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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

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Final Report for OEL/STEL deriving systems

FoBiG Forschungs- und Beratungsinstitut Gefahrstoffe GmbH

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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

OEL/STEL deriving systems

8 February 2018

Final Report

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List of acronyms

ACGIH	American Conference of Governmental Industrial Hygienists
BOEL	Binding Occupational Exposure Limit, without reference to a specific regulation
BOELV	Binding Occupational Exposure Limit Value (Term used only for EU OELs according to Council Directive 98/24/EC)
DNEL	Derived No Effect Level (concentration or dose), according to REACH terminology (e.g., ECHA, 2012)
DRR	Dose Response Relationship (used for non-cancer effects; but may also refer to "concentration response relationship", if, e.g. a correlation of effects with atmospheric concentration (mg/m^3) is established)
ERR	Exposure Risk Relationship (used for cancer effects)
IOEL	Indicative Occupational Exposure Limit, without reference to a specific regulation
IOELV	Indicative Occupational Exposure Limit Value (Term used only for EU OELs according to Council Directive 98/24/EC)
LOAEC	Lowest Observable Adverse Effect Concentration
LOD	Level of detection
LOQ	Limit of quantification
OEL	A general (Binding or Indicative) Occupational Exposure Limit value, without reference to a specific regulation
OELV	Occupational Exposure Limit Value (Term used only for EU OELs according to Council Directive 2004/37/EC), always binding
MRL	Minimal risk level
MS	Member States
ppm	Parts per million
STEL	Short-term Exposure Limit (with heterogeneous exact definitions)

1 Introduction

1.1 Background

Within Directive 98/24/EC (on the protection of the health and safety of workers from the risks related to chemical agents at work), Occupational Exposure Limits (OELs) are one of the major control instruments for workers' exposure to chemicals, and are among the most important tools for exposure assessment and management. The Carcinogens and Mutagens Directive (Directive 2004/37/EC), hereafter 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.

A comparison of the national OELs within EU member states (and other countries) for non-carcinogens and for carcinogens reveals some heterogeneity of established OELs. Therefore, and in order to analyse consequences of potential changes on OELs, it is of interest to understand the current procedures and methodologies of the national OEL systems.

1.2 Objectives

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

The specific objective of this report is to summarise and compare the different national systems for deriving OELs.

This report offers a general description of the national OEL setting systems, and complements this with examples for specific chemical agents. These examples may include, but are not limited to, substances addressed in the other reports.

1.3 Structure of the report

The report is organised as follows:

- Section 2 summarises existing OELs, STELs, and skin notations for the chemical agents within the scope of this study in EU Member States and selected non-EU countries;
- Section 3 describes and compares the national systems for setting OELs, STELs, and skin notations in EU Member States and selected non-EU countries, also providing examples for illustration; and
- Section 4 briefly recalls the importance of national enforcement systems in EU Member States, in order to ensure the established OELS are effective in delivering the intended benefits.

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

The report is complemented with **2 annexes** which provide more detailed information for individual EU Member States (ANNEX 1: links to national lists of OELs; ANNEX 2: links to (selected) national methodologies to derive OELs or non-carcinogens or carcinogens).

2 Summary of existing limits for the five chemical agents

Similarities and differences between OELs in EU-member states and other countries can best be demonstrated by documenting the national OELs for those substances (or groups of substances), which will be further analysed in the other reports of this project. Those are the OELs or analogue reference values for:

- cadmium and its inorganic compounds;
- beryllium and its inorganic compounds;
- inorganic arsenic compounds including arsenic acid and its salts;
- formaldehyde; and
- 4,4'-Methylene-bis (2-chloroanilinie) (MOCA).

National OELs for chromium (VI) are not addressed within this report on OEL systems in a systematic way, but will be described and discussed in the substance report on "Chromium (VI) fumes from welding or plasma cutting processes and similar work processes that generate fume". When national methodologies are compared using examples (see Section 3.4.5, this report), substance specific illustrations will also include chromium (VI).

Table 2-1 provides such a comparative listing with all available national values for atmospheric OELs (chronic exposure) for the five compounds and Table 2-2 provides the respective Short-Term Limit Values (STELs) for brief exposures. In Table 2-1 "skin" notations are also documented for those countries, where these have been assigned to a compound.

Table 2-3 demonstrates the ranges of OELs for the five substances (groups of substances), taken from the preceding tables (Table 2-1 and Table 2-2). These ranges also include most of the "outliers", i.e. OELs set only by one or a few countries, representing significant discrepancies to most of the other countries. However, specifically for Beryllium, it is demonstrated that very different OELs were established. Even though non-EU countries may influence this range to a limited extent, it is found that the inclusion of non-EU values does not significantly alter the interval of OELs or STELs. A more specific analysis of a single substance's OELs is provided in the substance reports. In this report on the OEL systems the various OELs are analysed for systematic differences, which are linked to the specific national procedure and methodology.

Table 2-1: OELs for five substances / groups of substances for EU-member states and selected other countries					
Member State, non-EU country/ compound	**Cadmium and inorganic compounds [mg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Beryllium and inorganic compounds [µg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Inorganic arsenic compounds including arsenic acid and its salts‡ [mg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Formaldehyde [mg/m³ (ppm)]§**	**MOCA [mg/m³ (ppm)]§**
Austria	0.03 (I) -manufacture of batteries, thermic extraction of zinc, lead and copper, welding of Cd containing alloys 0.015 (I) -other uses	5 (I) -whetting of Be metals and alloys, SKIN 2 (I) -other uses, SKIN	0.1 (I)	0.37 (0.3) -SKIN	0.02 (0.002) -SKIN
Belgium	0.01 (I) 0.002 (R)	2 (I)	0.01 (I)	-	0.11 (0.01) -SKIN
Bulgaria	0.05	2	0.05	1.0 (0.83)	-
Croatia**	0.03 (R) -CdS and CdS pigments 0.025 -CdF_2, CdO, $CdCl_2$	2 -except aluminium beryllium silicate	0.1 -SKIN notation only for AsO_3 and As_2O_3	2.5 (2.0)	0.005 (0.0005) -SKIN
Cyprus	0.05 (T) -metal powder and fumes, SKIN	2 -SKIN	0.01 -SKIN	3.0 (2.0) -SKIN	-
Czech Republic	0.05 -SKIN	1	0.1	0.5 (0.42) -SKIN	-
Denmark	0.005 –powder, dust, and smoke+	1 -powder and compounds, SKIN	1 -calcium arsenate 0.01 (T) -other inorganic As compounds	0.4 (0.3)	0.11 (0.01) -SKIN
Estonia	0.05 (T) 0.01 (I)	2	0.03	0.6 (0.5)	-
Finland**	0.004 (R)	0.1 (I) -SKIN	0.01 (I) +	0.37 (0.3)	0.11 (0.01) -SKIN
France§§	0.05 (I) +	2 (I)	0.2 -As_2O_3+	0.6 (0.5)	0.22 (0.2) -SKIN
Germany	0.001 (I) 1.6 µg/m³ (R) -“tolerable risk” * 0.16 µg/m³ (R) -“acceptable risk”	0.14 (I) –except aluminium beryllium silicate 0.06 (R) –except aluminium beryllium silicate	8.3 µg/m³ (I) -“tolerable risk”* 0.83 µg/m³ (I) -“acceptable risk”	0.37 (0.3)	-
Greece	0.025	5	0.1	2.5 (2.0)	0.22 (0.2) -SKIN

Table 2-1: OELs for five substances / groups of substances for EU-member states and selected other countries					
Member State, non-EU country/ compound	**Cadmium and inorganic compounds [mg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Beryllium and inorganic compounds [µg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Inorganic arsenic compounds including arsenic acid and its salts‡ [mg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Formaldehyde [mg/m³ (ppm)]§**	**MOCA [mg/m³ (ppm)]§**
Hungary	0.05 -CdF_2, $CdCl_2$, CdO 0.015 -except CdF_2, $CdCl_2$, CdO+	2	0.03 -As_2O_5, SKIN 0.1 -As_2O_3, SKIN 0.01 -other inorganic As compounds, SKIN	0.6 (0.5) -SKIN	-
Ireland	0.03 (R) -CdS and CdS pigments 0.01 (T) -except CdO fume and CdS pigments 0.025 (R) –CdO 0.002 (R) -except CdO fume and CdS pigments	0.2 -SKIN+	0.01 (T)	0.24 (0.2) +	0.005 (0.0005) -SKIN
Italy	-	-	-	-	-
Latvia	0.01	1 (I)	0.01 +	0.5 (0.42)	-
Lithuania	0.05 (I) 0.01 (R)	2 (I)	0.03	0.6 (0.5)	-
Luxembourg	-	-	-	-	-
Malta	-	-	-	-	-
Netherlands	0.005 (R) -CdO, CdS,$CdCl_2$+	-	0.0028 [Excess cancer risk: 4×10^{-4} – 0.0028 mg/m³]2	0.15 (0.12)	0.02 (0.002) -SKIN
Poland	0.01 (I) 0.002 (R)	0.2 (I)	0.01 (I)	0.5 (0.42) -SKIN [0.37 (0.3)] – intended change~	0.02 (0.002) -SKIN
Portugal**	0.01 (I) 0.002 (R)	0.05 (I) -SKIN	0.01	0.37 (0.3)	0.11 (0.01) -SKIN
Romania	0.05	2	0.01	1.2 (1.0)	0.22 (0.2) -SKIN

Table 2-1: OELs for five substances / groups of substances for EU-member states and selected other countries					
Member State, non-EU country/ compound	**Cadmium and inorganic compounds [mg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Beryllium and inorganic compounds [µg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Inorganic arsenic compounds including arsenic acid and its salts‡ [mg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Formaldehyde [mg/m³ (ppm)]§**	**MOCA [mg/m³ (ppm)]§**
Slovakia	0.15 (I)-others 0.03 (I) -production of batteries, production of zinc, lead and copper after heat treatment, welding of cadmium-alloyed metals	5 (I) -refers to whetting of Be metals and alloys, except aluminium beryllium silicate 2 (I) –refers to other uses, except aluminium beryllium silicate	0.1 (I)	0.37 (0.3) -SKIN	0.02 (0.002) -SKIN
Slovenia	0.03 (I) -production of batteries, production of zinc, lead and copper after heat treatment, welding of cadmium-alloyed metals 0.015 (I) -other uses	5 (I) –refers to grinding, except aluminium beryllium silicate 2 (I) –refers to other uses, except aluminium beryllium silicate	0.1 (I) -H_3AsO_4 plus salts	0.62 (0.5) -SKIN	0.02 (0.002) -SKIN
Spain	0.01 (I) 0.002 (R)	0.2 (I)	0.01 (T)	-	0.1 (0.01) -SKIN
Sweden	0.02 (T) 0.002 (R)	2 (T)	0.01 (T)	0.37 (0.3) -SKIN	###
United Kingdom	0.025 -except CdS pigments, SKIN+ 0.03 -CdS and CdS pigments, SKIN+	2 -SKIN	0.1 (T) -SKIN	2.5 (2.0) -SKIN	0.005 (0.0005) -SKIN
SCOEL**	0.001 (I)	0.02 (I)	-	0.369 (0.3)	- -SKIN
Selected non-EU countries					
Australia	0.01	2	0.05 (T)	1.2 (1.0)	0.22 (0.02) -SKIN
Brazil	-	-	-	2.3 (1.6) -48 hours/week	-
Canada, Ontario	0.01 (I)+	2	0.01 (T)	Pending	0.005 (0.0005) -SKIN

Table 2-1: OELs for five substances / groups of substances for EU-member states and selected other countries					
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	0.002 (R)+				
Canada, Québec	0.025 - except CdO fume and CdS pigments+	0.15	0.1 (T)	-	0.22 (0.02) -SKIN
China	0.01	0.5	0.01 (T)	-	-
India	0.05	2	0.2 -soluble compounds	1.5 (1.0)	-
Japan, JSOH+,**	0.05	2	0.003 [Excess cancer risk: 1 x 10^{-3} - (0.003 mg/m³); 1 x10^{-4} - (0.0003 mg/m³)]	0.12 (0.1)	0.005 (0.0005) -SKIN
South Korea[1]	0.01 (T) 0.002 (R)	2	0.01 (T)	0.75 (0.5)	0.11 (0.01) -SKIN
Kazakhstan		1			
Russia		1			
USA; ACGIH**	0.01 0.002 (R)	0.05 (I) -SKIN	0.01 (T)	0.12 (0.1)	0.11 (0.01) -SKIN
USA, OSHA	0.005 (T)	0.2 (T)	0.01 (T)	0.9 (0.75)	-
USA, NIOSH$,**	#	#	#	0.02 (0.016)	0.003 (0.0003) -SKIN

Table 2-1: OELs for five substances / groups of substances for EU-member states and selected other countries					
Member State, non-EU country/ compound	**Cadmium and inorganic compounds [mg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Beryllium and inorganic compounds [µg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Inorganic arsenic compounds including arsenic acid and its salts‡ [mg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Formaldehyde [mg/m³ (ppm)]§**	**MOCA [mg/m³ (ppm)]§**

‡ inorganic arsenic compounds including arsenic acid and its salts, arsine exempted, for all occupations, as As, if not stated otherwise in this column.
+ 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 and for MOCA according to 1 ppm = 10.9 mg/m³; 1 mg/m³ = 0.09 ppm.
SKIN: Skin notation assigned.

*** Limit values are indicative.*
§§ Limit values are recognised values– not according to decree modified on 30 June 2004 – thus not legally binding.
** In Germany, this concentration is not regarded as a fixed OEL (AGS; TRGS 910; https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/TRGS-910.pdf? blob=publicationFile&v=4), but as an upper limit, i.e. "tolerable risk level": usually 4:1000 excess risk. However, exposures below the "tolerable risk level" but above the "acceptable risk level" need to be minimised in order to avoid cancer risk.*
Handling of MOCA requires authorisation from the Swedish Work Environment Authority.
† Official Japanese values could not be identified. Therefore recommendations from the Japan Society for Recommendation of Occupational Exposure Limits (JSOH), which are not mandatory, are stated.
$ "For NIOSH RELs, "TWA" indicates a time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek" ;
Online: https://www.cdc.gov/niosh/npg/pgintrod.html#exposure
 # No recommended exposure limits (RELs) established - Reference to "Appendix A - NIOSH Potential Occupational Carcinogens". NIOSH has changed policy with regard to carcinogenic substances. Under the old policy, RELs for most carcinogens were non-quantitative values labelled "lowest feasible concentration (LFC)." The effect of the new policy will be the development, whenever possible, of quantitative RELs that are based on human and/or animal data, as well as on the consideration of technological feasibility for controlling workplace exposures to the REL. Changes in the RELs and respirator recommendations that reflect the new policy will be included in future editions. Limit values for carcinogens will in the future be termed: RMLCA (Risk Management Level for a Carcinogen).

References:
Questionnaire information (this project) or GESTIS (IFA, 2017), or country specific lists of OEL from web-search.

1: IFA (2017) Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung. GESTIS - Internationale Grenzwerte für chemische Substanzen.
2: HCN (2012) Health-Based Calculated Occupational Cancer Risk Values. Arsenic and inorganic arsenic compounds. Publication no. 2012/32.

Table 2-2: Short-term Exposure Limits (STELs) for five substances / groups of substances for EU-member states and selected other countries					
Member State, non-EU country/ compound	**Cadmium and inorganic compounds [mg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Beryllium and inorganic compounds [µg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Inorganic arsenic compounds including arsenic acid and its salts [mg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Formaldehyde [mg/m³ (ppm)]§**	**MOCA [mg/m³ (ppm)]§**
Austria	0.12 (I) -battery production, zinc-, lead- or copper winning, welding of cadmium containing alloys 0.06 (I) -other uses	20 (I) -whetting of Be metals and alloys, SKIN 8 (I) other uses, SKIN	0.4 (I)	0.74 (0.6) -15 min, SKIN	0.08 (0.007) -15 min, SKIN
Belgium	-	10 (I) -SKIN	-	0.38 (0.3) –momentary, 15 min	-
Bulgaria	-	-	-	2.0 (1.7)	-
Croatia**	0.05 -CdO	-	-	2.5 (2.0)	-
Cyprus	-	-	-	-	-
Czech Republic	0.1 -ceiling	2 -ceiling	0.4 -ceiling	1.0 (0.8) –ceiling, SKIN	-
Denmark	-	-	-	0.4 (0.3) -ceiling	- [+]
Estonia	-	-	-	1.2 (1.0) –ceiling, 15 min	- [+]
Finland**	-	4 (I) -15 min, SKIN	-	1.2 (1.0) –ceiling, 15 min	-
France	0.05 -CdO, fume or respirable dust	2	-	1.2 (1.0)	-
Germany	0.008 (I)	0.14 (I) -except aluminium beryllium silicate 0.06 (R) -except aluminium beryllium silicate	-	0.74 (0.6) -15 min	-
Greece	0.1	-	-	2.5 (2.0)	-
Hungary	-	-	-	0.6 (0.5) -15 min, SKIN	-
Ireland	0.05 (R) -CdO, fume or respirable dust	-	-	0.5 (0.4) -15 min	-
Italy	-	-	-	-	-
Latvia	0.05	-	0.04 -15 min	-	-
Lithuania	-	-	-	1.2 (1.0) -ceiling	-
Luxembourg	-	-	-	-	-
Malta	-	-	-	-	-

Table 2-2: Short-term Exposure Limits (STELs) for five substances / groups of substances for EU-member states and selected other countries					
Member State, non-EU country/ compound	**Cadmium and inorganic compounds [mg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Beryllium and inorganic compounds [µg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Inorganic arsenic compounds including arsenic acid and its salts [mg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Formaldehyde [mg/m³ (ppm)]§**	**MOCA [mg/m³ (ppm)]§**
Netherlands	-	-	-	0.5 (0.42) -15 min	-
Poland	-	-	-	1.0 (0.8) -15 min, SKIN 0.74 (0.6) -intended change˜	-
Portugal**	-	-	-	-	-
Romania	-	-	0.1	3.0 (2.0)	-
Slovakia	-	-	-	0.74 (0.6) -15 min, SKIN	-
Slovenia	0.12 (I) -production of batteries, production of zinc, lead and copper after heat treatment, welding of cadmium-alloyed metals) 0.06 (I) -other uses	20 (I) –refers to grinding, except aluminium beryllium silicate 8 (I) –refers to other uses, except aluminium beryllium silicate	0.4 (I) -H_3AsO_4 plus salts	0.62 (0.5) -SKIN	0.08 (0.007) -SKIN
Spain	-	-	-	0.37 (0.3)	-
Sweden	-	-	-	0.74 (0.6) -15min, SKIN	-
United Kingdom	0.05 -CdO fume, SKIN+	-	-	2.5 (2.0) -15 min, SKIN	-
SCOEL**	-	0.2 (I)	-	0.738 (0.6) -15 min	-
Selected non-EU countries					
Australia	-		-	2.5 (2.0)	-
Brazil	-	-	-	-	-
Canada, Ontario	-	10.0	0.05	1.2 (1.0) -STEL 1.8 (1.5) -ceiling	-
Canada, Québec	-	-	-	-+	-
China	0.02	1.0 -15 min	0.02 (T) -15 min	0.5 (0.4) -ceiling, 15 min	-
India	-	-	-	3.0 (2.0)	-
Japan, JSOH†,**	-	-	-	0.24 (0.2) -ceiling	-
South Korea[1]	-	-	-	1.5 (1.0)	-
USA; ACGIH**	-	-	-	0.37 (0.3) –ceiling, 15 min	-

Table 2-2: Short-term Exposure Limits (STELs) for five substances / groups of substances for EU-member states and selected other countries					
Member State, non-EU country/ compound	**Cadmium and inorganic compounds [mg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Beryllium and inorganic compounds [µg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Inorganic arsenic compounds including arsenic acid and its salts [mg/m³] I=inhalable; R=respirable; T=total dust - fraction**	**Formaldehyde [mg/m³ (ppm)]§**	**MOCA [mg/m³ (ppm)]§**
USA, OSHA	-	2 (T)	-	2.4 (2.0)	-
USA, NIOSH**	-	0.5 -ceiling	0.002 -ceiling, 15 min	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 and for MOCA according to 1 ppm = 10.9 mg/m³; 1 mg/m³ = 0.09 ppm.
SKIN: Skin notation assigned.

