Overall IOM conclusion: there is a limited case for introducing some regulatory action.

<sup>d</sup> MDA is on the REACH Authorisation List (EC 1907/2006, Annex XIV) with sunset date set for 21/02/2013 (date from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted) and latest application date set for 21/02/2013 (the date by which applications must be received by ECHA if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date).

Table 16. Mineral oils <sup>a</sup>						
Evaluation	Carcinogenicity	Occupational Exposure Limits				Reference
		4·10 <sup>-3</sup> (mg/m <sup>3</sup> )	4·10 <sup>-4</sup> (mg/m <sup>3</sup> )	4·10 <sup>-5</sup> (mg/m <sup>3</sup> )	Other (mg/m <sup>3</sup> )	
<b>IARC/WHO</b>	1 (untreated or mildly treated); 3 (highly-refined)					IARC, 1987b; IARC, 2012
<b>EU</b>	Depending on composition <sup>b</sup>					EC, 2008
<b>SCOEL</b>	Group A <sup>c</sup> (unrefined / mildly refined)				5 (highly refined base oils, inhalable fraction) <sup>c</sup>	SCOEL, 2011b (SUM/ 163)
<b>NL</b>	2 <sup>d</sup>				5 <sup>e</sup>	SER, website; GR, 2011a (2011/12)
<b>DE</b>					-	IFA, GESTIS
<b>FR</b>					-	INRS, 2008
<b>IOM</b>					- <sup>f</sup>	IOM, 2011s
<b>REACH</b>	Not classified <sup>g</sup>				No DNEL/DMEL <sup>g</sup>	ECHA, website

<sup>a</sup> Mineral oils are obtained by vacuum distillation of the residue of the atmospheric distillation of crude petroleum oils. These oils, commonly called mineral base oils, are further refined by solvent treatment, hydrotreatment, and/or hydrocracking. The base oil composition, therefore, depends on the original crude petroleum oil and on the refining process. Mineral base oils may have carcinogenic properties that appear to be related to their polycyclic aromatic compounds content, which is dependent on their refinement.

<sup>b</sup> Mineral oils are divided into 3 groups, with CLP classification specified for each group:

- Unrefined or mildly refined base oils: classified in category 1A

- Highly refined base oils: considered non-carcinogenic

- Other lubricant base oils (amongst others used in metal working fluids): oils with a DMSO extractable fraction equal to or greater than 3% by weight are classified in category 1B; oils with less than 3% by weight DMSO extractable material are not classified.

<sup>c</sup> Classification into group A accounts for unrefined or mildly refined base oils and other lubricant base oils (>3% DMSO extractable fraction). The derived OEL of 5 mg/m<sup>3</sup> accounts for severely refined mineral oils and is threshold-based (based on a NOAEL for inhalation of aerosols).

<sup>d</sup> Recommendation of the Dutch Health Council to classify working with metal working fluids (containing other lubricant base oils) as CLP Carc. Cat. 2 (report 2011/12).

<sup>e</sup> The current OEL of 5 mg/m<sup>3</sup> is adopted from the American Conference of Governmental Industrial Hygienists (ACGIH). Private OELs of 1.6 mg/m<sup>3</sup> (aerosols of highly refined mineral base oils) and 0.1 mg/m<sup>3</sup> (inhalable part originating from metal working fluids) were derived in 2011 and are not statutory. Both private OELs are threshold-based and derived from a corresponding NOAEL for inhalation of aerosols (GR report 2011/12).

<sup>f</sup> IOM focused on mineral oils as used engine oils. IOM conclusions based on preventative work practices and personal protective equipment: i. Avoidance of €0.3 - 1.6bn health costs, ii. The total estimated cost of introducing best practice over the next 60 years is judged to be between about €46m and €920m, iii. No important social, macro-economic or environmental impacts expected. Overall IOM conclusion: there is a limited case for introducing an OEL (but it is probably inappropriate to introduce an inhalation OEL, because the main route of exposure is by skin contact and the main risk is from PAHs).

<sup>g</sup> Substance is described as white mineral oil (petroleum), highly refined. Absence of classification was based on harmonized classification (white mineral oil) and self-classification (mineral oil, highly refined base oils with viscosity > 20.5 mm<sup>2</sup>/s at 40°C, highly refined base oils with viscosity ≤ 20.5 mm<sup>2</sup>/s at 40°C).

