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Opinion

Opinion on the preparation of a Commission Directive establishing a 4th list of indicative occupational exposure limit values (IOELVs) under Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

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Proposal of the Commission on the preparation of a Directive establishing a 4th list of Indicative Occupational Exposure Limit Values (IOELVs)

The Working Party on Chemicals (WPC) has prepared this opinion on a proposal of a list of substances for which an Indicative Occupational Exposure Limit Value (IOELV) could be set out under a Commission Directive, pursuant to Directive [98/24/EC](#)¹. The WPC invites the Plenary of the Advisory Committee on Safety and Health at Work (ACSH) to adopt it.

1. BACKGROUND

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work states in its article 3 that the Commission “*shall propose European objectives in the form of indicative occupational exposure limit values for the protection of workers from chemical risks, to be set at Community level.*”

The Scientific Committee on Occupational Exposure Limits (SCOEL), as an independent scientific body develops Recommendations on health-based limit values, based on which the Commission Services propose IOELVs at EU level after consultation of the Advisory Committee on Safety and Health at Work (ACSH), specifically through its Working Party on Chemicals (WPC).

Three Commission Directives establishing IOELVs for a total of 113 chemical substances have been adopted up to now (Directives [2000/39/EC](#)², [2006/15/EC](#)³, [2009/161/EC](#)⁴). Directive [91/322/EEC](#)⁵, derived from the repealed Directive [80/1107/EEC](#)⁶, is still in force and establishes limit values for another 10 chemical substances. The ACSH understands that the scientific basis for these 10 substances is under revision by SCOEL in light of new evidence.

The WPC, in accordance with its mandate for 2012-2013 (Doc. 02011/11) and its extension for 2014-2015 (Doc. 02039/13) has discussed possible IOELVs for a number of chemical substances and has prepared the present opinion on the preparation of a Directive establishing a 4th list of IOELVs.

2. SUMMARY OF THE DISCUSSIONS IN THE WPC

DG EMPL.B3 established a list of candidate substances for an IOELV at EU level, consisting of those for which SCOEL adopted a Recommendation for health-based Occupational Exposure Limits (OELs) that are not yet included in the existing lists of IOELVs, together with substances with an existing IOELV for which SCOEL has reviewed their Recommendation in the light of new scientific information.

¹ OJ L 131, 5.5.1998, p. 11

² OJ L 142, 16.6.2000, p. 47

³ OJ L 38, 9.2.2006, p. 36

⁴ OJ L 338, 19.12.2009, p. 87

⁵ OJ L 177, 5.7.1991 p. 22

⁶ OJ L 327, 3.12.1980, p. 8

These discussions were carried out in meetings of the WPC between June 2013 and October 2014.

A summary of the discussions, focused on the technical feasibility of the values recommended by SCOEL, and the conclusions reached, are shown below for each substance or group of substances.

Biological limit values do not form part of this proposal. However, the ACSH recognises the importance of such values for some substances and encourages the WPC and the Commission services to continue to discuss this issue in order to identify the most suitable approaches for biological monitoring of workers exposed to chemicals.

Ethyl acetate (CAS No. 141-78-6)

General remarks

The proposal is based on SCOEL Recommendation SUM 1, revised in 2008:

8h-TWA: 200 ppm (734 mg/m³)

15 min-STEEL: 400 ppm (1468 mg/m³)

All the interest groups agree with the proposed values.

Methylene chloride (CAS No. 75-09-2)

General remarks

The proposal is based on SCOEL Recommendation SUM 130, adopted in 2009:

8h-TWA: 100 ppm (353 mg/m³)

15 min-STEEL: 200 ppm (706 mg/m³)

Skin notation is proposed.

All the interest groups agree with the proposed values.

Vinylidene chloride (CAS No. 75-35-4)

General remarks

The proposal is based on SCOEL Recommendation SUM 132, adopted in 2008:

8h-TWA: 2 ppm (8 mg/m³)

15 min-STEEL: 5 ppm (20 mg/m³)

All the interest groups agree with the proposed values.

Employers Interest Group comments

Co-polymerisation seems to be a sector in which there is a feasibility issue to comply with both the short-term and 8 hours limit values.

Tetrachloroethylene (CAS No. 127-18-4)

General remarks

The proposal is based on the SCOEL Recommendation SUM 133, adopted in 2009:

8h-TWA: 20 ppm (138 mg/m³)

15 min-STEL: 40 ppm (275 mg/m³)

Skin notation is proposed.