***Limit values are recognised values – not according to decree modified on 30 June 2004 – thus not legally binding.*
§§ Limit values are recognised values with an indicative character – not according to decree modified on 30 June 2004 – thus not legally binding.
† Official Japanese values could not be identified. Therefore, recommendations from the Japan Society for Recommendation of Occupational Exposure Limits (JSOH), which are not mandatory, are stated.

References:
Questionnaire information (this project) or GESTIS (IFA, 2017), or country specific lists of OEL from web-search.

1: IFA (2017) Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung. GESTIS - Internationale Grenzwerte für chemische Substanzen.

Table 2-3: Ranges of OELs for five substances / groups of substances for EU-member states and selected other countries					
	Cadmium and inorganic compounds [mg/m³] I=inhalable; R=respirable; T=total dust - fraction	Beryllium and inorganic compounds [µg/m³] I=inhalable; R=respirable; T=total dust - fraction	Inorganic arsenic compounds including arsenic acid and its salts [mg/m³] I=inhalable; R=respirable; T=total dust - fraction	Formaldehyde [mg/m³ (ppm)]	MOCA [mg/m³ (ppm)]
Range (TWA)	0.001[$] (I) – 0.05 (I)[+]	0.020 (I) – 5 (I)	0.003[$] – 0.2*	0.12 (0.1) – 3 (2)[#]	0.005 (0.0005) – 0.22 (0.02)[§§]
STEL/ceiling	0.008 (I) - 0.12 (I)	0.06 (R) – 20 (I)	0.02 – 0.4 (I)[§]	0.24 (0.2) – 3 (2)[##]	0.08 (0.007) (single value, 2 countries)
*+ = [0.001-0.15], if OEL for Slovakia (others) is included; * [0.003-1], if OEL for calcium arsenate (Denmark) is included; $ = lower bound not fixed, because obligation to minimize without fixed OEL in some countries; §= [0.002-0.4], if NIOSH recommendation (ceiling) is included; # = [0.02-3] if NIOSH recommendation (REL) is included; ## = [0.12-3], if NIOSH recommendation (ceiling) is included; §§ = [0.003-0.22], if NIOSH -TWA is included;*					

3 National systems for deriving exposure limits

The purpose of this section is to a) describe and b) compare the national systems for setting OELs and STELs and find the main reasons for systematic differences in OELs.

3.1 Introduction

Providing the background for an OEL will help to understand the justification for that value, or may explain, if international harmonisation of OELs is suggested. Differences may be maintained, if more restrictive national OELs are feasible, depending on the national level the national level and justified using the data and the definition of the OEL in that country. However, the main focus of this report is to provide transparency into the respective rationales, and to assess agreement with regard to the health and health-risk dimension of this impact assessment.

This section is laid out as follows:

- Section 3.2 provides information on national OEL-deriving systems, information on STEL-deriving systems, and information on national systems for "skin" notations, for EU Member States;
- Section 3.3 provides the same information as Section 3.2, but for countries outside the European Union;
- Section 3.4 details variations in national OEL-deriving, STEL-deriving and "skin" notation-deriving systems, and their systematic differences, with examples in Section 3.4.5;
- Any substance specific background for the OELs and STELs established in single countries is provided in the respective substance reports.

Comparisons of national OEL systems within the EU or beyond have been performed before. In 2003, Walters et al. (2003) described the role of occupational exposure limits in the health and safety systems of EU Member States with a review of the OEL systems and a more detailed analysis for Germany, Greece, Italy, the Netherlands, and Sweden. In 2009, an "Exploratory Survey of Occupational Exposure Limits for Carcinogens, Mutagens and Reproductive substances at EU Member States Level" was published by the European Agency for Safety and Health at Work, based on an international analysis from 2007 (EU-OSHA, 2009). In 2014, the International Social Security Association published a document with a comprehensive description of the OEL systems in some European and non-European countries (i.e. Austria, Finland, France, Germany, Italy, Poland, Sweden, Switzerland, United Kingdom, USA, and Japan) (ISSA, 2014). While those papers mainly focussed on the OEL-setting systems, some other publications tried to analyse the reasons for the differences in OELs, generally (Ding et al., 2011; Schenk, 2010; Schenk et al., 2008b), or with respect to STELs (Maponya, 2015), or with respect to carcinogens (Ding et al., 2014). Recently Devau et al. summarised the main reasons for variations in Occupational Exposure Limits (Deveau et al., 2015a). All of these sources were considered in the present analysis and compared with information obtained from a Member State questionnaire specific to this project.

3.2 Description of national OEL-deriving systems within the EU

3.2.1 European Union

The Scientific Committee on Occupational Exposure Limits (SCOEL) provides a list of Indicative Occupational Exposure Limit values (IOEL) established in accordance with the Chemical Agents Directive. IOELs are developed as "recommendations" or "opinions" by the committee and are "health-based" and non-binding, taking into account the availability of measurement techniques.

For carcinogens, SCOEL discriminates four groups of "modes of action" (MoA):

- Group A: Non-threshold genotoxic carcinogens, for risk low-dose assessment the linear non-threshold (LNT) model appears appropriate;
- Group B: Genotoxic carcinogens, for which the existence of a threshold cannot be sufficiently supported at present. In these cases, the LNT model may be used as a default assumption, based on scientific uncertainty;
- Group C: Genotoxic carcinogens for which a practical threshold is supported; and
- Group D: Non-genotoxic carcinogens and non-DNA reactive carcinogens; for these compounds a true ("perfect") threshold is associated with a clearly founded NOAEL.

Health-based OELs are derived by SCOEL for carcinogens of groups C and D. For carcinogens (group A, B), SCOEL may describe and assess data on the excess risk, but does not define an "acceptable" risk level. However, the ECHA/RAC committee may propose binding OELs based on a defined risk level[2].

SCOEL established a methodology to derive OELs and STELs (SCOEL, 2013). Similarly, ECHA established guidance for deriving DNELs (ECHA, 2012). Within this discussion of OEL systems, the assessment of DNELs is not relevant, because they are established by REACH registrants for another regulatory purpose. However, as the DNEL-methodology is partly used within OEL-methodologies and because ECHA/RAC was recently involved into OEL assessments (carcinogenic substances), the two Committees described similarities and differences between the two approaches in a Joint Task Force analysis (ECHA/RAC-SCOEL, 2017). Differences in methodology may lead to differences in reference values (i.e. OELs, which are or are not linked to the ECHA-methodology or the SCOEL-methodology). However, differences between the SCOEL- and ECHA/RAC-methodology usually are found to be small (ECHA/RAC-SCOEL, 2017).

SCOEL may also assign notations, such as "skin"-notation or notations for dermal sensitisation.

Based on a list of priority substance, established by DG Employment, substances are analysed for best available scientific data by SCOEL and a "draft recommendation" is prepared. This is followed by a six month consultation period, possibly leading to amendments. SCOEL adopts a recommendation, which usually is accepted by DG Employment and published. DG Employment then consults the Advisory Committee on Safety and Health, which may lead to either one of the routes for final regulatory adoption:

- If the proposed OELs are only based on scientific considerations, they become IOELVs and are incorporated into proposals for Commission Directives in accordance with the chemical agent directive; and

[2] https://chemicalwatch.com/crmhub/60128/echa-looks-at-binding-occupational-exposure-limits-for-three-more-carcinogensworkers/ , assessed November 2017

- If the proposed OELs also take into account socio-economic and technical feasibility factors, then the Council and European Parliament Route is taken and Binding Occupational Exposure Limit Values are established, which are incorporated into proposals for Council and Parliament Directives in accordance with the CMD. [3]

3.2.2 Austria

The Austrian OELs are proscribed by the regulation on occupational exposure limit values ("Grenzwerteverordnung"). There is a list of national OELs, which have a binding character, and the list is updated when need arises.

The procedure in Austria for setting exposure limit values involves social partners, AUVA (Austrian accident insurance board) and experts, and is chaired by the Ministry of Economy and Labour. The Austrian MAK Committee consists of various stakeholders and mostly decides on the scientific basis of other foreign committees on occupational exposure levels. Therefore, OELs and methodology in Austria are usually adopted from other countries (e.g. Germany), or scientific bodies, like SCOEL.

For carcinogens, currently technical guidance values ("Technische Richtkonzentrationen") are derived, which include technical feasibility considerations. OELs for non-carcinogenic substances are health-based.

The list of OELs in Austria generally also includes short-term limit values (STELs), which are adopted from lists in other countries (e.g. SCOEL and Germany). They vary from the international STEL specifications (usually for 15 min/period, 4 periods/day with a 60 min break in between periods) by establishing STELs for 30 min/period or 60 min/period, 1 or 2 periods per day. In addition, specific notations (e.g. "skin notation", "skin sensitiser", etc.) can be assigned.

Details on the OEL system in Austria, the procedure for setting exposure limits, and the methodology are taken from questionnaire responses (this project). Some supplemental information was provided by other reports (EU-OSHA, 2009; ISSA, 2014). It should be noted, that this supplemental information is from earlier publications and therefore may not reflect the most recent status.

3.2.3 Belgium

There is a list of national OELs in Belgium, however, there is no specific methodology for the setting of limit values for non-carcinogens or for carcinogens. Belgium starts from values defined by ACGIH, SCOEL, EU determined indicative/binding limit values, and uses those values in a consultation procedure with social partners (workers' and employers' organisations). These partners can propose different values based on several criteria: health, measurability, technical, and socio-economic. A public consultation procedure is established that foresees a two-stage process:

- publication of the proposal on the authority's website and with a two-month period to file objections; and
- presentation of a more elaborate file for OELs for which an objection is received within a 5-month period.

[3] http://www.google.de/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwiLqvbZxsXXAhUEAxoKHVz3Dr4QFggqMAA&url=http%3A%2F%2Fec.europa.eu%2Fsocial%2FBlobServlet%3FdocId%3D3879%26langId%3Den&usg=AOvVaw1VF_ndkWkWIxj0UcwsQ17i, assessed November 2017

Based on the aforementioned files, the technical and socio-economic evaluation is performed within the High Council for Prevention and Protection at Work, where social partners and experts are represented. After the consultation procedure, the Minister of Employment decides which value will be adopted. Those values have a binding character.

The list of OELs is updated regularly, but less often than every year.

The list of OELs in Belgium generally also includes short-term limit values (STELs), which are adopted from other committees. In addition, specific notations (e.g. “skin notation”, “skin sensitiser”, etc.) are assigned, if appropriate.

Details on the OEL system in Belgium, the procedure for setting exposure limits and the methodology are taken from questionnaire responses (this project). Some supplemental information was provided by other reports (EU-OSHA, 2009). It should be noted, that this supplemental information is from earlier publications and therefore may not reflect the most recent status.

3.2.4 Bulgaria

There is a list of national OELs in Bulgaria, and those are binding in character.

In Bulgaria, OELs - including those for carcinogens - are usually adopted from other countries (not further specified). OELs are based on socio-economic and/or technical and/or health considerations (aggregate assessment). A national methodology publication is not available, and the procedure in Bulgaria for setting exposure limit values is not reported in detail.

The list of OELs is updated when need arises. The list of OELs in Bulgaria generally also includes short-term limit values (STELs) which are adopted from other countries, if appropriate.

In addition, specific notations (e.g. “skin notation”, “skin sensitiser”, etc.) are assigned.

Details on the OEL system in Bulgaria, the procedure for setting exposure limits and the methodology are taken from questionnaire responses (this project). Bulgaria was not covered by earlier analyses (EU-OSHA, 2009; ISSA, 2014).

3.2.5 Croatia

In Croatia there is a list of national OELs, but they are indicative in character.

OELs may be either health-based or risk-based and may also include socio-economic and/or technical feasibility considerations. A national methodology publication is not available and the procedure in Croatia for setting exposure limit values is not reported in detail.

The list of OELs is updated when need arises. The list of OELs in Croatia generally also includes short-term limit values (STELs) (not further specified). In addition, specific notations (e.g. “skin notation”, “skin sensitiser”, etc.) are assigned, if appropriate. Details on the OEL system in Croatia, the procedure for setting exposure limits and the methodology are taken from questionnaire responses from this study). Croatia was not covered by earlier analyses (EU-OSHA, 2009; ISSA, 2014).

3.2.6 Cyprus

In Cyprus, there is a list of national OELs, and these are binding in character.

OELs are based on socio-economic and/or technical and/or health considerations and a national methodology publication is not available. The procedure for setting exposure limit values is a legislative process. Draft legislation is prepared by the Department of Labour Inspection based on the needs to promote health and safety at work. The draft is discussed with the Labour Advisory Body that represents employers and employees and that consults the Ministry of Labour Welfare and Social Insurance. Upon agreement with the Labour Advisory Body the draft legislation is submitted to a public consultation. The public consultation involves publishing the draft legislation on the departmental webpage, sending it to industrial federations, other governmental bodies and other committees. The conclusions of the public consultation along with an impact analysis are sent to the Ministry of Labour Welfare and Social Insurance and forwarded to the Law Office of Cyprus for legislative control. The final draft of the legislation along with an explanatory statement and the completed impact analysis is submitted to the Ministerial Cabinet for approval. Once, it is approved by the Ministerial Cabinet the Minister of Labour Welfare and Social Insurance submits it to the Parliament for adoption. If the legislation is adopted by the Parliament it is then published in the governmental gazette.

The list of OELs is updated when need arises. The list of OELs in Cyprus generally also includes short-term limit values (STELs) which are adopted from other countries, if appropriate. Deviating from international STELs, STELs in Cyprus are established for 15 min/period, but not to 4 periods per day and a minimum distance between periods of 60 minutes. In addition, specific notations (e.g. “skin notation”, “skin sensitiser”, etc.) are assigned.

Details on the OEL system in Cyprus, the procedure for setting exposure limits and the methodology are taken from questionnaire responses (this project). Cyprus was not covered by earlier analyses (EU-OSHA, 2009; ISSA, 2014).

3.2.7 Czech Republic

In the Czech Republic, there is a list of national OELs, which are binding in character. OELs are usually adopted from SCOEL. OELs are based on health considerations. A national methodology publication is not available. However, the Czech Republic reports to have a documented methodology for the scientific evaluation of substances. OELs are proposed by the Committee for Occupational Exposure Limits of the National Institute of Public Health in Prague (OEL Commission; members of the Commission are appointed also to assess health risk of chemicals and biocides), further discussed at the Government Council for Safety, Hygiene and Health at Work.

The list of OELs is updated when need arises. The list of OELs in the Czech Republic generally also includes short-term limit values (STELs) which are adopted from other countries, if appropriate. In addition, specific notations (e.g. “skin notation”, “skin sensitiser”, etc.) are assigned.

Details on the OEL system in the Czech Republic, the procedure for setting exposure limits and the methodology are taken from questionnaire responses (this project). The Czech Republic was also covered by an earlier analysis (EU-OSHA, 2009). It should be noted that this supplemental information is from an earlier publication and therefore may not reflect the most recent status.

3.2.8 Denmark

In Denmark, there is a list of national OELs, and these are binding in character

For implementing EU OELs there is a standard practice: when EU OELs are lower than the national OEL, EU OELs are implemented; and when national OELs are lower than EU OELs, the national OELs

are maintained. These OELs enter national regulation as part of the usual legislative process, where the social partners are consulted. When setting national OELs, the Working Environment Authority gets the documentation from experts from the National Research Institute for the Working Environment and/or from the Nordic Expert Group. This documentation is then processed in a committee consisting of qualified experts and representatives from the social partners. The "Quality Group" consists of scientific experts from the following research institutes, for consultation: National Research Centre for Working Environment, Danish Working Environment Authority, Danish Veterinary and Food Administration, Department of Environmental Medicine, Odense University, Department of Working Medicine, Aarhus, and Danish Environmental Protection Agency. The proposed OEL then enters the usual legislative process as described for the EU OELs.

There is a national methodology to derive OELs, but the respective publication was not available for evaluation. OELs are mainly health-based, but technical and socio-economic considerations can be included in setting the value. For carcinogens, Denmark is considering an acceptable risk as an excess cancer risk of 1:1,000,000 or in special cases 1:100,000 for working lifetime exposure. The list of OELs is updated when need arises, usually, when implementing EU OELs. In Denmark, the list of OELs generally also includes short-term limit values (STELs). However, the setting of STELs in Denmark is different to international STELs because the binding OEL (8 hours) is multiplied by two and must never be exceeded over a period of 15 minutes. In addition, specific notations (e.g. "skin notation", "skin sensitiser", etc.) are assigned.

Details on the OEL system in Denmark, the procedure for setting exposure limits and the methodology are taken from questionnaire responses (this project). Some supplemental information was provided by another report (EU-OSHA, 2009). It should be noted that this supplemental information is from earlier publications and therefore may not reflect the most recent status.

3.2.9 Estonia

In Estonia, there is a list of national OELs, which are binding in character. OELs are usually adopted from other countries (not specified) and based on socio-economic and/or technical and/or health considerations. A national methodology publication is not available. The procedure in Estonia for setting exposure limit values is not reported in detail. The list of OELs is updated when need arises. In Estonia, the list of OELs generally also includes short-term limit values (STELs) and is adopted from other countries (e.g. Sweden), if appropriate. In addition, specific notations (e.g. "skin notation", "skin sensitiser", etc.) are assigned, if appropriate.

Details on the OEL system in Estonia, the procedure for setting exposure limits and the methodology are taken from questionnaire responses (this project). Estonia was covered by an earlier analysis (EU-OSHA, 2009), however, with no additional data to be considered in this report.

3.2.10 Finland

In Finland, there are two types of exposure limits. EU indicative OELV values are transposed and additional national indicative OELV values are given as HTP values (Haitalliseksi tunnettu pitoisuus; concentrations known to be harmful) for more than 400 substances by a decree of the Ministry of Social Affairs and Health. EU binding OELVs (only 5 at the moment) are transposed separately (by three different decrees).

The legal status of the HTP values differs from the binding values as by law the "employer shall take HTP values into account when assessing the quality of the workplace air, the exposure of employees and the significance of measurement results".

The criteria documents for the substances are prepared by experts from the Finnish Institute of Occupational Health. The experts propose health-based values, which are calculated on a case by case basis, meaning that no fixed uncertainty/assessment factors have been set. There are no fixed acceptable risk levels for non-threshold substances (e.g. genotoxic carcinogens). SCOEL recommendations and other relevant documents (e.g. MAK or ACGIH documents) are part of the data used as background information. The criteria documents are accepted in a tripartite working party of the tripartite "Advisory board on preparation of occupational safety regulations". The working party also suggest a limit value usually based on the health-based values proposed by the experts, but socio-economic issues may in some cases have an impact on the HTP values. Officially, the final decision on which value to propose to the Ministry of Social Affairs and Health is done by the "Advisory board on preparation of occupational safety regulations", which, in practise, follows the advice given by the working party.