Evaluation	Carcinogenicity	Occupational Exposure Limits				Reference
		4·10 <sup>-3</sup> (mg/m <sup>3</sup> )	4·10 <sup>-4</sup> (mg/m <sup>3</sup> )	4·10 <sup>-5</sup> (mg/m <sup>3</sup> )	Other (mg/m <sup>3</sup> )	
<b>IARC/WHO</b>	2B					IARC, 1999
<b>EU</b>	1B					EC, 2008
<b>SCOEL</b>	-				-	SCOEL, 2011d
<b>NL</b>		3.6		<u>0.036</u>		SER, website; GR, 1999b (1999/13OSH)
<b>DE</b>					- (processing is planned/ongoing)	IFA, GESTIS
<b>FR</b>					-	INRS, 2008
<b>IOM</b>					19 <sup>a</sup>	IOM, 2011f
<b>REACH</b>	1B				No DNEL/DMEL	ECHA, website

<sup>a</sup> IOM conclusions based on OEL = 19 mg/m<sup>3</sup>: i. No predicted health benefits from setting an OEL, ii. No additional costs assumed, iii. No social or macro-economic costs or significant environmental impacts foreseen. Overall IOM conclusion: insufficient justification for introducing an OEL (uncertainty occupational cancer risk).

<b>Table 18. Propylene oxide (= 1,2-epoxypropane) (CAS No. 75-56-9)</b>						
<b>Evaluation</b>	<b>Carcinogenicity</b>	<b>Occupational Exposure Limits</b>				<b>Reference</b>
		<b>4·10<sup>-3</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-4</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-5</sup> (mg/m<sup>3</sup>)</b>	<b>Other (mg/m<sup>3</sup>)</b>	
<b>IARC/WHO</b>	2B					IARC, 1994
<b>EU</b>	1B					EC, 2008
<b>SCOEL</b>	Group C				2.41 <sup>a</sup>	SCOEL, 2010c (SUM/161)
<b>NL</b>		10 <sup>b</sup>		0.1 <sup>b</sup>	Current OEL NL: <u>6</u> <sup>c</sup>	SER, website; GR, 1997b (1997/02 WGD)
<b>DE</b>					- (evaluation is ongoing)	IFA, GESTIS
<b>FR</b>					50	INRS, 2008
<b>IOM</b>					[4.8 or 12.1] <sup>d</sup>	IOM, 2011d
<b>REACH</b>	1B				Inhalation: DNEL <sub>local effects</sub> = 5 mg/m <sup>3</sup> <sup>e</sup>	ECHA, website

<sup>a</sup> Threshold-based OEL. The OEL was based on local changes at the rat nasal epithelium and local glutathione depletion in the nasal tissue of the rats.

<sup>b</sup> Levels derived in report 1997/2 WGD.

<sup>c</sup> The current OEL of 6 mg/m<sup>3</sup> is based on the advice of the 'Subcommissie MAC-waarden' from 1998. It is not known whether this OEL is threshold-based or risk-based. The current OEL was re-evaluated by SER in 2006 to determine if an OEL of 0.1 mg/m<sup>3</sup> is feasible. The SER concluded that re-evaluation of the literature is required and advised the Dutch Health Council to request a new evaluation. Propylene oxide is listed on the work programme of the Health Council of the Netherlands.

<sup>d</sup> IOM conclusions based on OEL = 4.8 or 12.1 mg/m<sup>3</sup> (original values of 2 and 5 ppm converted by author): i. No important health effects (cancer incidence already less than one per year up to 2060, with limited health costs) ii. No important costs expected (current exposure is judged to be well below 4.8 mg/m<sup>3</sup>, iii. No social or macro-economic costs or significant environmental impacts foreseen. Overall IOM conclusion: no strong case for introducing an OEL (no/limited health impact).

<sup>e</sup> Long-term exposure, local effects.