All the interest groups agree with the proposed values.

Sulphur dioxide (CAS No. 7446-09-5)

General remarks

The proposal is based on the SCOEL Recommendation SUM 27, revised in 2009:

8 h-TWA: 0,5 ppm (1,3 mg/m³)

15 min-STEL: 1 ppm (2,7 mg/m³)

WIG and GIG agree with the proposed values.

Employers Interest Group comments

Employers would like to stress on the detection problem at the level proposed by SCOEL. The lowest limit of detection of new sensors for SO₂ is 0.5 ppm which is the 8 h-TWA value recommended by SCOEL. In addition, there are several gases with cross sensitivities to SO₂ gas detectors.

Governments Interest Group comments

It is recognised that there are in certain industrial areas problems to comply with this limit value and that compliance could probably only be achieved by wearing PPE. The main problem lies with the STEL and not with the 8h-TWA value.

Manganese and inorganic compounds

General remarks

The proposal is based on the SCOEL Recommendation SUM 127, adopted in 2011:

8h-TWA: 0,2 mg/m³ (inhalable fraction)

8h-TWA: 0,05 mg/m³ (respirable fraction)

All the interest groups agree with the proposed values.

Amitrole (CAS No. 61-82-5)

General remarks

The proposal is based on the SCOEL Recommendation SUM 157, adopted in 2009:

8h – TWA: 0,2 mg/m³

Although amitrole is considered as a carcinogen group D by SCOEL (non-genotoxic for which a health threshold can be defined), it is not classified as a carcinogen 1A or 1B under the CLP Regulation (EC No [1272/2008](#))⁷.

All the interest groups agree with the proposed value.

Aerosols of severely refined Mineral Oils

General remarks

The WPC considered SCOEL SUM 163 adopted in 2010 which recommended an 8h – TWA of 5 mg/m³ (inhalable fraction).

The definition of the agent in the SCOEL Recommendation is: “*Severely refined mineral oils, with negligible PAH content, which are not classified as Carcinogenic in the EU and only used once (not recycled)*”.

WPC members expressed concern on the definition of this chemical agent and questioned the usefulness of such a limit, as in practice employers and workers would find it difficult to understand its scope and application. These aerosols could contain critical substances (e.g., n-hexane). It was agreed that the definition of mineral oils and the scope of the use should be clarified.

The WPC discussed the possibility of requesting SCOEL to recommend a value for metal working fluids, in the light of potential new studies, and taking into account the scientific basis of national limit values already adopted.

These issues need further attention within the WPC. Pending these discussions no proposal is made for an IOELV for ‘Aerosols of severely refined Mineral Oils’.

Carbon tetrachloride (CAS No. 56-23-5)

General remarks

The proposal is based on the SCOEL Recommendation SUM 31, reviewed in 2009:

8h – TWA: 1 ppm (6,4 mg/m³)

15 min – STEL: 5 ppm (32 mg/m³)

Skin notation for this substance is proposed.

All the interest groups agree with the proposed values.

⁷ OJ L 353 31.12.2008, p.1

Acrolein (CAS No. 107-02-8)

General remarks

The proposal is based on the SCOEL Recommendation SUM 32, reviewed in 2007:

8h – TWA: 0.02 ppm (0,05 mg/m³)

15 min – STEL: 0.05 ppm (0,12 mg/m³)

All the interest groups agree with the proposed values.

Carbon monoxide (CAS No. 630-08-0)

General remarks

The proposal is based on the SCOEL Recommendation SUM 57, adopted in 1995:

8h – TWA: 20 ppm (23 mg/m³)

15 min – STEL: 100 ppm (117 mg/m³)

A proposed noise notation is under consideration by SCOEL. If agreed this could be included for carbon monoxide in a future Commission proposal.

Some concern was raised within the WPC regarding the feasibility of implementation and a potential need for a transitional period of these limit values in the mining sector. Since 2013, the *Standing Working Party* on the mining industry (SWP) has been kept informed about developments on limit values for substances that are of specific interest to their sector. Specifically the proposal for carbon monoxide has been presented during their meeting of April 2014.

It was also raised as an issue for the emergency services. However, limit values are intended to control exposures that occur on a regular basis (8 h/day, 5 days/week), which is not the case for emergencies. Moreover it was confirmed that the provisions of the Framework Directive do not apply directly to the emergency services when the specific activities performed are in conflict with it (see article 2 of the Framework Directive).