A national methodology publication exists, but was not available for analysis. The decree including the list of HTP values (concentrations known to be harmful; see A1) is updated every other year. In Finland, the list of OELs generally also includes short-term limit values (STELs), if appropriate. In addition, specific notations (e.g. "skin notation", "skin sensitiser", etc.) are assigned, if appropriate.

Details on the OEL system in Finland, the procedure for setting exposure limits and the methodology are taken from questionnaire responses (this project). Some information was also found in other reports (EU-OSHA, 2009; ISSA, 2014), but does not add to the results of the actual analysis.

3.2.11 France

In France, OELs (Valeurs limites d'exposition professionnelle, VLEP) are set by the Ministry of Employment and Solidarity. There are currently two categories of regulatory OELs set by decree:

- Binding VLEPs set by decree from the Council of State (Conseil d'Etat). They are determined for the most hazardous chemicals for which exposure can be measured with validated methods;
- Recommended VLEPs set by decree in relation to the French Labour Code. Sometimes, recommended VLEPs correspond to very hazardous chemicals for which exposure can be measured only with partially validated methods.

After endorsement, the VLEPs are published in the French Official Journal and in the publications of the Institute National de Recherche et de Sécurité (INRS). INRS publishes some of the VLEPs on the internet (www.inrs.fr).

The French system for regulatory OELs is based on risk assessment being separated from risk management, and consists of three different steps:

- The French Agency for Food, Environmental and Occupational Health and Safety (ANSES) proposes VLEPs to the Ministry of Employment and Solidarity. Those VLEPs result from the work of the ANSES-VLEP committee (CES VLEP);
- The Ministry decides whether or not to take the VLEPs recommended by ANSES into account, and, where applicable, prepares a draft decree;

- That draft is then submitted for advisory notice to the French steering committee for working conditions (COCT). This step enables the social partners (employers and employees) to propose delayed application of the regulatory VLEPs in view of technical or economic feasibility problems.

The ANSES-VLEP committee is made up of independent scientific experts appointed for three years by the ANSES scientific committee, after a public call to recruit.

These tasks are conducted by the VLEP committee using a methodology developed by the experts and published by ANSES (ANSES, 2014).

In France, the list of OELs generally also includes short-term limit values (STELs). In addition, specific notations (e.g. "skin notation", "skin sensitiser", etc.) are assigned, if appropriate.

No details on the OEL system in France, the procedure for setting exposure limits and the methodology were available from questionnaire responses (this project). Therefore, details are adopted from ISSA (2014).

3.2.12 Germany

In Germany, there is a list of national OELs and all health-based OELs are binding. "Tolerated concentrations" for carcinogenic substances (see below) have legal consequences comparable to an OEL. "Accepted concentrations" for carcinogenic substances still underlie the minimisation principle but minimisation is not enforced for proportionality reasons. Concentrations above the accepted concentrations (but below the tolerated concentration) are tolerated for a certain time as long as a plan for reduction has been set up at company level and peak exposures are avoided (by PPE if necessary). So these values could be regarded as "indicative".

A subgroup of the Hazardous Substances Committee (HSC) prepares the values, HSC discusses and accepts the values and the Ministry accepts and publishes the values. HSC is tripartite and established as an advisory committee to the Ministry of Labour and Social Affairs by Hazardous Substance Ordinance (HSO). Compliance with an OEL is stipulated in the HS-Ordinance.

In Germany, OELs are based on a specific methodology (AGS, 1998; 2010). In many cases the recommendations for health-based OELs (MAK values derived by MAK Commission) or the European Union (IOELVs) form the basis for proposals for inclusion into TRGS 900.

There is also a methodology with regard to carcinogenic substances. Details on the methodology for carcinogens are provided in a guidance document (AGS, 2008; 2013; 2014). For carcinogens, no OELs are derived. However, excess risk from cancer is quantified and specific concentrations are regarded as "tolerable" (usually 4:4000) or "acceptable" (target: 4:100,000; interim: 4:10,000). Health-based OELs are also calculated for carcinogens, but only become effective, if lower than the "tolerable risk" concentration from carcinogenic effects. In this case, the non-cancer health-based OEL becomes "binding" (upper limit). However, exposure reduction is still requested, as indicated by the "acceptable" cancer risk concentration ("indicative").

The list of OEL is published regularly, but updated only if new data are available and assessed (meeting of decision panel: twice/year).

In Germany, the list of OELs generally also includes short-term limit values (STELs). The methodology is briefly covered in the annual list of OELs (e.g., AGS, 2016). STEL are indicated together with the limit value TRGS 900 and TRGS 910 by multiplication of the OEL with excursion factors

("Überschreitungsfaktoren"). In addition, specific notations (e.g. "skin notation", "skin sensitiser", etc.) are assigned, if appropriate[4].

Details on the OEL system in Germany, the procedure for setting exposure limits and the methodology are taken from questionnaire responses (this project). Some information was provided by other reports (EU-OSHA, 2009; ISSA, 2014), but does not add to the results of the actual analysis.

3.2.13 Greece

In Greece, there is a list of national OELs, which are binding in character.

Binding OELs are set according to the relative EC legislation for OELs and updated whenever this is amended. The limit values are included in national legislation (Presidential Decrees), which is issued after a social dialogue process with the interested parties (workers and employers organisations, scientific bodies, etc). Also, another source of limit values that has been used in the past (before 2000) is the American Conference of Governmental Industrial Hygienists (ACGIH). These limit values are still valid, except for those that have been revised by the EC.

A national methodology publication is not available. The list of OELs is updated when needed. In Greece, the list of OELs generally also includes short-term limit values (STELs). In addition, specific notations (e.g. "skin notation", "skin sensitiser", etc.) are assigned, if applicable.

Details on the OEL system in Greece, the procedure for setting exposure limits and the methodology are taken from questionnaire responses (this project). Some information is also provided by another report (EU-OSHA, 2009), but does not add to the results of the actual analysis.

3.2.14 Hungary

In Hungary, there is a list of national OELs, which are binding in character. A national methodology publication is not available; however, it is stated that there exists a national methodology and that some methodological aspects may be addressed within the published national list of OELs. OELs are health-based. No further details on the procedure for setting exposure limit values are available.

In Hungary, the list of OELs generally also includes short-term limit values (STELs), if appropriate. In addition, specific notations (e.g. "skin notation", "skin sensitiser", etc.) are assigned, if appropriate.

Details on the OEL system in Hungary, the procedure for setting exposure limits and the methodology are taken from questionnaire responses (this project). No supplemental information was provided in other reports (EU-OSHA, 2009; ISSA, 2014).

3.2.15 Ireland

In Ireland, there is a list of national OELs, which are binding in character.

OELs in Ireland are adopted from other countries: indicative OELVs, binding OELVs and TLVs from the ACGIH. These are implemented through updates of the Irish Code of Practice for the Safety, Health

[4] http://onlinelibrary.wiley.com/doi/10.1002/3527600418.mb0hmrkkrie5617/pdf

and Welfare at Work (Chemical Agents) Regulations 2001, in accordance with the procedure for publishing Codes of Practice under our Safety, Health and Welfare at Work Act 2005[5].

No further details were available on the procedure for setting exposure limit values. A national methodology publication is not available. OELs are mainly health-based, but technical and socio-economic considerations can be included, when implementing IOELVs and BOELVs. The list of OELs is updated but less often than every year.

In Ireland, the list of OELs generally also includes short-term limit values (STELs), if appropriate. In addition, specific notations (e.g. "skin notation", "skin sensitiser", etc.) are assigned, if appropriate.

Details on the OEL system in Ireland, the procedure for setting exposure limits and the methodology are taken from questionnaire responses (this project). No supplemental information was provided by other reports (EU-OSHA, 2009; ISSA, 2014).

3.2.16 Italy

In Italy, there is a list of national OELs, which are usually adopted from thr ACGIH. No further details are available. However, some framework information may be available from the national list of OELs.[6]

In Italy, OELs are called "Valori limite di esposizione professionale"(VLEPs). They are set by decree, approved jointly between the Ministro del Lavoro e delle Politiche Sociali (Ministry of Labour and Social Affairs) and the Ministro della Salute (Ministry of Health).

VLEPs are set with the support of the Advisory Committee for the development and updating of occupational exposure limit values and biological limit values for chemical agents, and in agreement with the Permanent Conference for relations between the State, the regions and the autonomous provinces of Trento and Bolzano.

The Advisory Committee was set up by decree in the year 2011 and, among its tasks, it has to provide an advisory service to the Ministry of Labour and to the Ministry of Health on the implementation at national level of exposure limit values proposed in European Union directives.

No details on the OEL system in Italy, the procedure for setting exposure limits, and the methodology used were available from the consultation. The reported data are cited from an earlier analysis (ISSA, 2014).

3.2.17 Latvia

In Latvia, there is a list of national OELs, which are binding in character. OELs are usually adopted from the Board of Nordic Countries, the Russian Commission on Occupational Health and OEL setting and the German MAK-values. A national methodology publication is not available.

According to published sources, Latvia also has a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors. Usually, the Institute of Occupational Safety and Environmental Health, Social partners such as the Free Trade Union Confederation of Latvia and the Employers' Confederation of Latvia participate in elaboration

[5] http://www.hsa.ie/eng/Legislation/Codes_of_Practice/Code_of_Practice_for_the_Chemical_Agents_Regulations_2016/

[6] www.gazzettaufficiale.it/eli/gu/2012/09/18/218/sg/pdf

of drafting of legal acts (Cabinet regulations, Law). Other specialists are welcome, if there is a necessity to discuss specific issues. As the Ministry of Welfare of the Republic of Latvia is responsible for transposition of EU directives, the Ministry involves other stakeholders in discussions regarding new OELs. Discussions are performed within the Technical Committee No. 19 "Work Environment" of the National Standardisation body "Latvijas Standarts".

OELs are health-based and include quantitative cancer risk considerations in the case of (genotoxic) carcinogenic substances. For carcinogens, Latvia reports to have adopted criteria on the acceptability of risk, however, no details are available. The list of OELs is updated when need arises. In Latvia, the list of OELs generally also includes short-term limit values (STELs), if appropriate. In addition, specific notations (e.g. "skin notation", "skin sensitiser", etc.) are assigned, if appropriate.

Details on the OEL system in Latvia, the procedure for setting exposure limits and the methodology are taken from questionnaire responses (this project). Some supplemental information was provided by other reports (EU-OSHA, 2009; ISSA, 2014). It should be noted, that this supplemental information is from earlier publications and therefore may not reflect the most recent status.

3.2.18 Lithuania

In Lithuania, there is a list of national OELs which are binding in nature. A national methodology publication is not available. The OELs are usually adopted from other countries (e.g., Sweden and Soviet Union research institutes).

Interests of the state, workers, and employers in relation to establishing occupational exposure limit values for chemical substances, are combined through the Occupational Health and Safety Commission, established following the principle of tripartite cooperation between social partners (parties), which operates under the regulations of the Occupational Health and Safety Commission, approved by Resolution No. 13 of the Government of the Republic of Lithuania of 9 January 2002. The Commission examines draft legislation, makes recommendations, and proposals to the Ministry of Social Security and Labour, the Ministry of Health, other state institutions and bodies.

OELs are health-based and include quantitative cancer risk considerations in the case of (genotoxic) carcinogenic substances. However, OELs in Lithuania do also consider technical feasibility and socio-economic considerations. The list of OELs is updated when need arises. In Lithuania, the list of OELs generally also includes short-term limit values (STELs), if applicable. In addition, specific notations (e.g. "skin notation", "skin sensitiser", etc.) are assigned, if applicable.

Details on the OEL system in Lithuania, the procedure for setting exposure limits and the methodology are taken from questionnaire responses (this project). Supplemental information was provided by other reports (EU-OSHA, 2009; ISSA, 2014), with no additional data to be considered in this report.

3.2.19 Luxembourg

In Luxembourg, there is a list of national OELs, which have a binding character. The OELs are usually adopted from other countries (not specified). A national methodology publication is not available. The list of OELs is updated if need arises.

In Luxembourg, the list of OELs generally does not include short-term limit values (STELs). However, specific notations (e.g. "skin notation", "skin sensitiser", etc.) are assigned.

No details on the OEL system in Luxembourg, the procedure for setting exposure limits, and the methodology used were available from the consultation. Some supplemental information was provided by other reports (EU-OSHA, 2009; ISSA, 2014). In response to the earlier questionnaire on OELs for carcinogens, Luxembourg did not make a reference to a consultation process linked to the derivation of OELs. It should be noted, that this supplemental information used by the previous studies may no longer reflect the most recent status.

3.2.20 Malta

In Malta, there is a list of national OELs, but no information is available on whether they are binding or indicative in nature. A national methodology publication is not available. In Malta, the procedure for setting exposure limit values is not reported.

No details on the OEL system in Malta are available from the consultation. Malta was not covered by earlier analyses (EU-OSHA, 2009; ISSA, 2014).

3.2.21 The Netherlands

In the Netherlands, the new OEL system (since 2007) is based on private OELs, i.e. OELs that are set by individual companies themselves. Employers and employees are responsible for dealing safely with substances in the workplace. This means that they must together set OELs to prevent damage to the employees' health owing to exposure to particular substances.

In addition to these private OELs, the Ministry of Social Affairs and Employment sets public (i.e. statutory) OELs for the following substances:

- Substances for which the EU requires limit values (in practice, these are Binding Occupational Limit Values and Indicative Occupational Limit Values); and
- Substances for which it is not expected that the EU will require a limit. This group comprises substances 'without owners' and substances with a large chance of causing damage to health (high-risk substances), including those for which the government deems it necessary to establish a public limit.

A public (i.e. statutory) OEL is set based on:

- An IOELV or BOELV set by the European Commission. These are usually based on the recommendations of the Scientific Committee on Occupational Exposure Limits (SCOEL), but these national OEL may differ from the EU IOELV; and
- A report by the Dutch Health Council. The Ministry of Social Affairs and Employment creates a Working Programme for this, and issues a request for advice to the SER's Working Conditions Committee. The Ministry's current position is that a statutory OEL can only be determined once the Health Council has made a recommendation.

Public OELs are listed in Appendix XIII of the Working Conditions Regulations. Appendix XIIIA covers non-carcinogens, and Appendix XIIIB carcinogens.

In principle, all OELs within the new system (i.e. both private and public OELs) are health-based OELs, with the exception of OELs for carcinogenic and mutagenic substances for which no safe health-based OEL can be set. These substances will continue to be subject to feasibility tests and the results of the tests will play an important role in establishing OEL levels. For carcinogens, the Netherlands have adopted criteria based on the acceptability of risk.

A national methodology publication on health-based OELs is not available. However, such a methodology is published for carcinogens (Gezondheidsraad, 2010).

In the Netherlands, the list of OELs generally also includes short-term limit values (STELs), if applicable. In addition, specific notations (e.g. "skin notation", "skin sensitiser", etc.) are assigned, if applicable.

No details on the OEL system in the Netherlands, on the procedure for setting exposure limits and the methodology were are available from the consultation. The above information is therefore cited from an internet presentation of the Dutch OEL system[7]. More details are available from the referenced website. Furthermore, supplemental information may be found in other reports (EU-OSHA, 2009). It should be noted, that this supplemental information may not reflect the most recent status, specifically, as the Netherlands have changed their system in 2007 and the report from OSHA is based on a questionnaire from 2007.

3.2.22 Poland

In Poland, there is a list of national OELs, which have a binding character. A national methodology publication is available (Skowron and Czerczak, 2015).

Depending on the reference periods, they are called:

- NDS (najwyższe dopuszczalne stężenie), a time weighted average concentration for an eight-hour workday;
- NDSCh (najwyższe dopuszczalne stężenie chwilowe), an average concentration over 15 minutes that may be reached only twice a day, at intervals not shorter than one hour;
- NDSP (Najwyższe dopuszczalne stężenie pułapowe), the maximum admissible ceiling concentration; and
- NDN (najwyższe dopuszczalne natężenie), the maximum admissible intensity.

The Polish OEL value proposition is the documentation of occupational exposure limits developed by the Group of Experts for Chemical and Aerosol Agents of the Interdepartmental Commission for Maximum Admissible Concentrations and Intensities for Agents Harmful to Health in the Working Environment.

The maximum admissible concentrations (MACs) for chemical compounds were set up in 1983 by the Minister of Labour and Social Policy together with the Minister of Health and Social Welfare. The Secretariat of the Commission is located in CIOP-PIB. The Commission includes representatives of health and labour administration, various sectors of industry, trade unions and research institutes in the fields of occupational safety and medicine. The main responsibility of the Commission is the submission of the documented proposals of exposure limits for chemical and physical agents in the working environment to the Minister of Labour and Social Policy, who is responsible for the introduction of those values into legislation. Moreover, the Commission proposes methods of chemical agents measurement, which are standardized by the Polish Committee for Standardization and, and if sufficient data exist, the biological limit values (BLV) are promulgated by the Minister of Health.

[7] https://www.ser.nl/en/oel_database/oel_system.aspx

For carcinogens, the Polish MAC Commission has adopted a socially accepted risk at the level of 10^{-4} to 10^{-3}. That means that Polish society has accepted the possibility of the extra risk of one cancer per 10 000 or 1000 people exposed to a carcinogenic substance (Skowron and Czerczak, 2015).

The list of OELs is updated yearly. In Poland, the list of OELs generally also includes short-term limit values (STELs). However, the setting of STELs in Poland is different to international STELs because the 15 minutes period should not occur more than twice during a workday instead of 4 periods per day for international STELs.

Specific notations (e.g. "skin notation", "skin sensitiser", etc.) are assigned, where indicated. Where the contact of chemicals with skin can add significantly to the body burden in addition to that caused by inhalation, a skin notation should be used. In Poland, the skin notation was set mainly based on a dermal LD50 being below 1000 mg/kg and it occurs only in the Commission booklet "Harmful agents in the working environment – limit values" (Skowron and Czerczak, 2015).

Details on the OEL system in Poland, the procedure for setting exposure limits and the methodology are taken from questionnaire responses (this project). Some supplemental information was provided by other reports (ISSA, 2014). It should be noted, that this supplemental information is from earlier publications and therefore may not reflect the most recent status.

3.2.23 Portugal

In Portugal, there is a list of national OELs, which are indicative in character. A national methodology publication is not available.

OELs are based on the ACGIH values from 2014, except for those that have specific European legislation. Besides the adoption of the European OELs, the Process of Standardization on Chemicals is developed by a Technical Commission where several experts from Authority for Working Conditions and other public and private entities take part.

The list of OELs generally also includes short-term limit values (STELs). Specific notations (e.g. "skin notation", "skin sensitiser", etc.) are assigned, if applicable. The list of OELs is updated as and when need arises.

Details on the OEL system in Portugal, the procedure for setting exposure limits, and the methodology are taken from questionnaire responses (this project).

3.2.24 Romania

In Romania, there exists a list of national OELs. No further information on the binding or indicative character is available. A national methodology publication is not available.

The procedure for setting exposure limit values in Romania is not reported.

No details on the OEL system in Romania are available from questionnaire responses (this project), and Romania was not covered by earlier analyses (EU-OSHA, 2009; ISSA, 2014).

3.2.25 Slovakia

In Slovakia, there is a list of national OELs. A national methodology publication is not available. Most OELs have been adopted from MAK (Germany), the UK, Sweden or the Netherlands. OELs are mainly

health-based, but technical and socio-economic considerations can be included, when implementing IOELVs and BOELVs.