<b>Table 19. Respirable crystalline silica <sup>a</sup> (CAS No. 14808-60-7, 14464-46-1, 15468-32-3)</b>						
<b>Evaluation</b>	<b>Carcinogenicity</b>	<b>Occupational Exposure Limits</b>				<b>Reference</b>
		<b>4·10<sup>-3</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-4</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-5</sup> (mg/m<sup>3</sup>)</b>	<b>Other (mg/m<sup>3</sup>)</b>	
<b>IARC/WHO</b>	1					IARC, 2011
<b>EU</b>	-					EC, 2008
<b>SCOEL</b>					< 0.05 (respirable dust) <sup>b</sup>	SCOEL, 2003a (SUM/94)
<b>NL</b>	Carcinogenic (non-stochastic genotoxic) <sup>c</sup>				<u>0.075</u> (respirable fraction) <sup>d</sup>	SER, website; GR, 1992 (RA 5/92); GR, 1998b (1998/02 WGD)
<b>DE</b>					- (evaluation is ongoing)	IFA, GESTIS
<b>FR</b>					quartz: 0.1 (respirable aerosol); cristobalite: 0.05 (respirable aerosol); tridymite: 0.05 (respirable aerosol)	INRS, 2008
<b>IOM</b>					0.05, 0.1 or 0.2 <sup>e</sup>	IOM, 2011v
<b>REACH</b>	Not classified <sup>f</sup>				No data available: testing technically not feasible <sup>f</sup>	ECHA, website

<sup>a</sup> Three forms of crystalline silica: quartz (=silicon dioxide) (CAS No. 14808-60-7), cristobalite (14464-46-1) and tridymite (15468-32-3).

<sup>b</sup> A clear threshold for silicosis development (main effect) cannot be identified. Reduced exposure to 0.05 mg/m<sup>3</sup> is expected to reduce the prevalence of silicosis to ≤ 5%.

<sup>c</sup> The committee of the Dutch Health Council designates quartz as a carcinogen with a non-stochastic genotoxic mode of action, implicating that its carcinogenicity is characterized by a threshold (report 1998/02 WGD).

<sup>d</sup> OEL is threshold-based and derived from a NOAEL for silicosis and tuberculosis (report RA 5/92).

<sup>e</sup> IOM conclusions based on OEL = 0.05, 0.1 or 0.2 mg/m<sup>3</sup>: i. Reduction in predicted lung cancer deaths/registrations expected from all 3 OELs (number of "avoided" cancers would be 4,061 - 5,479). The total net health benefits are estimated to be €27,858m - €74,096 (OEL = 0.05 mg/m<sup>3</sup>), €25,522m - €67,921m (OEL = 0.1 mg/m<sup>3</sup>) and €21,171m - €56,393m (OEL = 0.2 mg/m<sup>3</sup>), ii. The estimated costs of compliance are thought to be lower or within the range of the estimated benefits, indicating that the benefits of introducing an OEL may outweigh the costs of compliance, iii. Introduction of an OEL of 0.05 or 0.1 mg/m<sup>3</sup> may be very expensive for a large proportion of the affected sectors, leading to company closures or relocation of activities to outside the EU. This is not expected for OEL = 0.2 mg/m<sup>3</sup>. No significant environmental impacts are expected. Overall IOM conclusion: strong case for introducing an OEL.

<sup>f</sup> REACH registrant dossier 'Reaction mass of Quartz (SiO<sub>2</sub>) and glass, oxide, chemicals and mullite and cristobalites'.

<b>Table 20. Rubber process fumes and dust</b>						
<b>Evaluation</b>	<b>Carcinogenicity</b>	<b>Occupational Exposure Limits</b>				<b>Reference</b>
		<b>4·10<sup>-3</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-4</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-5</sup> (mg/m<sup>3</sup>)</b>	<b>Other (mg/m<sup>3</sup>)</b>	
<b>IARC/WHO</b>	1 <sup>a</sup>					IARC, 2012
<b>EU</b>	-					EC, 2008
<b>SCOEL</b>					- (evaluation ongoing)	SCOEL in preparation (SUM/173)
<b>NL</b>					-	SER, website
<b>DE</b>					-	IFA, GESTIS
<b>FR</b>					0.6 (rubber fume)	INRS, 2008
<b>IOM</b>					6 (dust) and 0.6 (fume) <sup>b</sup>	IOM, 2011w
<b>REACH</b>	-				-	ECHA, website

<sup>a</sup> Classification for working in the rubber manufacturing industry.