All the interest groups agree with the proposed values. However, further to the final discussions on the substance in the WPC, the *Standing Working Party* on the mining industry (SWP) expresses doubts regarding the ability of the mining sector to comply with these limit values.

Methyl formate (CAS No. 107-31-3)

General remarks

The proposal is based on the SCOEL Recommendation SUM 59, revised in 2004:

8h – TWA: 50 ppm (125 mg/m³)

15 min – STEL: 100 ppm (250 mg/m³)

Skin notation is proposed, because of its potential for irritation.

All the interest groups agree with the proposed values.

Tetraethyl silicate (CAS No. 78-10-4)

General remarks

The proposal is based on the SCOEL Recommendation SUM 64, revised in 2008:

8h – TWA: 5 ppm (44 mg/m³)

SCOEL recognized the benefits of a STEL to prevent irritation, but noted that there is insufficient data to support a recommendation for a short-term exposure limit.

All the interest groups agree with the proposed value.

Hydrogen cyanide (CAS No. 74-90-8)

General remarks

The proposal is based on the SCOEL Recommendation SUM 115, adopted in 2010:

8h – TWA: 1 mg CN/m³ (0,9 ppm)

15 min – STEL: 5 mg CN/m³ (4,5 ppm)

Skin notation for this substance is proposed.

All the interest groups agree with the proposed values.

Employers IG comments:

The Cyanides Sector Group of CEFIC submitted a note to DG EMPL stressing that new studies had been published since 2010 and that the SCOEL Recommendation approach could be refined, in particular shifting from a *strength-of-evidence* approach to a *weight-of-evidence* approach. However, this would not affect the values recommended by SCOEL.

Employers of the electroplating (galvanoplastic) industry express their concern regarding the technical feasibility, according to best available technologies, of the proposed value.

Potassium cyanide (CAS No. 151-50-8)

General remarks

The proposal is based on the SCOEL Recommendation SUM 115, adopted in 2010:

8h – TWA: 1 mg CN/m³

15 min – STEL: 5 mg CN/m³

Skin notation for this substance is proposed.

All the interest groups agree with the proposed values.

Employers of the electroplating (galvanoplastic) industry express their concern regarding the technical feasibility, according to best available technologies, of the proposed value.

Sodium cyanide (CAS No. 143-33-9)

General remarks

The proposal is based on the SCOEL Recommendation SUM 115, adopted in 2010:

8h – TWA: 1 mg CN⁻/m³
15 min – STEL: 5 mg CN⁻/m³

Skin notation for this substance is proposed.

All the interest groups agree with the proposed values.

Employers of the electroplating (galvanoplastic) industry express their concern regarding the technical feasibility, according to best available technologies, of the proposed value.

Hydrogenated terphenyl (CAS No. 61788-32-7)

General remarks

The proposal is based on the SCOEL Recommendation SUM 72, adopted in 1994:

8h – TWA: 19 mg/m³ (2 ppm)
15 min – STEL: 48 mg/m³ (5 ppm)

All the interest groups agree with the proposed values.

Acetic acid (CAS No. 64-19-7)

General remarks

An IOELV of 10 ppm (8h-TWA) is set in Directive 91/322/EEC for this substance.

The proposal of a new IOELV is based on the SCOEL Recommendation SUM 98, adopted in 2012:

8h – TWA: 25 mg/m³ (10 ppm)
15 min – STEL: 50 mg/m³ (20 ppm)

All the interest groups agree with the proposed values.

Calcium hydroxide (CAS No. 1305-62-0)

General remarks

An IOELV of 5 mg/m³ (8h-TWA) is set in Directive 91/322/EEC for this substance.

The proposal of a new IOELV is based on the SCOEL Recommendation SUM 137, adopted in 2008:

8h – TWA: 1 mg/m³ (respirable dust)
15 min – STEL: 4 mg/m³ (respirable dust)

All the interest groups agree with the proposed values.

Calcium oxide (CAS No. 1305-78-8)

The proposal is based on the SCOEL Recommendation SUM 137, adopted in 2008:

8h – TWA: 1 mg/m³ (respirable dust)
15 min – STEL: 4 mg/m³ (respirable dust)

All the interest groups agree with the proposed values.