A board of experts for occupational health from the Department of Occupational Health in the Public Health Authority of the Slovak Republic and from Regional Authority of Public Health in Banská Bystrica is in charge to follow the EU directives, to develop and prepare a professional draft documents or to transpose appropriate OSH directives. Pre-legislative consultation by social partners is part of the preparatory procedure for the adoption of limits. During the legislative procedure, all stakeholders have the right to comment on the proposal.

For carcinogens, Slovakia reports to have adopted criteria on the acceptability of risk and reports having a specific procedure for the revision of OELs for carcinogenic and mutagenic substances. Slovakia is affirmative about a procedure, but makes reference to having adopted German TRK values and limit values from other Member States and the EU, not having a national scientific committee in place (EU-OSHA, 2009).

The list of OELs generally also includes short-term limit values (STELs). Specific notations (e.g. “skin notation”, “skin sensitiser”, etc.) are assigned, if applicable (EU-OSHA, 2009).

Details on the OEL system in Slovakia, the procedure for setting exposure limits, and the methodology are taken from questionnaire responses (this project). Some supplemental information was provided by other reports (EU-OSHA, 2009). It should be noted, that this supplemental information is from an earlier publication and therefore may not reflect the most recent status.

3.2.26 Slovenia

In Slovenia, there is a list of national OELs, which have a binding character. OELs in Slovenia are usually adopted from other countries (mainly Germany; TRGS 905 for carcinogens). Therefore, a procedure for setting exposure limit values does not exist. A national methodology publication is not available. However, changes are indicated: “After the new EU directive is coming into force, the new draft is prepared. After negotiations with social partners, a new regulation is published.”

OELs are based on socio-economic and/or technical and/or health considerations (aggregate assessment). However, Slovenia indicated in an earlier questionnaire that they do not have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors (EU-OSHA, 2009).

The list of OELs is updated if need arises. The list of OELs in Slovenia generally also includes short-term limit values (STELs), if applicable. In addition, specific notations (e.g. “skin notation”, “skin sensitiser”, etc.) are assigned, if applicable.

Details on the OEL system in Slovenia, the procedure for setting exposure limits, and the methodology are taken from questionnaire responses (this project). Some supplemental information was provided by other reports (EU-OSHA, 2009). It should be noted, that this supplemental information is from an earlier publication and therefore may not reflect the most recent status.

3.2.27 Spain

In Spain, there is a list of national OELs, which have a binding character.

The Working Group for defining the OELs (National Institute for Security, Health and Welfare (INSSBT) at Work) does not following a specific methodology. The working group (Grupo de Trabajo de la Comisión Nacional de Seguridad y Salud en el Trabajo) includes representatives of:

- the Spanish Ministry of Energy, Tourism and Digital agenda, Ministry of Justice, Ministry of Health, Social Services and the Ministry of Employment and Social Security;
- Regional authorities in Spain;
- Business organizations (CEOE and CEPYME); and
- Trade unions CCOO and UGT.

They study different sources of information and then decide which one to use. The main ones are:

- Occupational Exposure Limits. Recommendations of Scientific Committee for Occupational Exposure Limits (SCOEL) to Chemical Agents;
- Deutsche Forschungsgemeinschaft (DFG): List of MAK and BAT (VCH Verlagsgesellschaft, Weinheim (Germany));
- Institut Für Arbeitsschutz Der Deutschen Gesetzlichen Unfallversicherung (IFA) database on hazardous substances. GESTIS - International limit values for chemical agents;
- International Agency For Research On Cancer (IARC);
- American Conference of Governmental Industrial Hygienists (ACGIH); and
- Dutch Expert Committee for Occupational Standards (DECOS).

Most of the existing OELs have been derived for non-carcinogenic properties, except for the ones that have been included in the CMD or were adopted from other countries.

There is no standard procedure to consider also socio-economic and/or technical considerations (mainly because they do not have information for example regarding number of workers exposed to the agents in Spain).

According to Royal Decree 374/2001, the National Institute for Security, Health and Welfare (INSSBT) at Work annually publishes the OELs.

In Spain, the list of OELs generally also includes short-term limit values (STELs; Exposición de corta duración). In addition, specific notations (e.g. “skin notation” (via dérmica), “skin sensitiser” (notación de sensibilizante), etc.) are assigned, if appropriate.

Details on the OEL system in Spain, the procedure for setting exposure limits and the methodology are taken from questionnaire responses (this project). Some supplemental information was provided by other reports (EU-OSHA, 2009), however, with no additional data to be considered in this report.

3.2.28 Sweden

In Sweden, there is a list of national OELs, which have a binding character. A national methodology publication is available (Arbetsmiljöverket, 2005).

The Swedish Working Group starts the work with a criteria document for the substance in question (from the Nordic expert group or EU, SCOEL). The document is supplemented by scientific documentation with particulars of use, quantities, number of exposed workers and exposure levels at work situations. This information is collected from different sources:

- The Product register at the National Chemicals Inspectorate;
- General statistics concerning industry and trade;

- Contacts with wholesale traders and users;
- Information from industry and labour unions; and
- Reports from exposure measurements.

For the organisations to be able to discuss proposals with their associations and member companies, the time for the referral is normally three months. In general, Sweden makes a number of amendments thereafter, according to the points of view brought in by the consultation bodies.

The Authority proposes new limit values and makes assessments of the consequences of the proposal. For each substance, the assessment includes an evaluation of the positive health effects and if possible an estimation of the costs of necessary measures to comply with the proposed value.

For carcinogens without a health-based threshold, OELs are set with consideration for socio-economic factors.

The list of OELs is updated when need arises. In Sweden, the list of OELs generally also includes short-term limit values (STELs), if appropriate. In addition, specific notations (e.g. "skin notation", "skin sensitiser", etc.) are assigned, if appropriate.

Details on the OEL system in Sweden, the procedure for setting exposure limits and the methodology are taken from questionnaire responses (this project). Some supplemental information was provided by other reports (ISSA, 2014). It should be noted that this supplemental information is from earlier publications and therefore may not reflect the most recent status.

3.2.29 United Kingdom

In the United Kingdom (UK), there is a list of national OELs ("*EH40/2005 Workplace exposure limits"*[8]), some with a binding and some with an indicative character, which is updated when the need arises. A national methodology publication is not available as any new OELs are adopted from another country or organisation (primarily the relevant EU directives).

A new framework for implementing OELs was introduced by the Health and Safety Commission following an amendment to the Control of Substances Hazardous to Health (COSHH) Regulations 2002 (S.I. 2004 No. 3386) in 2005. This framework introduced the eight principles of good control practice and the new Workplace Exposure Limits (WEL), replacing the Occupational Exposure Standards (OESs) and Maximum Exposure Limits (MELs)[9]. Regulation 7(7) (of COSHH) puts the primary emphasis for achieving adequate control on the application of the eight principles introduced in Schedule 2A, followed by a duty not to exceed any relevant WEL[10]. WELs are referred to as a time-weighted average (TWA) exposure limits for long-term exposure (8 hours) or short-term exposure (STEL, 15 minutes).

For new OELs, the UK adopts those included in EU Directives developed using the EU Commissions process. The Working Party on Chemicals (WPC), a sub-group of the EU's tripartite Advisory Committee on Safety and Heath at Work (ACSH) - UK is one of only four governments represented – considers setting OELs for substances. The WPC opinions on appropriate exposure limit values for these substances are subsequently reviewed by the ACSH before the EU Commission makes proposals

8 www.aufficiale.it/eli/gu/2012/09/18/218/sg/pdf

9 HSE (2011): EH40/2005 Workplace exposure limits, available at http://www.hse.gov.uk/pubns/priced/eh40.pdf

10 HSE (2011): EH40/2005 Workplace exposure limits, available at http://www.hse.gov.uk/pubns/priced/eh40.pdf

for a new (or amended Directive). During the transposition process in which the EU directive is implemented the legally binding UK guidance (HSE publication: *EH40/2005*) is updated.

OELs have been derived for carcinogenic or non-carcinogenic properties, depending on the chemical agent. Similarly, some OELs are health-based, and some are risk-based, depending on the chemical agent in question. However, OELs in the UK also consider technical feasibility and socio-economic considerations (impact assessment is performed during implementation).

The publication, "*EH40/2005 Workplace exposure limits",* also includes short-term limit values (STELs), and specific notations (e.g. "skin notation", "skin sensitiser", etc.), if applicable. The methodology for setting STELs also follows the EU level process.

Details on the OEL system in the UK, the procedure for setting exposure limits, and the methodology are taken from questionnaire responses (this project), as well as publications by the UK's HSE.

3.3 Description of national OEL-deriving systems in non-EU third countries

3.3.1 Australia

OELs are established by Safe Work Australia. Safe Work Australia is tasked with developing Australia's National Model Work Health and Safety (WHS) laws including requirements for the classification of workplace hazardous chemicals using the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and publishing Workplace Exposure Standards (WES).

Exposure standards have been established in Australia for approximately 700 substances and mixtures. These are legal concentration limits that must not be exceeded.

The mandatory WES (equivalent to an OEL) are described in the document Workplace Exposure Standards for Airborne Contaminants (Safe Work Australia, 2013).

As a national policy body, Safe Work Australia does not regulate WHS laws. The Commonwealth, states and territories retain responsibility for regulating and enforcing WHS laws in their jurisdictions.

As described in a discussion paper from Safe Work Australia (2015) "A*ustralia's workplace exposure standards were first adopted from the standards set by the American Conference of Governmental Industrial Hygienists (ACGIH) in the 1980s by the National Health and Medical Research Council. They were first published by Safe Work Australia's predecessor the National Occupational Health and Safety Commission (NOHSC) in 1990. About 80 of the 644 standards were updated between 1995 and 2005 by NOHSC, however the vast majority have not been updated since they were adopted*".

According to the website of Safe Work Australia, the organisation is currently reviewing exposure standards to ensure they are based on the highest quality evidence and supported by a rigorous, scientific approach. During 2015, they held a public consultation process to examine the role of exposure standards and how they could be reviewed and maintained. In 2016, Golder Associates Pty Ltd was engaged to conduct an initial scientific evaluation of Australia's workplace exposure standards and provide a proposed revised list of exposure standards.

Building on this initial work, Safe Work Australia is now finalising three methodologies for sourcing exposure standard information, evaluating individual workplace exposure standards and revising the

list of airborne contaminants. This will ensure final recommendations are sound and supported by a robust evidence base. Throughout 2017, Safe Work Australia will develop and peer-review the methodologies both internally and with Health Canada. The methodologies will be made available to stakeholders when finalised. The methodologies are still not available.

In early 2018, Safe Work Australia will evaluate the list of workplace exposure standards according to the peer reviewed methodologies and develop the documentation required to support the recommendations for each airborne contaminant. Safe Work Australia expects to complete this work by mid-2018.

Details on the OEL system are obtained from consulting national experts and/or aggregated desk research, if not stated otherwise.

3.3.2 Brazil

Exposure limits in Brazil are given in the Tabela de Limites de Tolerância in Annex No. 11 of Regulatory Standard NR N-15 (see Annex I). The EOLs are established by the Ministry of Labour and Employment, Ministério do Trabalho e Previdência Social.

OELs, designated Limites de Tolerância (LET), are issued under the authority of Decree (Portaria) No.3214 of 8 June 1978, as amended subsequently.

Details on the OEL system are obtained from consulting national experts and/or aggregated desk research, if not stated otherwise.

3.3.3 Canada

In Canada, OELs are regulated within each of ten provinces and three territories. In the following, the situation in the two largest territories is addressed.

Ontario:
In Ontario, exposure limits are listed in Regulation 833, R.R.O. 1990 - Control of Exposure to Biological or Chemical Agents (see Annex I).

Proposed changes affecting the control of hazardous substances under the Occupational Health and Safety Act are made by the Ontario Ministry of Labour (MOL) and can be found at: https://www.labour.gov.on.ca/english/about/consultations/oels/index.php.

According to the Ministry of Labour: *"Consultation on the annual revised limits recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) is the foundation of the Ministry of Labour (MOL)'s OEL update process. Through this process, the MOL has successfully updated OELs for over 200 hazardous substances since 2004. This is the MOL's 11th consultation under the OEL update process. It is based on the ACGIH's annually recommended changes to OELs for the years 2014 and 201*5."

Québec:
In Québec, exposure limits are listed in Annex I of the Regulation respecting occupational health and safety (see Annex I, this document). The following terms are used.

- TWAEV: Time-weighted average exposure value: The time-weighted average concentration for an 8-hour workday and a 40-hour workweek of a chemical substance (in the form of gases, dusts, fumes, vapours or mists) present in the air in a worker's respiratory zone. For any work period equal to or longer than 4 hours but less than 8 hours or a period in excess of 8 hours but less than or equal to 16 hours, an adjusted average exposure value (AAEV) must be established in accordance with the guide to the adjustment of permissible exposure values for unusual work schedules, published by the Institut de Recherche Robert-Sauvé en santé et en Sécurité du Travail. Under no circumstance may the AAEV be higher than the TWAEV;
- STEV: Short-term exposure value: The 15-minute time-weighted average concentration for exposure to a chemical substance (in the form of gases, dusts, fumes, vapours or mists), present in the air in a worker's respiratory zone which should not be exceeded at any time during a workday, even if the time weighted average exposure value is not exceeded. The average exposure for a 15-minute consecutive period may be include between the TWAEV and the STEV, insofar as such exposures are not repeated more than 4 times a day and have intervals between them of periods of at least 60 minutes; and
- C: CEILING: The designation "C" in the STEV/Ceiling column refers to a concentration never to be exceeded during any length of time whatsoever.

The bipartite Board of Directors of the Québec Commission for Occupational Health and Safety (Commission de la santé et de la sécurité du travail – CSST) has given the task of revising the OEL list to a Joint Technical Committee (JTC). The JTC consists of employers, labour representatives and expert advisers. In principle, all substances listed by the U.S. organisation ACGIH are taken into account.

A guide for the adjustment of permissible exposure values (PEVs) for unusual works schedules describes the processes of TWAEV adjustment (Drolet, 2015). The guide was produced as a result of the work of numerous people during projects or activities conducted in the past in collaboration with the Department of Environmental and Occupational Health of the Université de Montréal (DSEST) and the Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST). Among others, it describes an Excel-based tool for TWAEV adjustment.

According to Deveau et al. (2015b), the ACGIH TLVs are adopted as de facto legally binding standards in many Canadian provinces.

No information on the OEL-deriving system in Québec has been identified.

Details on the OEL system are obtained from consulting national experts and/or aggregated desk research, if not stated otherwise.

3.3.4 China

According to China Chemical Inspection and Regulation Services (CIRS), OELs for hazardous chemicals are set by GBZ 2.1-2007 - "Occupational exposure limits for hazardous agents in the workplace." The standard was revised by the Ministry of Health in 2007 and implemented from 1 November 2007. The version used is an unofficial English translation obtained from Code of China, a professional Chinese code translator.

There are three types of OELs for hazardous chemicals in China (GBZ, 2007).

- Maximum allowable concentration (MAC): The concentration of toxic chemicals that cannot be exceeded at workplace at any time within a working day;
- Permissible concentration-time weighed average (PC-TWA): The average allowable exposure concentration of an 8-hour working day and 40-hour week; and
- Permissible concentration short-term exposure limit (PC-STEL): The allowable exposure concentration in short time (15min) under the premise of complying with PC-TWA.

As of 2011, China had issued 398 workplace health standards for occupational hazardous agent exposure, including 339 for chemicals, 47 for particulates and dusts, 2 for biological agents and 10 for physical factors.

The OELs are not regularly updated; the most recent standard is from 2007.

In China, the process for developing OELs is described in Figure 3-1 from Singh (2010).

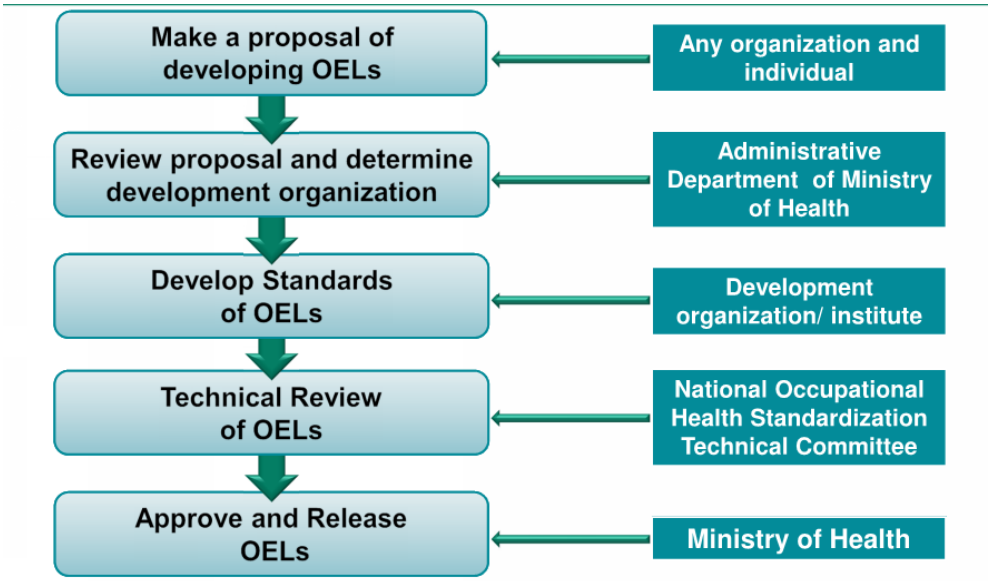

Figure 3-1: The process for developing of OELs in China
Source: Singh (2010)

Chief Drafting Organizations ("development organization/institute" in the figure) of the current standard are (GBZ, 2007):

- Occupational Health and Poison Control Institute of and Chinese Center for Disease Control and Prevention, School of Public Health of Fudan University;
- Tongji School of Public Health of Huazhong University of Science and Technology;
- School of Public Health of Peking University; and
- The China National Institute of Standardization develops and distribute the standards[11].

[11] Evans, P & Piney, M. (WATCH) (2006): COSHH 2002 (as amended) and effective control of exposure, available at http://www.hse.gov.uk/aboutus/meetings/iacs/acts/watch/091106/p6annex1.pdf

The OELs are established on the basis of the "Guide for establishing occupational exposure health standards" issued by the Ministry of Health of the People's Republic of China (GBZ, 2008).

The general parts of the guidance translated for the purpose of this study specify that limit values are established taking into account, between others:

- Scientific/health based information (incl. physicochemical, toxicological, epidemiological information);
- Limit values in other countries (their possible applicability for the Chinese situation is assessed in feasibility studies); and
- Socio-economic considerations: "Recommended occupational exposure limits and establishment basis (including basic data or fact and expected protection level) are proposed on the basis of fully considering the economical-technical feasibility of China …"

Details on the OEL system are obtained from consulting national experts and/or aggregated desk research, if not stated otherwise.

3.3.5 India

Worker Health & Safety is regulated under the Factories Act, 1948 (amended in 1987) and extends to the whole of India. The enforcement of the rules is the responsibility of the states as in the case of environmental regulations (Singh, 2010).

The Factories Act, 1948, 41-F sets Permissible Limits of Exposure of Chemical and Toxic Substance (see Annex I).

The Directorate General, Factory Advice and Labour Institutes (DGFASLI) is a technical arm of the Government of India under the Ministry of Labour and advises on matters related to safety, health, and welfare of workers in factories and docks. It was set up with the objective of advising Central and state governments on administration of the Factories Act and coordinating the factory inspection services in the states.