<sup>b</sup> IOM conclusions based on OEL = 6 mg/m<sup>3</sup> (rubber dust) and 0.6 mg/m<sup>3</sup> (rubber fume): i. Health impact over 50 years is small (1 cancer case avoided) for an OEL for dust but larger (47 cancers avoided per year) for an OEL for fume. The health benefits are €24m - €46m (OEL dust) and €579m - 1,207m (OEL fume), ii. Total costs are €55m to €275m (OEL dust) and €466m to €3,212m (OEL fume) iii. No social or macro-economic costs associated with an OEL for rubber dust, however, action is required from most enterprises to comply with an OEL for fume, which may affect viability of small and medium sized enterprises. No significant environmental impacts foreseen. Overall IOM conclusion: there is a case for introducing an OEL for rubber fume; no strong case for introducing an OEL for rubber dust (no/limited health impact).

<b>Table 21. o-Toluidine (CAS No. 95-53-4)</b>						
<b>Evaluation</b>	<b>Carcinogenicity</b>	<b>Occupational Exposure Limits</b>				<b>Reference</b>
		<b>4·10<sup>-3</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-4</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-5</sup> (mg/m<sup>3</sup>)</b>	<b>Other (mg/m<sup>3</sup>)</b>	
<b>IARC/WHO</b>	1					IARC, 2012
<b>EU</b>	1B					EC, 2008
<b>SCOEL</b>	-				-	SCOEL, 2011d
<b>NL</b>					- <sup>a</sup>	SER, website
<b>DE</b>					- (evaluation ongoing)	IFA, GESTIS
<b>FR</b>					9	INRS, 2008
<b>IOM</b>					0.4 or 4.4 <sup>b</sup>	IOM, 2011t
<b>REACH</b>	1B				No DNEL/DMEL	ECHA, website

<sup>a</sup> o-Toluidine is listed on the work programme of the Health Council of the Netherlands.

<sup>b</sup> IOM conclusions based on OEL = 0.4 or 4.4 mg/m<sup>3</sup>: i. No important reduction in bladder cancer deaths or registrations expected (exposures are already low), ii. No cost implications for 4.4 mg/m<sup>3</sup> and limited costs (€0.03m and €0.09m) for 0.4 mg/m<sup>3</sup>, iii. No important social, macro-economic or environmental impacts expected. Overall IOM conclusion: there is a limited case for introducing an OEL.

Evaluation	Carcinogenicity	Occupational Exposure Limits				Reference
		4·10 <sup>-3</sup> (mg/m <sup>3</sup> )	4·10 <sup>-4</sup> (mg/m <sup>3</sup> )	4·10 <sup>-5</sup> (mg/m <sup>3</sup> )	Other (mg/m <sup>3</sup> )	
<b>IARC/WHO</b>	2A					IARC, 1995
<b>EU</b>	1B					EC, 2008
<b>SCOEL</b>	Group C				54.7 <sup>a</sup>	SCOEL, 2009d (SUM/142)
<b>NL</b>					- <sup>b</sup>	SER, website
<b>DE</b>		60	33			IFA, GESTIS
<b>FR</b>					405	INRS, 2008
<b>IOM</b>					50 or 273 <sup>c</sup>	IOM, 2011y
<b>REACH</b>	1B <sup>d</sup>				Inhalation: DNEL = 54.7 mg/m <sup>3</sup> ; Dermal: DNEL = 7.8 mg/kg bw/day	ECHA, website

<sup>a</sup> OEL is threshold-based. Recommendation based on a NOAEL in exposed humans, which is related to the avoidance of renal toxicity. Biological monitoring is proposed.

<sup>b</sup> Former OEL was 190 mg/m<sup>3</sup>, based on report RA 3/83 (threshold effect). This OEL was withdrawn since 1-1-2007.

<sup>c</sup> IOM conclusions based on OEL = 50 or 273 mg/m<sup>3</sup>: i. No significant health benefit from an OEL of 273 mg/m<sup>3</sup>; a reduced number of liver cancer

deaths/registrations in 2060 and a health benefit between €1,118m and €430m is expected from an OEL of 50 mg/m<sup>3</sup>, ii. The cost is unlikely to be significant for large businesses but for small and medium sized enterprises (the majority of affected enterprises) it could represent a substantial proportion of their operating surplus, which could potentially lead to some business closures ii. No significant macroeconomic, social and environmental impacts are predicted. Overall IOM conclusion: there is a case for introducing an OEL.