Details on the OEL system are obtained from consulting national experts and/or aggregated desk research, if not stated otherwise.

3.3.6 Japan

According to Takahashi and Higashi (2006) "The Ministry of Health, Labour and Welfare, on an administrative basis, establishes and supervises the Administrative Concentration Level (ACL), which can be viewed as an Occupational Exposure Limit (OEL) legally binding employers to maintain a good working environment. The Japan Society for Occupational Health (JSOH), on a scientific basis, establishes the recommended OELs, which can be viewed as a reference value for preventing adverse health effects on individual workers. In the case of carcinogens, reference values are recommended instead of OELs, corresponding to a lifetime excessive risk of 10^{-3} and 10^{-4}. The former is based on monitoring of the ambient working environment (area monitoring) while the latter is based on the

[11] Evans, P & Piney, M. (WATCH) (2006): COSHH 2002 (as amended) and effective control of exposure, available at http://www.hse.gov.uk/aboutus/meetings/iacs/acts/watch/091106/p6annex1.pdf

[11] http://en.cnis.gov.cn

monitoring of the individual worker. The two OELs influence each other in the course of establishment."

Administrative Control Levels (ACL) for chemical substances are occupational standards, which are legally binding. They are established and updated by a national expert meeting convened on an ad hoc basis when deemed necessary by the Japanese Ministry of Health, Labour and Welfare in response to new scientific knowledge.

As a general rule, the expert meeting organised by the Ministry discusses:

- Threshold Limit Values (TLV) originating from the American Conference of Governmental Industrial Hygienists (ACGIH); and
- Occupational Exposure Limits (OEL) originating from Japan Society for occupational Health (JSOH).

It then determines values of its own.

The Japan Society for Occupational Health (JSOH) recommends the Occupational Exposure Limits (OELs) as reference values for preventing adverse health effects on workers caused by occupational exposure to chemical substances, continuous or intermittent noise, impulsive or impact noise, heat stress, cold stress, whole-body vibration, hand-arm vibration and time-varying electric, magnetic and electromagnetic fields and ultraviolet and ionizing radiation. JSOH is a non-governmental academic society of occupational health professionals (academics and practitioners). The recommended OELs are published in English in Journal of Occupational Health (JSOH, 2016).

Occupational Exposure Limit-Mean (OEL-M) for mean concentration of a chemical substance is defined as the reference value to the mean exposure concentration at or below which adverse health effects caused by the substance do not appear in most workers working for 8 hours a day, 40 hours a week under a moderate workload. Occupational Exposure Limit-Ceiling (OEL-C) of occupational exposure to a chemical substance is defined as the reference value to the maximal exposure concentration of the substance during a working day.

JSOH's Committee for Recommendation of Occupational Exposure Limits is a permanent subcommittee within the Society to which the above function has been delegated, together with that of assessing carcinogenicity and allergenicity. During preparation of OEL proposals, the Committee members give serious consideration to the TLVs proposed by ACGIH. Moreover, JSOH makes every effort to add its own perspective, particularly by considering recent and domestic publications.

As described by JOSH (2016) "*JSOH classifies the occupational carcinogens based primarily on the epidemiological evidences, but the results of the animal experiments and their extrapolation to human are also considered. The classification is made by strength of the evidence, but does not reflect the carcinogenic potency.*

JSOH considers that the classification of occupational carcinogens proposed by the International Agency for Research on Cancer (IARC) is appropriate in principle. JSOH also discussed the classification of several agents based on other information sources and finalized the list of occupational carcinogens in Table III-1a, b, c. Group 1 includes the agents which are carcinogenic to humans. Group 2 indicates the agents which are probably or possibly carcinogenic to humans, classifying them into two sub-

groups on the basis of degree of evidence: Group 2A is assigned to the agents with more sufficient evidence (probably carcinogenic to humans), Group 2B to those with less."

Details on the OEL system are obtained from consulting national experts and/or aggregated desk research, if not stated otherwise.

3.3.7 South Korea

The Ministry of Employment and Labour (MOEL) establishes and publishes OELs based on the Industrial Safety and Health Act (ISHA).

The first set of OELs in 1986 was identical to the Threshold Limit Values (TLVs) for the American Conference of Governmental Industrial Hygienists (ACGIH) at that time. Until 2006, there were the OELs for only three chemicals. From 2005 to 2006, the MOEL provided larger research funds to toxicological laboratories and academic institutions to gather and review data that would guide the revision of the outdated OELs (Jeong et al., 2010).

The Hazardous Agents Review Committee (HARC) established under the MOEL by the ISHA reviewed these research results and the MOEL notified revised OELs for 126 chemicals from 2007 to 2008.

A total of 656 chemicals have OELs under OSHA in South Korea (Park et al., 2015). The numbers of chemicals, which have eight-hour time weighted average (TWA) and short-term exposure limits (STEL) are 618 and 190, respectively.

The following is cited from Jeong et al. (2010). To prioritize the revision of the outdated OELs, the Hazardous Agents Review Committee HARC re-viewed the OELs set according to the following criteria.

- First, the chemical had to be a substance for which the current OEL equivalent in developed countries (the ACGIH TLVs, the Maximum Allowable Concentration (MAK) in Germany, the Workplace Exposure Limits (WELs) in the United Kingdom, or similar), was stricter than the Korean OEL at that time. The chemical classification under the 2003 regulatory framework included a list of OELs for 698 chemicals, 14 of which were permission-required substances, 168 of which were substances for which periodic measurement was required, and 516 of which were OEL-listed substances associated with no regulatory requirements. Any employer handling of the ‘‘permission-required” substances had to be approved in advance by the MOL. If using permission-required substances or substances requiring mandatory periodic measurement, employers were required to monitor the exposure levels of their workers and improve the workplace environment by monitoring the results once every 6 months, or once every 3 months.
- The second criterion was that substance in question had to cause occupational diseases or significant health risks in South Korea.
- Thirdly, the HARC examined the number of workers exposed to OEL-listed chemicals and also reconsidered the quantity of the chemical used, produced, imported, and exported based on the National Survey of Work Environment Status. This survey was conducted over a five-year period by the ISHA.

Based on the review results, the HARC selected 126 chemicals, 14 of which require permission (12 of these have no OELs), 103 with stricter OELs in developed countries than in South Korea, seven without an OEL in South Korea despite them having such limits in developed countries, and 2 (n-hexane and trichloroethylene) that had led to occupational diseases in Korea. The process is illustrated in Figure 3-2.

Jeong et al. (2010) also states that: "The suggestion of new chemical OELs was based on the presented evidence, and information regarding technical and socioeconomic considerations that would affect the adaptation to a new OEL."

Details on the OEL system are obtained from consulting national experts and/or aggregated desk research, if not stated otherwise.

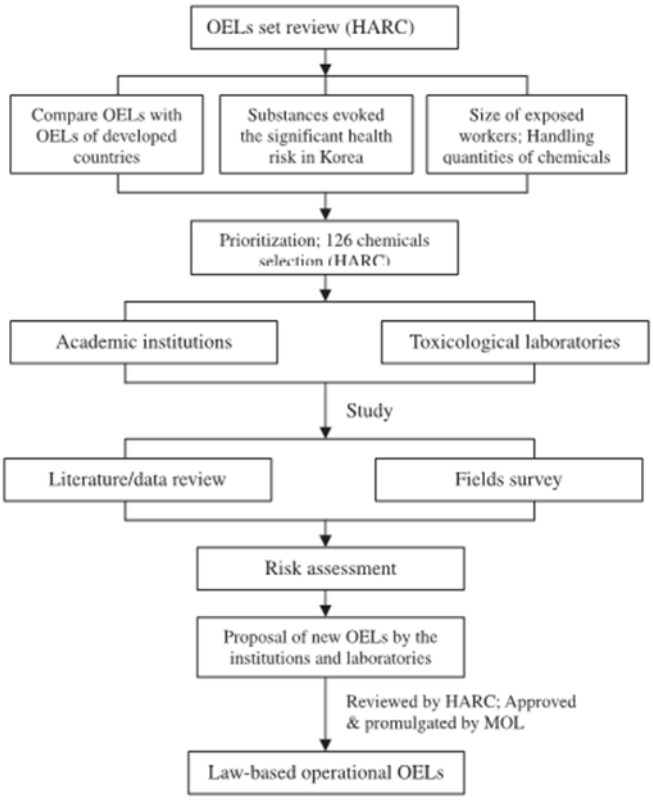

Fig. 1. The flow of overall processes in amending OELs. HARC, Hazardous Agents Review Committee; MOL, Ministry of Labor.

Figure 3-2: The flow of overall processes in amending OELs,
Source HARC, Hazardous Agents Review Committee, MOL, Ministry of Labor, South Korea.

3.3.8 USA

OSHA

In the USA, Permissible Exposure Limits (PELs) are regulatory limits on the amount or concentration of a hazardous substance in the workplace air. They may also contain a skin designation. PELs are published by the Occupational Safety and Health Administration (US OSHA).

PELs are based on an (TWA) exposure. PELs are addressed in specific standards for the general industry, shipyard employment and the construction industry.

US OSHA recognizes on its website[12] that "many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time. […] Since 1970, US OSHA promulgated complete 6(b) standards including new PELs for 16 agents, and standards without PELs for 13 carcinogens."

According to the website "OSHA's mandatory PELs in the Z-Tables remain in effect. However, OSHA recommends that employers consider using the alternative occupational exposure limits because the Agency believes that exposures above some of these alternative occupational exposure limits may be hazardous to workers, even when the exposure levels are in compliance with the relevant PELs."

NIOSH

As described on US OSHA's website: the "National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limits (RELs) are authoritative Federal Agency recommendations established according to the legislative mandate for NIOSH to recommend standards to OSHA. RELs are intended to limit exposure to hazardous substances in workplace air to protect worker health. In developing RELs and other recommendations to protect worker health, NIOSH evaluates all available medical, biological, engineering, chemical, and trade information relevant to the hazard. NIOSH transmits its recommendations to OSHA for use in developing legally enforceable standards. NIOSH also publishes its recommendations in publicly available sources such as the NIOSH Pocket Guide to chemical hazards, criteria documents, current intelligence bulletins, alerts, special hazard reviews, occupational hazard assessments, and technical guidelines."

According to their website[13] NIOSH has changed policy with regard to carcinogenic substances: "Under the old policy, RELs for most carcinogens were non-quantitative values labelled "lowest feasible concentration (LFC)". […] The effect of the new policy will be the development, whenever possible, of quantitative RELs that are based on human and/or animal data, as well as on the consideration of technological feasibility for controlling workplace exposures to the REL. […] Changes in the RELs and respirator recommendations that reflect the new policy will be included in future editions."

Further specific details can be found in the recently published NIOSH Chemical Carcinogen Policy[14], "historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 in a working lifetime. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible in many cases to control chemical carcinogens to a lower exposure level. In keeping with these advances, NIOSH will set a "risk management limit for a carcinogen" or an "RML-CA," at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 risk estimate, but only when occupational measurement of the carcinogen at the RML-CA is analytically feasible. When measurement of the occupational carcinogen at the RML-CA is not analytically feasible at the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the limit of quantification (LOQ) or reliable quantitation limit (RQL) of the analytical method for that occupational carcinogen. NIOSH defines an RMLCA as the maximum 8-hour time-weighted average concentration of an occupational carcinogen above which a worker should not be exposed. An excess lifetime risk level of 1 in 10,000 is considered to be a starting point for continually reducing exposures in order to reduce the remaining risk. NIOSH has established the terminology RML-CA instead of REL to acknowledgement that, for most carcinogens, there is no known safe level of exposure. NIOSH

[12] https://www.osha.gov/dsg/annotated-pels/
[13] https://www.cdc.gov/niosh/npg/nengapdxa.html
[14] https://www.cdc.gov/niosh/docs/2017-100/pdf/2017-100.pdf

acknowledges that some chemicals may have an exposure level below which carcinogenesis is not anticipated. The nonlinear response of these carcinogens will be addressed accordingly in any ensuing NIOSH guidance. However, in lieu of specific guidance, NIOSH believes that risk management based on the premise of no safe level is health-protective in most situations, and provides employers with an effective, simple, and unified approach to handling occupational carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures. Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical. Finally, several public commenters urged NIOSH to provide only the exposure limits that correspond to various risk levels, such as 1 in 1,000, 1 in 10,000, 1 in 100,000, or 1 in 1,000,000. Many of these commenters objected that NIOSH should not "recommend" one specific exposure level and should leave such a policy decision to US OSHA. These commenters observed that NIOSH is a scientific research agency and that US OSHA is the agency that is charged with making decisions about acceptable risks and feasibility. NIOSH agrees that it should provide information on the exposure levels that correspond to various levels of risk; however, NIOSH will continue to provide a health-based RML-CA to guide employers who seek to reduce exposures to occupational carcinogens to better protect their workers."

ACGIH

ACGIH is an abbreviation of American Conference of Governmental Industrial Hygienists which since 1946 has been establishing Threshold Limit Values (TLVs) and Biological Exposure Indices (BEIs). As described on OSHA's website: "ACGIH is a private, not-for-profit, nongovernmental corporation. It is not a standards setting body. ACGIH is a scientific association that develops recommendations or guidelines to assist in the control of occupational health hazards. TLVs and BEIs are health-based values and are not intended to be used as legal standards. TLVs refer to airborne concentrations of chemical substances and represent conditions under which it is believed that nearly all workers may be repeatedly exposed, day after day, over a working lifetime, without adverse effects. BEIs are guidance values for assessing biological monitoring results – concentrations of chemicals in biological media (e.g. blood, urine). BEIs® represent the levels of determinants that are most likely to be observed in specimens collected from healthy workers who have been exposed to chemicals in the same extent as workers with inhalation exposure at the TLV." The TLVs are based on the Time-Weighted Average (TWA): Concentration for a conventional eight-hour workday and a 40-hour workweek. Short-Term Exposure Limit (STEL): a 15-minute TWA exposure that should not be exceeded at any time during a workday.

Details on the OEL system are obtained from consulting national experts and/or aggregated desk research, if not stated otherwise.

3.4 Comparison of the national systems

National OEL systems (from both inside and outside the EU) have been described in Section 3.2 and Section 3.3. This documentation permits some conclusions for structural comparison (Section 3.4.1). However, reasons for the quantitative differences in the various national OELs can often only be analysed after a closer look to the specific toxicological criteria, which may be treated differently in the specific substance assessments. Those criteria and the sources of uncertainty leading to different answers are addressed in Section 3.4.2. Although all of the criteria may contribute to differences in

national OELs, some key determinants can be found, which significantly contribute to the (sometimes large) range of OELs for one substance. Such key determinants are summarised and examples are provided in Section 3.4.5.

Section 3.4.3 addresses some of the differences in methodology to derive STELs and Section 3.4.4 addresses differences in the methodology to assign "skin" notations.

3.4.1 Structural comparison

provides a list with comparative information based on the more detailed data reported in Section 3.2. All of EU-28 countries publish a national list of OELs, but the number of substances in the national list is different (not analysed). Only a few member states have developed a national method with specified guidance as to how OELs should be derived. Therefore, any statistics on the "majority of OELs" will be heavily biased, as the national lists do not represent independent national assessments, but are influenced by how many countries adopted the OEL from some source country. The information on "binding" or "indicative" OELs does not clearly discriminate between carcinogenic or non-carcinogenic substances. Some EU-28 counties reported that both - "binding" and "indicative" values - are in place. Possibly, this statement refers to the fact that these different types of OELs for carcinogenic and non-carcinogenic substances should be discriminated with respect to the "binding" or "indicative" character.

Only very few countries make use of a calculated excess cancer risk by linking acceptability criteria to this excess risk figure. The Netherlands and Germany have a "traffic light" approach with two different levels of acceptability associated (in addition to Japan and Switzerland, not covered in this Table). Poland, France and ECHA/RAC apply a one-tier demarcation based on acceptability criteria (Ding et al., 2014).

In the questionnaire, the question on "health-based"/"risk-based" or "influenced by technical feasibility and/or socio-economic criteria" for OELs did not discriminate between carcinogenic or non-carcinogenic substances. Therefore, responses by national experts that they do consider socio-economic criteria (response "SE/T" in), may possibly only be correct for carcinogens and not for OELs of non-carcinogenic substances.

In conclusion, the structural comparison provides some insight into the OEL systems analysed in this report, but discloses only to a limited extent why OELs vary across EU member states, as indicated for the six substances in the other reports. For this analysis, a closer look into national methodologies is necessary (see Section 3.4.2).

Table 3-1: OEL systems – structural comparisons for EU-member states and selected other countries

Countries	OEL-list	Methods	Non-carcinogens		Carcinogens		Cancer risk acceptability?
Austria	Yes	Adopted	Binding	HB	Binding	SE/T	No (only 1 OEL)
Belgium	Yes	Adopted	Binding	SE/T	Binding	SE/T	No
Bulgaria	Yes	Adopted	Binding	SE/T	Binding	SE/T	No
Croatia	Yes	No	Indicative	SE/T	Indicative	SE/T[$]	No
Cyprus	Yes	No	Binding	SE/T	Binding	SE/T	No
Czech Rep.	Yes	Adopted	Binding	HB	Binding[$]	HB[$]	No
Denmark	Yes	Brief method	Binding	SE/T	Binding	SE/T	Yes
Estonia	Yes	Adopted	Binding	SE/T	Binding	SE/T	No

Table 3-1: OEL systems – structural comparisons for EU-member states and selected other countries							
Countries	**OEL-list**	**Methods**	**Non-carcinogens**		**Carcinogens**		**Cancer risk acceptability?**
Finland	Yes	Yes	Indicative	SE/T	Both	SE/T	No
France	Yes	Yes	Both	SE/T	Both	SE/T	No
Germany	Yes	Yes	Binding	HB	Binding	HB	Yes
Greece	Yes	No	Binding	SE/T	Binding[$]	SE/T[$]	No
Hungary	Yes	Brief method	Binding	HB	Binding[$]	HB[§, $]	No
Ireland	Yes	Adopted	Binding	HB[§]	Binding	HB[§]	No
Italy	Yes	No	Not known	Not known	Not known	Not known	No
Latvia	Yes	Adopted	Binding	SE/T	Binding	SE/T	No
Lithuania	Yes	Adopted	Binding	SE/T	Binding	SE/T[$]	No
Luxembourg	Yes	Adopted	Binding	SE/T	Binding[$]	SE/T[$]	No
Malta	Yes	No	Not known	Not known	Not known	Not known	No
Netherlands	Yes	Yes	Binding	HB	Both	SE/T	Yes
Poland	Yes	Yes	Binding	HB	Binding	HB[§]	Yes
Portugal	Yes	Adopted	Indicative	HB	Both	HB[§, $]	No
Romania	Yes	Not known	Not known	Not known	Not known	Not known	No
Slovakia	Yes	Adopted	Binding	HB[§]	Binding	SE/T	Yes
Slovenia	Yes	Adopted	Binding	SE/T	Binding	SE/T[$]	No
Spain	Yes	Adopted	Binding	SE/T	Binding	SE/T[$]	No
Sweden	Yes	Yes	Binding[#]	SE/T	Binding	SE/T	No
UK	Yes	Adopted	Both	SE/T	Both	SE/T	No
SCOEL	Yes	Yes	Indicative	HB	Indicative*	HB*	no
Selected non-EU countries							
Australia	Yes	In preparation	Binding	Not known	Binding	Not known	Not known
Brazil	Yes	Not known	Binding	Not known	Binding	Not known	Not known
Canada (Ontario)	Yes	Not known[+]	Binding	Not known	Binding	Not known	Not known
Canada (Québec)	Yes	Not known[+]	Binding	Not known	Binding	Not known	Not known
China	Yes	Yes[+]	Binding	SE/T	Binding	SE/T	Not known
India	Yes	Not known	Binding	Not known	Binding	Not known	Not known
Japan (Ministry of Health Labour and Welfare)	Yes	Yes[+]	Binding	SE/T	Binding	SE/T	Not known
Japan (Japan Society for Occupational Health, JSOH)	Yes	Yes[+]	Indicative	HB	Indicative	HB	Yes
South Korea	Yes	Not known[+]	Binding	SE/T	Binding	SE/T	Not known

Table 3-1: OEL systems – structural comparisons for EU-member states and selected other countries							
Countries	**OEL-list**	**Methods**	**Non-carcinogens**		**Carcinogens**		**Cancer risk acceptability?**
USA (OSHA)	Yes	Not known	Binding	SE/T	Binding	SE/T	Not known
USA (NIOSH)	Yes	Yes	Indicative	SE/T[$$]	Indicative	SE/T[$$]	Yes
USA (ACGIH)	Yes	No	Indicative	HB	Indicative	HB	No

Source: FoBiG
Notes: Basis: Only health-/risk-based (HB); or: Some socio- economic/ feasibility (SE/T)

 # A few non-carcinogenic STELs are indicative.
§ Except adopted IOELVs/BOELVs, then SE/T.
$ No response received on additional questions regarding carcinogens, therefore information is assumed according to the obligatory EU directive.
**SCOEL does not recommend OELs for genotoxic carcinogens; OELs for substances with non-carcinogenic effects and with threshold-cancer effects ("practical threshold") are health-based.*
+ ACGIH values are taken into account. In China also values from other jurisdictions. In South Korea also MAK values of Germany and WELs of the United Kingdom.
$$ only technical feasibility (not below a limit of detection) is taken into account.