<sup>d</sup> Trichloroethylene is on the Candidate List of Substances of Very High Concern for authorisation under REACH and is included in the third Annex XIV recommendation of ECHA of 20 December 2011 for inclusion of substances in the Authorisation List (EC 1907/2006, Annex XIV).

Evaluation	Carcinogenicity	Occupational Exposure Limits				Reference
		$4 \cdot 10^{-3}$ (mg/m <sup>3</sup> )	$4 \cdot 10^{-4}$ (mg/m <sup>3</sup> )	$4 \cdot 10^{-5}$ (mg/m <sup>3</sup> )	Other (mg/m <sup>3</sup> )	
<b>IARC/WHO</b>	2A					IARC, 2008
<b>EU</b>	1B					EC, 2008
<b>SCOEL</b>	Group A				Not feasible to set an OEL <sup>a</sup>	SCOEL, 2008 (SUM/155)
<b>NL</b>		1.2		<u>0.012</u>		SER, website GR, 1999c (1999/15OSH)
<b>DE</b>					-	IFA, GESTIS
<b>FR</b>					-	INRS, 2008
<b>IOM</b>					22 <sup>b</sup>	IOM, 2011I
<b>REACH</b>	1B				No DNEL/DMEL	ECHA, website

<sup>a</sup> Risk-based approach. SCOEL recommends to use the existing quantitative risk assessment for vinyl chloride (SCOEL/SUM/109) also for vinyl bromide, considering a three times higher potency of vinyl bromide compared to vinyl chloride. Accordingly, the hepatic angiosarcoma risk for 4.37 mg/m<sup>3</sup> vinyl bromide during a working life is considered to be  $9 \times 10^{-4}$ .

<sup>b</sup> IOM conclusions based on OEL = 22 mg/m<sup>3</sup>: i. No predicted health benefits and low impact (current exposures are lower than the proposed OEL), ii. No additional costs associated with compliance with a limit of 22 mg/m<sup>3</sup>, iii. No social or macro-economic costs or environmental impacts foreseen. Overall IOM conclusion: no strong case for introducing an OEL (no/limited health impact).

Table 24. Vinyl chloride monomer (CAS No. 75-01-4)						
Evaluation	Carcinogenicity	Occupational Exposure Limits				Reference
		$4 \cdot 10^{-3}$ (mg/m <sup>3</sup> )	$4 \cdot 10^{-4}$ (mg/m <sup>3</sup> )	$4 \cdot 10^{-5}$ (mg/m <sup>3</sup> )	Other (mg/m <sup>3</sup> )	
<b>IARC/WHO</b>	1					IARC, 2012
<b>EU</b>	1A				7.77 <sup>a</sup>	EC, 2004; EC, 2008
<b>SCOEL</b>					Not assigned <sup>b</sup>	SCOEL, 2002 (SUM/109)
<b>NL</b>					7.77 <sup>c</sup>	SER, website
<b>DE</b>					7.7 <sup>c,d</sup>	IFA, GESTIS
<b>FR</b>					2.59	INRS, 2008
<b>IOM</b>					2.56 or 5.11 <sup>e</sup>	IOM, 2011z
<b>REACH</b>	1A				Inhalation: DMEL = 7.7 mg/m <sup>3</sup>	ECHA, website

<sup>a</sup> Binding OEL (BOEL) as listed in Directive 2004/37/EC, Annex III. BOEL is based on technical feasibility.

<sup>b</sup> Risk-based approach. SCOEL reports that 2.59 mg/m<sup>3</sup> vinyl chloride during a working life would be associated with a cancer risk for hepatic angiosarcoma of about  $0.3 \times 10^{-3}$ .

<sup>c</sup> Adopted from EU.

<sup>d</sup> National evaluation ongoing.