3.4.2 Criteria determining different OEL quantifications

presents an extended, but still incomplete, list of criteria which are differently treated in national OEL assessments and therefore can results in significantly different established values. The list was generated based on long-term experience in OEL setting and methodology discussions by the authors. Criteria are taken from assessments on non-carcinogenic effects and carcinogenic effects. Different decisions according to the various methodologies may well explain the observed differences in OELs as described in Table 2-3 (above) for the six carcinogens of this study or for other carcinogenic or non-carcinogenic substances. Given the high number of uncertainties, the resulting ranges are still moderate, indicating some mutual compensation of the different types of deviations. Moreover, there are many substances for which the data is highly qualified and expert opinion is rather homogeneous, therefore reducing the discrepancies between the assessment outcomes. The most relevant criteria in are taken up in Section 3.4.5 for examples.

Table 3-2: Extended list of observed reasons for divergent OELs	
Criterion	**Reason for potential differences in resulting OEL**
Definition of OEL	Assessment dimensions may be just "health-based", or may include technical feasibility and/or socio-economic parameters
Substance definition	OELs may differ for "soluble" vs. "insoluble" compounds for one chemical group of substances (e.g. inorganic cadmium compounds) or may be handled without discriminating solubility with only one OEL for all group members. Similarly, different salts of a metal could be handled as different or identical entity. If similar compounds are all linked to one OEL, there may be different rules, which of the single compounds is regarded representative for the group of compounds
Protection level	"Very sensitive" groups of workers (e.g. due to polymorphism or multiple sensitivity or airway hyper agility) may be protected to a different degree
Adversity	For example, minor sensory irritation or "nuisance" may be regarded as an adverse or non-adverse effect, depending on expert judgement

Table 3-2: Extended list of observed reasons for divergent OELs	
Criterion	**Reason for potential differences in resulting OEL**
Minimum data	Some national committees abstain from establishing OELs if only poor data is available (e.g. group IIb substances, German MAK-commission (e.g. DFG, 2017)), others find it feasible to derive OELs
Indicative or binding character (national level)	For example, in the Netherlands, there are "private" (indicative) and "public" (binding) OELs, which are established by different procedures and therefore may entail different quantitative OELs
Documentation requirements	Thorough documentation usually leads to more transparency and to more systematic analysis of the criteria in assessment and derivation of OELs with potential quantitative consequences due to different completeness of discussion
Induction of re-evaluations (periodically, international initiation, case-by-case- new data)	This very important criterion links to timeliness of scientific data and methodological updates, which significantly influences current OELs in place
Basic scenario for workplace exposure assumptions (work-life, working hours/day etc.)	Most OELs refer to 40 years of exposure (full shift, i.e. 8 hrs/day; 5 days/week; 48 weeks per year), however, with few exemptions
Particle fractions (applicable size distribution: inhalable fraction, respirable fraction, total dust)	Particle size may influence a) deposition pattern of particles in the respiratory tract, b) phagocytosis in the lung, c) subsequent local effects and d) further toxicokinetics. Particle size distributions may differ between the experimental study or critical epidemiological study used for OEL-quantification and the workplace conditions, for which the OEL is applied. Therefore, adequate transformation from respirable or total dust to inhalable dust scenario may be needed for equivalent protection levels. Similarly, study results with particles (inhalable fraction) may not be used for workplace exposure to fumes with submicron - sized particles without adaptions. These necessary transformations are heterogeneously handled, when OELs are established for the respective particle fractions
Sensory irritants	Different handling of this criterion in time extrapolation and variability; different expert opinions on how to handle animal data on sensory irritation (e.g. Bos et al. 2002)
Selection of relevant study and relevant species, reliability demands	Key criterion for OEL assessments is the "expert opinion" on the quality of data, sometimes guided by consensus quality criteria (e.g. Klimisch Score, see for example Schneider et al. 2009), but not unambiguously avoiding differences in expert discretion
Default interpretation of assessment factors	Some methodologies are based on a default system of assessment factors or uncertainty factors, others reject any default (e.g. see discussion in ECHA/RAC-SCOEL, 2017); moreover, reasons to deviate from defaults may be heterogeneous. Consideration of defaults is often linked to different appreciation of expert opinion, being able to quantify extrapolation factors in case of poor data with or without statistical standard assumptions (i.e. defaults). The consequences of starting extrapolation with or without defaults have been analysed by Schenk and Johanson (2010)
LOAEC⍰NOAEC extrapolation (factors, conditions for benchmark dose response modelling)	Size of factor depends on a) spacing of controlled studies, b) acceptance of benchmark response for LOAEL/NOAEL equivalence for quantal or continuous data with or without confidence interval (BMD/BMDL), c) quality of exposure data in epidemiological studies, d) agreement on default slope of dose response

Table 3-2: Extended list of observed reasons for divergent OELs	
Criterion	**Reason for potential differences in resulting OEL**
Time extrapolation (less than workday to workday)	Usually linear extrapolation is assumed. May differ, however, due to "mode of action" ("concentration dependent" or "time dependent"), and due assumptions on exercise/ activity.
Time extrapolation (subacute, subchronic, chronic) systemic effects	Time extrapolation may differ due to national methodology, existing or non-existing defaults, reasons to deviate or maintain defaults
Time extrapolation(subacute, subchronic, chronic) local effect	Time extrapolation may differ due to national methodology, existing or non-existing defaults, reasons to deviate or maintain defaults and type of local effect (e.g. sensory irritation vs. respiratory tissue damage)
Interspecies extrapolation systemic effects (allometric scaling)	Allometric scaling is usually accepted in more recent assessments (ECHA/RAC-SCOEL, 2017), however, may have caused differences in earlier assessments still in place. Explicitly used for route-to-route extrapolations. However, implicitly also included, if equal doses are assumed from inhalation concentrations in animals and humans
Interspecies extrapolation systemic effects (variability aspects: toxicokinetic/ toxicodynamic)	Interspecies variability due to toxicokinetic or toxicodynamic reasons is often addressed separately from allometric scaling as an additional default factor (e.g. ECHA, 2012), but not by all national OEL methodologies
Interspecies extrapolation local effects (human equivalent concentration" HEC; dosimetry, particles, volatile chemical agents)	Key criterion for extrapolation from animal studies; sometimes assumed to justify reduction in allometric scaling or interspecies variability factor. For particles "human equivalent concentrations" (HEC) depend on assumptions of particle size distributions in animal and human exposure scenario and on normalizing area (FoBiG, 2011)
Starting point: human data	It is generally assumed that human data are to be preferred to animal data in assessment strategies. However, this has to be weighted against quality of study data (human or animal, respectively) and therefore is a relevant reason for discrepancies in OELs. With regard to the priority between human and animal data there may be some differences between the SCOEL and the ECHA/RAC approach (ECHA/RAC-SCOEL, 2017)
Intraspecies extrapolation (targeting sensitive individuals) (variability aspects: toxicokinetic/ toxicodynamic)	Workers are often assumed to be a more homogeneous group of exposed persons compared to general population; respective assumption differs. Based on human studies, the minimum size of the exposed group with effect observations as reason to reduce or maintain a default intraspecies factor, is a matter of discussion
Route-to-route extrapolation (oral-inhalation; oral-dermal)	Reasons where route-to-route extrapolations are tolerated or not tolerated differ in specific assessments (e.g. because of consideration of "first-pass effects" and potential local effects, and pathway specific absorption); high uncertainty for dermal OELs, because of assumptions on percutaneous absorption
Safety factors for severity of effects (if any)	In some OEL methodologies certain effects (like reproductive effects or threshold carcinogenic effects may be addressed by including as severity factor)
Safety factors for adequacy of data (if any)	Some OEL methodologies may include a modifying factor in case of poor data (low reliability) or missing data on specific toxicological endpoints

Table 3-2: Extended list of observed reasons for divergent OELs	
Criterion	**Reason for potential differences in resulting OEL**
Reproductive toxicants (a) reproductive function	Reproductive toxicants are often differently assessed with regard to adversity (e.g. slight libido effects), time extrapolation (minimum duration of tests to assume qualitative and quantitative coverage of endpoint), interspecies extrapolation (e.g. minor change in sperm counts in rodents may be differently assessed with respect to human relevance) and intraspecies extrapolation (e.g. intraspecies variability from endocrine effects)
Reproductive toxicants (b) developmental effects (if not excluded)	Reproductive effects on the neonates are often not covered in OEL assessments, as only adults are exposed directly at the workplace. Again, time extrapolation, interspecies extrapolation, intraspecies extrapolation and adversity are issues for debate, if classified reproductive toxicants are, at all, addressed in OEL systems
Skin- or airway-sensitising chemical agents	Usually, OELs do not (or only to a limited degree) cover protection from skin- or airway-sensitising effects. However, some OEL systems may partially consider this endpoint, others do not. This discussion also includes adversity assessment, e.g. on preclinical respiratory effects
Non-genotoxic carcinogens	There is high uncertainty on quantitative assessment of a non-stochastic mode of action for carcinogenicity. This is regarded as a key factor for heterogenic OELs for this type of substances
Special rules (e.g. mixtures, UVCB, etc.)	For mixtures national OELs rarely provide unambiguous rules. However, sometimes the additivity rule is mentioned. However, because of different definitions of the "similarity criterion" (where substances are regarded as sufficiently similar that an additivity assumption is regarded as being justified), the practical outcome may be considerably different
Acceptability of risk	Quantification of an accepted (or tolerated) risk for carcinogens is no part of the OEL methodology in many countries. However, some countries (like the Netherlands, Germany) associate certain risk levels with acceptability. Acceptability may then be linked to OEL. This may subsequently result in different OELs, depending on the size of the "acceptable" (or "tolerable") risk level
Criteria beyond excess health risk	SCOEL and some national committees decline to derive a "risk-based" OEL. In this case, for genotoxic carcinogens, the OEL by be defined from other criteria beyond a fixed cancer excess risk (e.g. technical feasibility, socio-economic criteria). Inclusion of technical or socio-economic criteria may be different for carcinogens (risk based health assessment) from non-carcinogenic substances (with threshold type of health effects)
Linearity (excess risk)	Excess risk is usually provided as a risk per unit (e.g. risk per µg/m³), only few countries include considerations on a nonlinear slope into excess risk quantification, leading to differences compared to linear exposure risk relationships
Starting point depending on classification	Some OELs for cancer effects are derived without considering the classification (either Carc. Cat. 1A or 1B in CLP); however, others assume that risk cannot be quantified from human (epidemiological) data, if classification is from animal data (Carc. Cat. 1B) and human data are not sufficiently qualified for a Carc. Cat. 1A classification
Tumour sites	Tumour sites considered for OEL quantification may differ, because of: a) between animal study observations and humans, b) different tumours in one species with different scientific opinion on the most relevant site for quantification, c) different aggregational level of tumours (e.g. combine

Table 3-2: Extended list of observed reasons for divergent OELs	
Criterion	**Reason for potential differences in resulting OEL**
	different types of tumours in the respiratory tract or limit to squamous cell carcinoma in the pulmonary part
Species specific tumours	In some assessments certain tumours in animal studies may or may not be considered as species specific or may be regarded as only qualitatively (but not quantitatively) relevant for humans
Comparison: cancer effects vs. non-cancer effects	In some OEL assessments non-cancer and cancer effects are considered in parallel and the more potent effect (health-based or high cancer risk) may be decisive for OEL selection. However, in other assessments no comparison between those two types of effects (cancer potency, non-cancer effect threshold) takes place
Selection of relevant study, reliability demands, minimum information necessary	The criteria to apply epidemiological risk quantifications are handled differently (e.g. minimum quality in handling of possible confounders, significance criteria for risk term (Odds Ratio; Standard Mortality Ratio; etc.), handling of heterogeneity of data, different quality of exposure assessment (e.g. Job Exposure Matrix sufficient or personal exposure air measurement data required)
Basic scenario for workplace exposure assumptions (work-life, working hours/day etc.) and comparisons to scenario: general population	Calculated transformations from animal exposure scenario (less than lifetime or lifetime with or without post exposure observational period) with usually intermittent exposure (e.g. 6hours/day; 5 days/week) under resting conditions to the occupational exposure scenario (working lifetime exposure) are handled differently
Definition of starting point ("point of departure") for extrapolations	The starting point for extrapolation from observed or modelled data is differently defined in the different OEL assessments. For tumour data, this may be the benchmark (BMD) with a 10 % response with or without lower confidence limit (BMDL/ BMD) or a tumour incidence of 25% above background (T25) (Sanner et al. 2001); the modelling of the BMD may be done by different statistical procedures (e.g. "linear multistage", "Weibul" "lognormal" etc.)
Mode of action (consequences for extrapolation procedure)	Most extrapolations of the exposure risk relationship to the low risk area are either linear or assume a threshold (including, possibly, a "practical threshold"). However, others also consider sublinear exposure risk relationship conditions for extrapolation, leading to different extra risks and associated OELs (e.g. AGS, 2013)
Relevance of genotoxicity for effect	Direct genotoxic chemical-substance interactions (primary genotoxicity) is usually associated with a linear exposure risk relationship without threshold. However, extrapolation rules are less clear in case of a) weak primary genotoxicity and strong non-genotoxic effects, b) secondary genotoxic effects (e.g. oxidative damages of DNA) or epigenetic changes (e.g. reduced DNA repair) as "mode of action" for carcinogenicity
Handling of background risk / risk in control group	Calculation of excess risk needs assumptions about background risk for the respective type of tumours in the non-exposed reference population. In current extra risk calculations highly divergent background risks are assumed (e.g. for lung cancer, 5-9 %)
Exposure characteristics (cumulated, e.g. ppm-years; vs. average, etc.)	Effects may be influences by peak-exposures, cumulative exposure or average exposure levels and continuous vs. intermittent exposure patterns. Often the critical exposure term is not clearly established and heterogeneous assumptions are used to derive OELs

Table 3-2: Extended list of observed reasons for divergent OELs	
Criterion	**Reason for potential differences in resulting OEL**
Latency	Excess risk and significance of risk are influenced by assumptions on latency times (time to tumour data), which, however, are divergent and often uncertain, but may influence quantitative results
Intraspecies considerations (variability, polymorphism)	Epidemiological cancer studies may be influenced by personal risk factors of the exposed workers and by healthy worker effects. Quantification of extra risk usually are controlled to different extent for such parameters

3.4.3 Differences in STEL criteria

Differences in STELs, as shown in Table 2-2 and Table 2-3, apparently are not based on systematic differences between national STEL-systems, but clearly depend on some substance specific characteristics.

Whereas for cadmium there was an almost unambiguous STEL derived (small range: 0.08-0.12 mg/m³), the range of the STEL for beryllium is broad (0.06-20 µg/m³). This broad range resembles the broad range for the 8h-TWA-OEL for Beryllium, which is similarly wide. For formaldehyde local effects (sensory irritation) determines both, the 8hrs-OEL and the STEL, with negligible difference between the two values. Generally, for substances for which systemic toxicity dominates (i.e. cadmium and MOCA), the "exceedance factor" between 8 hrs-TWA and STEL is larger compared to the two substances with dominating local effects (formaldehyde and beryllium).

There are no detailed methodologies on STELs in the national guidance documents. Most national systems describe:

- The duration of exceedance of the 8 hrs- TWA (mostly 15 minutes);
- the period between such peak exposures (mostly one hour); and
- the maximum number of such peaks/ day (mostly up to four times/day).

Most national methodologies discriminate STELs and "ceiling values". STELs for systemic effects are usually linked to higher exceedance factors than STELs for local effects (as also is true for the examples reported above).

In the German concept it is emphasised by the MAK commission that a STEL might only be relevant, if the critical effect is dependent on concentration and not from the dose-time-integral (c x t-product; area under curve: AUC). Therefore, for genotoxic carcinogens, the STEL is not essential, as the AUC is determining the potency. However, peak exposure nonlinearity restrictions have to be considered. For carcinogens with an enhancer or precursor effect, there may be a need to establish a STEL, if it is concentration dependent.

3.4.4 Differences in criteria for "skin" notation

A "skin" notation should indicate relevant percutaneous absorption of a substance, with subsequent systemic availability adding to the overall body burden, in addition to inhalation uptake. As can be seen from , for the "skin" notation of the five substances in this study, there are some significant differences in how "skin" notations are handled. SCOEL (2013) summarises:

"there are no agreed criteria for assigning these skin notations and this has resulted in great discrepancies in the proportion of chemicals to which the notation is assigned in different national lists."

For example, the cut-off criteria for the "skin" notations are somewhat different between Germany (Hartwig, 2017) and SCOEL (2013). Whereas SCOEL refers to a 10% or more uptake via skin in relation to the uptake from respiratory exposure, Hartwig suggests a fraction of 25% of the chronic systemic NOAEL indicative for "skin" notation. Further parameters to be considered are:

- "corrosive" or "skin irritating" properties, as those may lead to skin damage and changes in percutaneous uptake;
- aerosols, which deposit on the skin, need different standard testing procedures as are required for gases; and
- no systemic NOAEL can be deduced for genotoxic substances: a qualitative proof of uptake is needed to assign a "skin" notation.

Lavoué et al. (2008) compared criteria for "skin" notations between Switzerland and the US (ACGIH)[15]. In general, there was a rather good agreement between the Swiss and the ACGIH skin notations (between 82-87%), but the dermal-to-other routes lethal doses (LD50) were only moderately associated with QSAR-based transdermal fluxes. In conclusion, the authors found a "plausible but variable relationship between current skin notations and the different approaches" and request improvements of current skin notations. In a more recent publication, they provided a QSAR-tool (UPERCUT) to serve for improved assignment of "skin" notations[16]. Also, the NIOSH developed an updated methodology for "skin" notations[17]. However, harmonisation of the various approaches is still limited.