<sup>e</sup> IOM conclusions based on OEL = 2.56 or 5.11 mg/m<sup>3</sup>: i. No or limited health benefits, ii. The cost of compliance with an OEL of 5.11 mg/m<sup>3</sup> may be in the region of €15m to €30m over a period of 50 years and for an OEL of 2.56 mg/m<sup>3</sup> this would be €90m to €185m (taking into account annual production shutdowns for maintenance), iii. No social or macro-economic costs or environmental impacts expected. Overall IOM conclusion: no strong case for introducing an OEL (no/limited health impact).

<b>Table 25. (hard)Wood dust</b>						
<b>Evaluation</b>	<b>Carcinogenicity</b>	<b>Occupational Exposure Limits</b>				<b>Reference</b>
		<b>4·10<sup>-3</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-4</sup> (mg/m<sup>3</sup>)</b>	<b>4·10<sup>-5</sup> (mg/m<sup>3</sup>)</b>	<b>Other (mg/m<sup>3</sup>)</b>	
<b>IARC/WHO</b>	1					IARC, 2011
<b>EU</b>	-				5 (hardwood dust, inhalable fraction) <sup>a</sup>	EC, 2004; EC, 2008
<b>SCOEL</b>	-				Not assigned <sup>b</sup>	SCOEL, 2003b (SUM/102)
<b>NL</b>	1A (hardwood dust); 2 (softwood dust) c,d				2 (hard wood dust, inhalable fraction) <sup>d</sup>	SER, website; GR, 1991 (RA 8/91); GR, 1998c (1998/13 WGD); GR, 2000d (2000/08OSH)
<b>DE</b>					5 (hardwood dust) <sup>e</sup> ; 2 (reference value) <sup>f</sup>	IFA, GESTIS
<b>FR</b>					1 (total wood dust)	INRS, 2008
<b>IOM</b>					1 or 3 <sup>g</sup>	IOM, 2011o
<b>REACH</b>	-				-	ECHA, website

<sup>a</sup> Binding OEL (BOEL) for hardwood dust as listed in Directive 2004/37/EC, Annex III. BOEL is based on technical feasibility.

<sup>b</sup> The studies available do not provide adequate information for setting a health-based limit value for the protection of workers exposed to wood dust. The level of 0.5 mg/m<sup>3</sup> (total dust) and 1 mg/m<sup>3</sup> (inhalable dust) is probably below the levels to which the cases of sino-nasal cancers had been exposed.

<sup>c</sup> Classification according to report 1998/13 WGD. The original classification as described in the report (1 and 3 according to Directive 67/548/EEC) was translated according to Annex VII of the CLP regulation (EC 1272/2008) in 1A and 2.

<sup>d</sup> OEL for hard wood dust based on technical and socioeconomic feasibility; health-based OEL is 0.2 mg/m<sup>3</sup> (report RA 8/91). In a more recent report (2000/08OSH) it was concluded that it is unclear whether wood dust is direct genotoxic, indirect genotoxic or non-genotoxic and therefore no OEL should be derived. However, if linear extrapolation would be applied the additional life time risk is 5.8 mg/m<sup>3</sup> (4·10<sup>-3</sup>) and 0.06 mg/m<sup>3</sup> (4·10<sup>-5</sup>).

<sup>e</sup> Adopted from EU.

<sup>f</sup> Reference value for hardwood dust that represents the state of the art. An employer has to ensure that only minimum quantities of chemicals relevant to exposure are used. If state-of-the-art technical measures are applied, a workplace concentration of 2 mg/m<sup>3</sup> or less can be achieved in most industrial facilities. In such a case, the reference value is the occupational standard.

<sup>9</sup> IOM conclusions based on OEL = 1 or 3 mg/m<sup>3</sup>: i. The total health benefits are €9m - €44m (OEL = 3 mg/m<sup>3</sup>) and €51m - €252m (OEL = 1 mg/m<sup>3</sup>), ii. No economic impacts for OEL = 3 mg/m<sup>3</sup>; €3.8bn and €8.6bn for OEL=1 mg/m<sup>3</sup> (higher economic costs than the avoided health costs) iii. No significant change to social, macro-economic and environmental impacts (OEL = 3 mg/m<sup>3</sup>); small and medium sized enterprises will disproportionately be affected with an OEL of 1 mg/m<sup>3</sup>. Overall IOM conclusion: strong case for introducing an OEL.



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