3.4.5 Examples for systematic differences in OELs due to difference in OEL systems

OEL Definition

OELs are not directly comparable, if their definition is different. As shown in Table 3-1, there exist varying definitions of OELs in European countries, specifically for carcinogens. For example, the Netherlands and Germany define a solely risk-based OEL for carcinogens (or "tolerable risk level", similarly understood as an OEL). Other countries take into account technical feasibility or socio-economic criteria. This leads to significant differences in the resulting OELs:

[15] https://academic.oup.com/annweh/article/52/8/747/247368, assessed 2nd February 2018
[16] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4886196/pdf/mev091.pdf,assessed 2nd February 2018
[17] https://pdfs.semanticscholar.org/4084/bd303c5a269ee23e647539b7edfc08a38285.pdf, assessed 2nd February 2018

Example (substance)	Country	OEL based on	OEL
Chromium (VI)	The Netherlands	Risk-based	1 µg/m³
	Germany	Risk-based	1 µg/m³*
	Austria	Technical feasibility	100 µg/m³
	EU	Socio-economic criteria plus risk based	5 µg/m³

*) "Tolerable risk", 4:1000, similarly defined to an OEL, in this case defined as "Beurteilungsmaßstab" , i.e. "judgment value"

The difference between the Netherlands and the EU is not due to divergent toxicological opinions, as SCOEL (2017b) derives an identical excess risk as the Netherlands and Germany. In the case of the Austrian OEL ("TRK"), additional reasons contribute to the large difference in values.

Another example would be Beryllium, where the OEL of 0.2 µg/m³ by US OSHA is significantly higher than the IOEL recommended by SCOEL of 0.02 µg /m³, both assessments are, to a large extent, based on identical data, but US OSHA explicitly states that at the derived OEL (PEL) there remains some risk of experiencing Chronic Beryllium Disease and/or Beryllium Sensitisation (OSHA, 2015). It is noteworthy that this difference in the definition of an OEL is for a non-cancer endpoint.

Particle fraction

OELs for particles are usually linked to a definition which also includes a particle fraction, i.e. reference to the inhalable or respirable fraction, and for some OELs also on "total dust". The key issue here is transformation from one particle fraction (on which the assessment data are based) to another particle fraction (which is the standard scenario for the OEL, to be established). There are no straight forward or constant transformation factors available and simulated particle sampling can be interpreted differently. This leads to significant differences in OELs:

Example (substance)	Country	Particle fraction	OEL
Beryllium	Germany	Inhalable	0.14 µg /m³
		Respirable	0.06 µg /m³
	SCOEL	Inhalable	0.02 µg /m³

For the German OEL (inhalable fraction), data on the "total mass" were transformed by a factor of 2 in order to derive the OEL for the inhalable fraction (Kock et al., 2015). As effects for "total mass" and for "respirable" fraction did not differ significantly, an OEL of 0.06 µg /m³ was set for the respirable fraction. Essentially, based on the identical data, SCOEL applied no transformation factor (transformation factor = 1). The additional divergence by a factor of 3 (i.e. 0.06/0.02 µg /m³) is based on different expert interpretation of the data and therefore is not due to the discussion on the particle fraction transformation rules.

Similarly, SCOEL (2017a) established an OEL for cadmium (1 µg/m³, inhalable fraction), where the experimental background data were mainly for the respirable fraction (former SCOEL value, based on local effects in the respiratory tract, was 4 µg/m³, respirable fraction) (SCOEL, 2010). However, the ratio between the inhalable fraction and the respirable fraction is highly variable, with some workplaces, where this ratio would be close to 10 and others where the factor would be just >2. Spain uses a factor of 5 between the OEL for cadmium "inhalable" vs. "respirable", whereas Sweden applies

a factor of 10 for a transformation from “respirable” to “total” – and therefore a factor of ≥ 10 for a transformation from “respirable” to “inhalable”.

This transformation problem may also influence the applicability of the OEL for chromium (VI). This OEL was derived from human data with exposure to inhalable chromium, but is discussed for use for welding scenarios, where exposure is to fumes, i.e. mostly the respirable fraction.

In conclusion, different transformations from the various particle distributions at workplaces into adequate standard exposure scenarios lead to discrepancies in OELs and to uncertainties on the applicability of an OEL from a standard scenario to a scenario with a deviant particle size exposure profile.

Adversity

Toxicological experts frequently discuss issues on the adversity of an observed effect.

For example, proteinuria from exposure to cadmium compounds is often regarded as a minor physiological change with no indication of progression or subsequent major impairments of health if below some defined range, whereas others regard proteinuria as an early sign of kidney damage which may already have occurred; and (non-occupational) background exposure to cadmium is therefore regarded as a risk factor of relevant concern. Thus, national committees may decide differently, with significant consequences on the derived OEL.

Within the discussion on the beryllium OEL, some experts emphasise that symptoms of chronic beryllium disease (CBD) at lower concentrations were not observed with radiological standard methods and the type of the observed effect should be regarded as “subclinical”. In consequence, the observed effect should be regarded as a “lowest observed effect concentration” (LOEC) and not as a “lowest *adverse* observed effect concentration” (LOAEC), which has different quantitative consequences for the extrapolation to derive an OEL. However, no clear decision of an OEL for beryllium can be referenced, where a committee has concluded that subclinical CBD should be regarded as a non-adverse effect.

In conclusion, a decision on “adversity” is a key factor to define the “point of departure” (POD) in toxicological risk assessment, where different expert opinions may lead to quantitative differences. However, heterogeneous opinions cannot clearly be linked to systematic differences in OEL systems.

Induction of re-evaluations (significant delays)

One major reason for differences in OELs is the timeliness of the assessment. Many European OELs have been adopted from the U.S. ACGIH list of OELs (TLV). Examples are referenced in Section 3.2.

TLV from ACGIH are often higher, are less frequently updated, and are not derived by a detailed methodology. This may lead to relevant differences to other national OELs (Schenk, 2010; Schenk et al., 2008a). Below, we demonstrate the impacts of such delays in updates with the example of chromium (VI). The OEL by ACGIH for “water soluble” and “water-insoluble” chromium (VI) compounds has not been updated since 1981 or 1991, respectively. However, these OELs, established for 37 or 27 years, have probably been adopted by many countries, also without change since then. The most recent intended change from 2017 is not implemented yet. Even though the background of many national OELs is unknown, it can be assumed that the 50 or 10 µg/m³ limits, in place in most EU countries, are based on the assessments by ACGIH from 1981 and 1991, respectively, with no updates since then. However, the lower ones (Denmark, Finland, France, Lithuania, the Netherlands, Germany or ECHA, and now: ACGIH) are from more recent assessments.

ACGIH TLV Chronology for chromium (VI), established in	Specification by ACGIH	OEL adoption in other countries
0.1 mg/m³ (≥1974)	Certain insoluble chromates	
0.05 mg/m³ (≥1976)	Chromic acid and chromates	
0.05 mg/m³ (≥1981)	Cr(VI) water-soluble compounds, certain water insoluble Cr (VI) compounds	0.05 mg/m³: Belgium, Bulgaria, Croatia, Czech republic, Hungary, Ireland, Slovakia, Slovenia, Spain, still in place in 2017
0.01 mg/m³ (≥1991)	insoluble Cr (VI) compounds	0.01 mg/m³ Belgium, Hungary, Ireland, Spain: still in place in 2017
0.0002 mg/m³ (≥2017)	Cr (VI) compounds, inhalable fraction	Not yet officially adopted by ACGIH, and not by other countries

For MOCA, there is a listing from an assessment from 1986 by NIOSH[18] (220 µg/m³). This is the current OEL in Australia and Greece for MOCA, which is significantly higher than, e.g. the 20 µg/m³ derived in the Netherlands for MOCA. It may reasonably be assumed that the OEL of 220 µg/m³ was adopted from the NIOSH assessment in 1986 (currently NIOSH proposes a lower REL, but U.S. OSHA still refers to 220 µg/m³).

Expert opinion on best suitable study

Another relevant parameter influencing the OEL assessment outcome is the heterogeneity of expert opinions. For the six substances of this project this is not a dominating reason for discrepancies, but it is one factor. For example, the Netherlands and ECHA used an epidemiological study by Lubin et al. (2000) for their assessment of Arsenic compounds, whereas Germany used an updated version (Lubin et al. 2008), although the assessments by the Netherlands and ECHA were done later than the German assessment.

Country	Excess risk arsenic compounds	Source study
The Netherlands/ECHA:	1.4×10^{-4}	(Lubin et al., 2000)
Germany:	4.8×10^{-4}	(Lubin et al., 2008)

In the Lubin et al. (2008) study, data was reported which probably overestimated exposure, as the respective workers were using personal protection measures, thus reducing their exposure. Therefore, Germany adopted an estimate that "real" exposure was significantly lower than the one, measured from workplace room concentrations. Germany used a reduction factor on the exposure data published in Lubin et al. (2008) in their exposure estimate. The Netherlands decided not to use the more recent and updated data from Lubin et al. (2008) at all, because of the potential influence of the personal protection measures. They returned to the non-updated data set of Lubin et al. (2000) for this reason. This example demonstrates that different committees may handle uncertainties differently and may therefore choose different studies to base their OEL assessment on.

[18] https://monographs.iarc.fr/ENG/Monographs/vol99/mono99-13.pdf

Default assessment factors

Differently from non-cancer effects, extrapolation of excess cancer risk only includes some limited default (or substance specific) assessment factors. Specifically, intraspecies variability (extrapolation from people with average sensitivity to the more sensitive subpopulations) is not addressed within cancer risk extrapolation procedures for OELs.

However, differences in methodologies to use or not to use systematically extrapolation factors is one major reason for differences in OELs which, therefore, can be better demonstrated by non-cancer extrapolations to derive an OEL.

Example 1: Ethyl acrylate

The current range of the various national OELs for ethyl acrylate is from 5 to 100 mg/m^3. Most assessments (17 of a total 23, reported in IFA, 2017) are identical in result by reporting an OEL of 20 or 21 mg/m³ (5 ppm). This OEL is identical to the No Observed Adverse Effect Concentration (NOAEC) for respiratory tract irritation in an animal /rat) study, which was regarded appropriate by all known assessments. However, if there are explicit national methodologies which request an assessment factor from the animal NOAEC to the human NOAEC, to also protect the more sensitive subpopulations, this should therefore, in general, be > 1. For example, in Germany a default assessment factor of 5 is requested to extrapolate from an animal NOAEC to the OEL because of inter- and intraspecies variability. This factor 5 is to be used in that methodology, if there are no adequate human data to deviate from this default. At the time when the OEL was established, there were no such qualified human data. However, such a factor was not applied in the earlier assessments which still are in place. Most recently, a controlled human study has been performed (Kleinbeck et al., 2017), clearly demonstrating that the NOAEC of 5 ppm for irritating effects in experimental animals is not protective for humans. The German assessment now results in an OEL of 8.3 mg/m³ (2 ppm). This example demonstrates that the omission of assessment factors may sometimes be premature and may be an important reason for different national OELs.

Substance	Country (examples)	8 hrs TWA (mg/m³)	Assessment Factors
Ethyl acrylate (CAS: 140-88-5)	Austria, Belgium, SCOEL, Finland, France Ireland, Italy, etc.	20	Animal data: irritation, no assessment factor animal → human → sensitive subpopulation
	Germany (updated in 2015)	8.3	Human data: irritation
Ethylbenzene (CAS: 100-41-4)	Austria, Belgium, SCOEL, Hungary, Ireland, Italy, etc.	440	Human data: irritation; no assessment factors on animal data were applied to analyse hepatotoxicity as a potentially relevant endpoint
	France, Germany (updated in 2012)	88	Animal data: after inclusion of assessment factors hepatotoxicity more relevant than human data (irritation)

Example 2: Ethylbenzene

The current range of OELs for ethylbenzene is from 88 to 440 (434-442) mg/m³, i.e. 20-100 ppm. 18 of 28 OELs document the higher value (100 ppm) and 10 are lower (values as reported by IFA, 2017). All the known background papers for the higher OEL (100 ppm) refer to irritation effects as being decisive based on some limited human observations (e.g., ACGIH, 1991; Greim, 2000; Henschler, 1985; SCOEL, 1995). Six subjects exposed to 200 ppm experienced transient irritation of the eyes (Ruth, 1986). A non-standard small factor of 2 was used to set the OEL, mainly based on irritation. However, already all early assessments report some inhalation and/or oral animal studies, where hepatotoxicity was a relevant toxicological endpoint (Cragg et al., 1989; NTP, 1992; Wolf et al., 1956). If those early studies had been used to derive an OEL by default assessment factors (some of them after transforming the data from oral to inhalation exposure) they would have resulted in an OEL << 440 mg/m³. In 2007 finally, a study by Mellert et al. (2007) again reported hepatotoxic effects from oral exposure to ethylbenzene, and was now applied by Hartwig (2012) to establish a lower national OEL of 88 mg/m³ for ethylbenzene in Germany. Only if the tools of "route-to-route extrapolation" and assessment factors were used, the hepatotoxicity was detected to be the critical endpoint and decisive for OEL derivation.

Human or animal data

The background of all assessments on MOCA is not known. However, as indicated by IOM (2011) many experts link the cancer risk from MOCA to bladder cancer, for which there is some limited epidemiological data (Dost et al., 2009) and which would fit to cancer sites, attributed to similar substances. However, MOCA is a classified Carc. Cat. 1B carcinogen, where human data were not sufficient in evidence for classification and animal studies demonstrate other cancer locations being crucial. There may be significant differences in cancer potency, if derived from animal or human data, respectively and this may result in different OELs. Moreover, chances for successful medical treatment may differ for the various cancer sites. Therefore, selection of animal or epidemiological studies to derive an excess cancer risk may be important for subsequent steps of the impact assessment.

Similarly, the lung cancer risk of cadmium is much lower, if derived from human data compared to the one derived from animal studies. However, again, cadmium is a substance classified as Carc. Cat. 1B. Thus, in CLP classification, the epidemiological data were not regarded sufficient to determine the classification and therefore the cancer potency estimate. Even though from human and from animal data, respiratory cancer is regarded as most relevant, there are indications that other cancer sites may be similarly important and species comparisons on cancer site and in cancer potency are therefore inevitably highly uncertain.

Substance	Human data:	Animal data:	Comment:
MOCA	Risk: no significantly elevated risk (SMR) at low exposures Target organ: bladder cancer	Risk: 2 mg/m³ = 4:1000 risk Target organ: lung cancer	Substance classified in Carc. Canc. Cat. 1B; significantly different excess risk and impact, if human data are used
Cadmium	Risk: 22,4 µg/m³ = 4:1000 risk (Haney, 2016) Target Organ: lung cancer	Risk: 1.6 µg/m³ = 4:1000 risk (Germany) Target Organ: lung or other tumour sites	

Considerations on the mode of action

Assumptions and scientific evidence on the "mode of action" (MoA) will result in significantly different exposure-risk relationship (ERR-) curves. Direct genotoxic substances are often associated with linear ERR, whereas for indirect genotoxicity (secondary to other effects like impairment of the DNA repair system) non-linear ERRs or threshold ERRs are supported. A non-linear ERR (hockey stick type) does still have no threshold. For example, the German linear approach to derive the ERR for cadmium, is different from the one by SCOEL, who suggest a "practical threshold". Even if a threshold may theoretically be valid for some modes of action, there is rarely qualified data to unanimously quantify that threshold or to determine the slope of the ERR, if direct genotoxicity has only minor influence on the MoA.

Specifically, metals are rarely substances where direct genotoxicity is the dominating MoA. However, there may be different potencies in indirect genotoxicity and different influences of an epigenetic MoA. This leads to significant uncertainties in low dose extrapolations and in the ERR function. The different OELs for the metals demonstrate impressively different opinions on the MoA and cancer effect potency.

Differences in STEL

The STELs range is a factor of 15 (cadmium), 330 (beryllium), 20 (inorganic arsenic compounds), 8 (formaldehyde) and no range available (MOCA) (see Table 2-3). The range is the largest for beryllium, for which also the various national OELs spread over a large range. Differences in STELs are reduced from Be > As > Cd > formaldehyde; the interval size of OELs reduces similarly from Be > As > Cd > MOCA > formaldehyde. As the absolute value for a STEL is usually linked to the respective OEL, discrepancies between STELs would greatly reduce if the OELs were harmonised. No further systematic conclusions can be derived from the analysis of the STEL profiles for the six substances of this study.

It is suggested that in national guidance to derive OELs, a detailed methodology should be established to quantify STELs differentiating between:

- substances, where the critical toxicological endpoint are local effects;
- substances, where the critical toxicological endpoint are systemic effects;
- substances, which are (local or systemic) carcinogens; and
- substances, where accumulation properties are important for the critical effect.

In some countries all substances with an OEL also are assigned a STEL, whereas in other countries STELs are only assigned to specific types of substances.

Differences in SKIN notation

For cadmium and inorganic compounds, only very few countries assigned a "skin" notation, which can be relevant for some soluble cadmium compounds; it is also neglected by SCOEL.

We are not aware of "skin" notations for chromium (VI) compounds.

Few countries assigned a "skin" notation to inorganic arsenic compounds, which may be relevant for only some soluble arsenic compounds and is also neglected by SCOEL.

For Beryllium, the assignment of a "skin" notation is more heterogeneous. Even though SCOEL does not assign this notation, the Committee suggests: "*The absorption of beryllium through intact skin is*

low, as beryllium is bound by epidermal constituents. However, limited studies suggest that beryllium particles may be able to penetrate into human skin and induce BeS, which can progress to CBD. Although further research is needed, it is prudent to reduce both skin and inhalation exposures. Therefore, skin contact has to be avoided, but a skin notation referring to skin absorption is not recommended." This cautionary statement is well in line with the inconsistent current handling of this notation.

Also, for formaldehyde, many national assessments assigned a "skin" notation. However, this may be more the consequence of local skin effects than of percutaneous absorption. This is why SCOEL abstained from this assignment and explained*: "As a result of the predominantly local effects of formaldehyde, a "skin" notation is not required. Formaldehyde is a well-known contact allergen to the skin (skin sensitizer). A notation sensitisation (Dermal) is therefore added."*

Finally, MOCA, received a "skin" notation by most assessors including SCOEL. SCOEL comments: *"MOCA is taken up through both the respiratory tract and the skin; most of the absorbed substance is excreted within a few days in the urine and faeces... There has been considerable occupational exposure by cutaneous absorption in early years of use of MOCA, as evidenced by urine analysis… The rapid skin penetration of MOCA has also been confirmed experimentally with human skin in vitro... Most authors consider that absorption through the skin is the major route of uptake of the substance at the workplace."*

In conclusion, there is a theoretical problem as "skin" notation may be handled very heterogeneously because of a lack of a common methodology. Apart from chromium (VI) there was at least some heterogeneity in the assignment of this notation. For the other five substances of this study, the implications are limited if the SCOEL assignments are followed. However, it is suggested that a harmonised methodology should be established within the EU to handle the "skin" notation.

4 National systems for the enforcement of binding limits

The consultation gathered information about the methods of enforcement in the Member States. The data collected for 11 Member States is shown in Tables 4-1 to 4-11.

Table 4-1 Enforcement in member states - Austria	
Question	**Response**
How is the air exposure concentration determined?	☒ Measured ☒ Estimated
If **estimated**, please specify how:	
If **measured**, how many samples and how often do they need to be taken to demonstrate compliance?	There is no clear rule. The number of samples depends on the substance and the tasks the workers have to perform.
If **measured**, are there any rules on whether sampling has to be personal or for the work area?	The exposure assessment in general should include personal samples and at least one static sample.
If **measured**, does air sampling have to be carried out by an external contractor?	☐ Yes ☒ No However, most companies are not able to measure air concentrations by themselves.
If measured, how is compliance with the OEL determined? See below for an explanation.	The arithmetic mean of the air concentration measurement has to comply with the TWA and if there is a STEL, the measured concentration has to comply also with the STEL which could either be an average value over a certain period (e.g. 15 min) several times (e.g. 4 times) per an 8-hours-shift or the STEL could be a ceiling value.

Table 4-2 Enforcement in member states – Belgium	
Question	**Response**
How is the air exposure concentration determined?	☒ Measured
If **estimated**, please specify how:	☐ Estimated
If **measured**, how many samples and how often do they need to be taken to demonstrate compliance?	Generally: measured, unless the employer can demonstrate by other evaluation methods (not specified in legislation) that protection of workers is guaranteed.
If **measured**, are there any rules on whether sampling has to be personal or for the work area?	Preferably in the breathing zone.
If **measured**, does air sampling have to be carried out by an external contractor?	☒ Yes ☐ No Sampling can be done by the employer, a member of the prevention service, or a member of a certified laboratory. Analysis can be done by the employers' laboratory or by a certified laboratory. If the quality of the sampling/analysis is disputed by a labour inspector or prevention committee, or if the employer doesn't have the equipment to perform the measurements, they have to be performed by a certified laboratory. Asbestos measurements always have to be performed by a certified laboratory.

Table 4-2 Enforcement in member states – Belgium	
Question	**Response**
If measured, how is compliance with the OEL determined? See below for an explanation.	The legislation refers to NBN EN 689.

Table 4-3 Enforcement in member states - Bulgaria	
Question	**Response**
How is the air exposure concentration determined?	☒ Measured ☐ Estimated
If **estimated**, please specify how:	
If **measured**, how many samples and how often do they need to be taken to demonstrate compliance?	According to BDS EN 689 (national standard)
If **measured**, are there any rules on whether sampling has to be personal or for the work area?	According to BDS EN 689 (national standard)
If **measured**, does air sampling have to be carried out by an external contractor?	☐ Yes ☐ No
If measured, how is compliance with the OEL determined? See below for an explanation.	according to BDS EN 689 (national standard)

Table 4-4 Enforcement in member states - Finland	
Question	**Response**
How is the air exposure concentration determined?	☐ Measured ☒ Estimated
If **estimated**, please specify how:	The employer shall identify hazards caused by the chemical agents present at the workplace and assess their possible risks to the employees' health and safety. The risk assessment shall be presented in an appropriate manner in writing and it shall specify the prevention and protection measures that have been taken. The risk assessment may include clarifications why a more detailed risk assessment, e.g. measurements, is not necessary.
If **measured**, how many samples and how often do they need to be taken to demonstrate compliance?	Requirements for measurements, including how often they need to be taken depends on the conditions of the workplace. If the employees' exposure to hazardous chemical agents cannot be reliably assessed in any other manner, the employer shall carry out measurements regularly and always when the conditions change in a way that increases an employee's exposure. If the measurement results show that the limit values are not exceeded, further measurements shall, when necessary, be carried out at appropriate intervals to make sure that the situation remains unchanged. The closer the measurement results for airborne contaminants are to the limit values, the more often measurements shall be carried out. The Ministry of Social Affairs and Health may generally or in respect of a certain industry, field of activity, chemical or type of exposure, and the OSH inspectorate may in respect to a certain workplace issue regulations laying down e.g. when and how often measurements of chemical agents

Table 4-4 Enforcement in member states - Finland	
Question	**Response**
	shall be made and which methods of assessment, measurement, sampling and analysis shall be used in the measurement procedure. In practice the Ministry has not issued such regulations.
If **measured**, are there any rules on whether sampling has to be personal or for the work area?	No.
If **measured**, does air sampling have to be carried out by an external contractor?	☒ Yes ☐ No
If measured, how is compliance with the OEL determined? See below for an explanation.	There is no specific regulation on this. CEN standard EN 689 is used as a guideline.

Table 4-5 Enforcement in member states - Germany	
Question	**Response**
How is the air exposure concentration determined?	☒ Measured ☒ Estimated
If **estimated**, please specify how:	Different approaches possible according to TRGS 402: comparison with other workplaces, calculation, good practice, control banding …
If **measured**, how many samples and how often do they need to be taken to demonstrate compliance?	Depends on the measured values , assessment according to the rules of DIN EN 689, April 95 NOT according to PR EN 689 2017
If **measured**, are there any rules on whether sampling has to be personal or for the work area?	TRGS 402, personal sampling is preferred
If **measured**, does air sampling have to be carried out by an external contractor?	☐ Yes ☒ No
If measured, how is compliance with the OEL determined? See below for an explanation.	The measuring result(s) has/have to be lower than the OEL. https://www.baua.de/EN/Topics/Work-design/Hazardous-substances/pdf/TRGS-402.pdf?__blob=publicationFile&v=3 Measurements and evaluation of measured concentration is according to the following standards: DIN EN 689: Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy, April 1995 NOT PR EN 689 2017 DIN EN 482: Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents, October 2006

Table 4-6 Enforcement in member states - Greece	
Question	**Response**
How is the air exposure concentration determined?	x Measured ☐ Estimated
If **estimated**, please specify how:	
If **measured**, how many samples and how often do they need to be taken to demonstrate compliance?	There are no legislative provisions; however the requirements of the EN 689:1995 and the EN 482:1994 standards as well as those of the HSE report Monitoring strategies for toxic substances are acceptable.
If **measured**, are there any rules on whether sampling has to be personal or for the work area?	Yes. In P.D. 77/1993 (FEK 34 A'), Annex, par.c it is mentioned that measurements must be representative of the exposure of workers in the chemical agent, thus personal measurement is required. Work area (static) sampling is applied when personal measurement is not technically feasible.
If **measured**, does air sampling have to be carried out by an external contractor?	☐ Yes x No. Not exclusively.
If measured, how is compliance with the OEL determined? See below for an explanation.	There are no legislative provisions; however the requirements of the EN 689:1995 standard as well as those of the EN 482:1994 standard are acceptable.

Table 4-7 Enforcement in member states - Ireland	
Question	**Response**
How is the air exposure concentration determined?	☒ Measured ☐ Estimated
If **estimated**, please specify how:	
If **measured**, how many samples and how often do they need to be taken to demonstrate compliance?	The H.S.A require sampling and analysis methodology to be consistent with EN 689:1995 Workplace atmospheres – Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy, EN 689:1995 and recognised sampling and analytical method such as. MDHS, UK (Methods for Determining Hazardous Substances) or NIOSH (US) Manual of Analytical Methods Our advice to employers is included in the following publication: Information Sheet on our website: http://www.hsa.ie/eng/Publications_and_Forms/Publications/Occupational_Health/Occupational_Hygiene_Report_Writing_Information_Sheet.pdf
If **measured**, are there any rules on whether sampling has to be personal or for the work area?	As above
If **measured**, does air sampling have to be carried out by an external contractor?	☒ Yes ☐ No
If measured, how is compliance with the OEL determined? See below for an explanation.	As above

Table 4-8 Enforcement in member states - Latvia	
Question	**Response**
How is the air exposure concentration determined?	☒ Measured ☐ Estimated
If **estimated**, please specify how:	
If **measured**, how many samples and how often do they need to be taken to demonstrate compliance?	Number of samples depends on sampling methods, according to EN 689.
If **measured**, are there any rules on whether sampling has to be personal or for the work area?	There is no rules, but in most of cases laboratories provide personal sampling
If **measured**, does air sampling have to be carried out by an external contractor?	☒ Yes ☐ No
If measured, how is compliance with the OEL determined? See below for an explanation.	A single value combining all samples: • Arithmetic mean • 95th percentile

Table 4-9 Enforcement in member states - Portugal	
Question	**Response**
How is the air exposure concentration determined?	☒ Measured ☐ Estimated
If **estimated**, please specify how:	
If **measured**, how many samples and how often do they need to be taken to demonstrate compliance?	Depends on the method used. NIOSH is frequently used.
If **measured**, are there any rules on whether sampling has to be personal or for the work area?	Rules applied to samples are defined on the methods.
If **measured**, does air sampling have to be carried out by an external contractor?	☐ Yes ☒ No
If measured, how is compliance with the OEL determined? See below for an explanation.	Depends on the sampling strategy and the objective of the measurement.

Table 4-10 Enforcement in member states - Spain	
Question	**Response**
How is the air exposure concentration determined?	☒ Measured ☒ Estimated
If **estimated**, please specify how:	Control banding methodologies
If **measured**, how many samples and how often do they need to be taken to demonstrate compliance?	We use UNE-EN-689
If **measured**, are there any rules on whether sampling has to be personal or for the work area?	We recommend personal sampling

Table 4-10 Enforcement in member states - Spain	
Question	**Response**
If **measured**, does air sampling have to be carried out by an external contractor?	☐ Yes ☒ No
If measured, how is compliance with the OEL determined? See below for an explanation.	See appendix 4: http://www.insht.es/InshtWeb/Contenidos/Normativa/GuiasTecnicas/Ficheros/g_AQ.pdf

Table 4-11 Enforcement In Member States – United Kingdom	
Question	**Response**
How is the air exposure concentration determined?	☐ Measured ☒ Estimated
If **estimated**, please specify how:	
If **measured**, how many samples and how often do they need to be taken to demonstrate compliance?	The regulation places compliance with an exposure limit as secondary to following good practice in occupational hygiene. As such, exposure limits are seen as a relatively minor part of the compliance regime. HSE recognises that it is more efficient for smaller companies to spend their resources on control measures rather than measurement, so defines control standards in guidance contained in COSHH Essentials control sheets. In these control sheets, HSE has carried out the measurements and defined the control measures necessary to comply with an OEL. In some cases where there are no control sheets applicable to a process, HSE expects measurements to be carried out as part of the risk assessment and it is the duty of the company to ensure this is done competently following HSE and professional association guidance http://www.bohs.org/library/technical-publications/ . However, the measurements should not be an end in themselves.
If **measured**, are there any rules on whether sampling has to be personal or for the work area?	
If **measured**, does air sampling have to be carried out by an external contractor?	☒ Yes ☐ No
If measured, how is compliance with the OEL determined? See below for an explanation.	For the purpose of enforcement, it is not considered necessary to have a sufficient number of workplace measurements to have relative statistical certainty. Enforcement is going to be on a lack of control of the substance hazardous to health, not on airborne measurement. This is because of the statistical and methodological uncertainty associated with, for example, one air measurement. HSE's primary aim is to ensure that workers' exposure is being controlled. An inspector's own observations are very important (is the environment dusty? are the controls working and being used properly? etc.) This can be compared with information from the employer on the frequency of measurements, variation in levels over time, details of any advice given by consultants and action taken (or not taken). If a regulatory inspector had doubts about the level of control being achieved – this might be due to concerns about the consultancy reports or for some other reason - then they could seek advice from a specialist occupational hygienist and/or

Table 4-11 Enforcement In Member States – United Kingdom	
Question	**Response**
	arrange for the Health and Safety Laboratory to visit the workplace to take measurements. Inspectors tend to use exposure measurement information specifically when they identify a problem with the control of exposure and where there are particularly hazardous substances e.g. carcinogens / asthmagens. Employers will be required to carry out exposure monitoring to demonstrate that the exposure to workers is below the OEL and or as part of the safety management system for carrying out certain types of work e.g. asbestos removal.

A few further comments came from other Member States and respondents:

- **Cyprus**: [enforcement] Depending on the case;
- **Denmark**: [measurements are] estimated;
- **Hungary**: A single value combining all samples. Only accredited laboratory and international professional testing laboratory authorized to perform the measurements; and
- **Finland** from OSH experts: Recommended to follow standard EN 689, EN 482, EN 1540. Numbers of samples depend on the workplace facilities: one room/many rooms, different activities etc. Frequency depends on the levels and the routines of each workplace. If clearly below OEL, next measurement after 2-3 years. Compliance case by cases, always several individual samples. Usually looking at arithmetic means.

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Annex 1 Reference: Lists of national OELs

Table A1-1 Reference lists of national OELs	
Member State/ non-EU country	**Reference**
Austria	https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20001418 list of limit values: https://www.ris.bka.gv.at/Dokumente/Bundesnormen/NOR40198637/II_429_2011_Anhang_I_2011.pdf
Belgium	http://www.emploi.belgique.be/defaultTab.aspx?id=616 list of limit values: www.emploi.belgique.be/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=23914
Bulgaria	https://www.lex.bg/laws/ldoc/2135477597
Croatia	https://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_75_1507.html
Cyprus*	http://www.mlsi.gov.cy/mlsi/dli/dliup.nsf/All/4EC46BBBCE284C96C2257DE200382FAD?OpenDocument
Czech Republic	list of limit values: https://www.zakonyprolidi.cz/cs/2013-9
Denmark	https://arbejdstilsynet.dk/da/regler/bekendtgorelser/g/sam-graensevaerdier-for-stoffer-og-materialer list of limit values: https://www.retsinformation.dk/Forms/R0710.aspx?id=143596
Estonia	list of limit values: https://www.riigiteataja.ee/aktilisa/1301/1201/1011/VVm_293_lisa_uus.pdf
Finland	http://www.finlex.fi/fi/laki/alkup/2016/20161214 list of limit values: www.finlex.fi/data/sdliite/liite/6646.pdf
France	www.inrs.fr/dms/inrs/CataloguePapier/ED/TI-ED-984/ed984.pdf
Germany	list of OELs: TRGS 900 https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/TRGS-900.pdf?__blob=publicationFile Acceptance and tolerance values for carcinogenic substances: TRGS 910 https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/TRGS-910.pdf?__blob=publicationFile&v=4
Greece§	
Hungary	http://njt.hu/cgi_bin/njt_doc.cgi?docid=48596.333255
Ireland	list of limit values: http://www.hsa.ie/eng/Publications_and_Forms/Publications/Chemical_and_Hazardous_Substances/Chemical_Agents_COP_2016.pdf
Italy	www.gazzettaufficiale.it/eli/gu/2012/09/18/218/sg/pdf (see pages:24 to 26)
Latvia	http://www.lm.gov.lv/upload/en/cab._reg._no._325_-_requirements_when_coming_in_contact_with_chemical_substances.pdf
Lithuania	https://www.e-tar.lt/portal/legalAct.html?documentId=TAR.8012ED3EA143
Luxembourg	http://data.legilux.public.lu/file/eli-etat-leg-memorial-2016-235-fr-pdf.pdf
Malta	http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10728&l=1
Netherlands	list of limit values: https://www.ser.nl/en/oel_database/overviewcasnumbers.aspx
Poland	list of limit values: http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU20170001348/O/D20171348.pdf
Portugal	https://dre.pt/application/dir/pdf1sdip/2012/02/02600/0058000589.pdf Formaldehyde: Portuguese Rule NP 1796:2014 Segurança e Saúde do Trabalho: Valores-Limite e Índices Biológicos de Exposição Profissional a Agentes Químicos.
Romania	https://www.iprotectiamuncii.ro/legi/hg-1218-2006.pdf Carcinogens/mutagens: https://www.iprotectiamuncii.ro/legi/hg-1093-2006.pdf
Slovakia	list of limit values: http://www.epi.sk/zz/2006-355 Carcinogens/mutagens: http://www.epi.sk/zz/2006-356
Slovenia	list of limit values: https://www.uradni-list.si/_pdf/2007/Ur/u2007053.pdf Carcinogens/mutagens: www.pisrs.si/Pis.web/npb/2015-01-1603-2005-01-4409-npb1-p3.pdf
Spain	list of limit values: http://www.insht.es/InshtWeb/Contenidos/Documentacion/LEP%20_VALORES%20LIMITE/Valores%20limite/LEP%202017.pdf
Sweden	https://www.av.se/globalassets/filer/publikationer/foreskrifter/hygieniska-gransvarden-afs-2015-7.pdf
United Kingdom	http://www.hse.gov.uk/pUbns/priced/eh40.pdf
SCOEL	http://efcc.eu/media/3025/2013-05-scoel-recommendations.pdf
Non-EU countries	
Australia	https://www.safeworkaustralia.gov.au/system/files/documents/1705/workplace-exposure-standards-airborne-contaminants-v2.pdf
Brazil	list of limit values: http://www.unifal-mg.edu.br/segurancadotrabalho/files/file/nr_15_anexo11.pdf

Table A1-1 Reference lists of national OELs	
Member State/ non-EU country	**Reference**
Canada, Ontario	list of values: https://www.labour.gov.on.ca/english/hs/pubs/oel_table.php
Canada, Québec	http://legisquebec.gouv.qc.ca/en/showdoc/cr/S-2.1,%20r.%2013 list of values: http://legisquebec.gouv.qc.ca/en/resource/cr/S-2.1R13_EN_002_003.pdf?langCont=en&digest=E83BB51DF2D9CBD894A1CDA5E364FB48
China*§	http://www.cirs-reach.com/China_Chemical_Regulation/China_Occupational_Exposure_Limits.html
India	list of limit values: http://dgfasli.nic.in/html/factyact/csch2.htm
Japan, JSOH	list of limit values: https://www.sanei.or.jp/images/contents/310/OEL.pdf
South Korea#	http://www.dguv.de/ifa/gestis/gestis-internationale-grenzwerte-fuer-chemische-substanzen-limit-values-for-chemical-agents/index-2.jsp
USA; ACGIH$	http://www.acgih.org/home
USA, OSHA	https://www.osha.gov/dsg/annotated-pels/tablez-1.html
USA, NIOSH	https://www.cdc.gov/niosh/topics/chemical.html

Source: FoBiG
All stated web links were accessed on 16 November 2017.
** Only link to website is provided and not to a list of limit values.*
§ Only attached document was provided.
 # Country specific list could not be identified by web-search; data was obtained from GESTIS (IFA, 2017).
$ Values for ACGIH can also be obtained from the OSHA website.

Annex 2 Selected list of methodology documents

Member State/ non-EU country	Reference for OEL-deriving method
France	https://www.anses.fr/fr/system/files/VLEP2009sa0339RaEN.pdf
Germany	OEL : TRGS 901: https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/Bekanntmachung-901.html For carcinogenic substances: https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/TRGS-910-Anlage3.pdf?__blob=publicationFile&v=2
Netherlands	For carcinogenic substances: https://www.gezondheidsraad.nl/sites/default/files/A1007_0.pdf
Poland	http://ijomeh.eu/Rules-and-recent-trends-for-setting-health-based-occupational-exposure-limits-for-chemicals,1960,0,2.html
Sweden	https://www.av.se/arbetsmiljoarbete-och-inspektioner/publikationer/foreskrifter/medicinska-kontroller-i-arbetslivet-AFS-20056-foreskrifter/
SCOEL	https://circabc.europa.eu/sd/a/1bd6666f-5c8c-4d13-83c2-18a73dbebb67/SCOEL%20methodology%202013.pdf
China	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4466881/
India	http://www.dgfasli.nic.in/statutes5.htm
Japan, JSOH	https://pdfs.semanticscholar.org/b58f/3ab7f8a6ad61b356933aafaf8b3ec67cb9eb.pdf
South Korea	https://www.ncbi.nlm.nih.gov/pubmed/20709131
All stated web links were accessed on 16 November 2017.	

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