Note: The WPC notes that SCOEL will discuss at its meeting in December 2014 the difficulties of differentiating in practice between calcium oxide and calcium hydroxide, issues of measurement, and whether the proposed limit should refer to the respirable or inhalable fraction. If necessary the WPC will present a supplementary opinion to ACSH for these substances taking into account the recommendations of SCOEL.

Lithium hydride (CAS No. 7580-67-8)

An IOELV of 0,025 mg/m³ (8h-TWA) is set in Directive 91/322/EEC for this substance.

The proposal of a new IOELV is based on the SCOEL Recommendation SUM 141, adopted in 2010:

8h – TWA: --
15 min – STEL: 0,02 mg /m³ (inhalable dust)

All the interest groups agree with the proposed value.

Acrylic acid (CAS No 79-10-7)

The proposal is based on the SCOEL Recommendation SUM 128, adopted in 2012:

8h – TWA: 29 mg/m³ (10 ppm)
15 min – STEL: 59 mg/m³ (20 ppm)

All the interest groups agree with the proposed values.

Glycerol trinitrate (CAS No. 55-63-0)

The proposal is based on the SCOEL Recommendation SUM 147, adopted in 2008:

8h – TWA: 0,095 mg/m³ (0,01 ppm)
15 min – STEL: 0,19 mg/m³ (0,02 ppm)

Although this substance is considered as a carcinogen group C by SCOEL (carcinogen with a practical threshold), it is not classified as a carcinogen 1A or 1B under the CLP Regulation (EC No [1272/2008](#))

Skin notation for this substance is proposed.

All the interest groups agree with the proposed values.

Diacetyl (CAS No. 431-03-8)

The proposal is based on the SCOEL Recommendation SUM 149, adopted in 2014:

8h – TWA: 0,07 mg/m³ (0,02 ppm)

15 min – STEL: 0,36 mg/m³ (0,1 ppm)

All the interest groups agree with the proposed values.

3. LIST OF SUBSTANCES PROPOSED FOR A 4TH LIST OF IOELVs

CAS ⁽¹⁾	NAME OF AGENT	LIMIT VALUES				Notation ⁽²⁾
		8 hours ⁽³⁾		Short-term ⁽⁴⁾		
		mg/m ³ ⁽⁵⁾	ppm ⁽⁶⁾	mg/m ³	ppm	
	Manganese and Inorganic Manganese compounds (as Manganese)	0,2 ⁽⁷⁾ 0,05 ⁽⁸⁾	---	---	---	---
55-63-0	Glycerol trinitrate	0,095	0,01	0,19	0,02	skin
56-23-5	Carbon tetrachloride	6,4	1	32	5	skin
61-82-5	Amitrole	0,2	---	---	---	---
64-19-7	Acetic acid	25	10	50	20	---
74-90-8	Hydrogen cyanide (as cyanide)	1	0,9	5	4,5	skin
75-09-2	Methylene chloride	353	100	706	200	skin
75-35-4	Vinylidene chloride	8	2	20	5	---
78-10-4	Tetraethyl silicate	44	5	---	---	---
79-10-7	Acrylic acid	29	10	59	20	---
107-02-8	Acrolein	0,05	0,02	0,12	0,05	---
107-31-3	Methyl formate	125	50	250	100	skin
127-18-4	Tetrachloroethylene	138	20	275	40	skin
141-78-6	Ethyl acetate	734	200	1468	400	---
143-33-9	Sodium cyanide (as cyanide)	1	---	5	---	skin
151-50-8	Potassium cyanide	1	---	5	---	skin

¹ CAS: Chemical Abstract Service Registry Number

² A *skin notation* assigned to the occupational exposure limit value indicates the possibility of significant uptake through the skin

³ Measured or calculated in relation to a reference period of eight as a time-weighted average

⁴ A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified

⁵ mg/m³: milligrams per cubic metre of air at 20° C and 101,3 KPa

⁶ ppm: parts per million by volume in air (ml/m³)

⁷ Inhalable fraction

⁸ Respirable fraction

CAS ⁽¹⁾	NAME OF AGENT	LIMIT VALUES				Notation ⁽²⁾
		8 hours ⁽³⁾		Short-term ⁽⁴⁾		
		mg/m ³ ⁽⁵⁾	ppm ⁽⁶⁾	mg/m ³	ppm	
	(as cyanide)					
431-03-8	Diacetyl	0,07	0,02	0,36	0,1	---
630-08-0	Carbon monoxide	23	20	117	100	---
1305-62-0	Calcium hydroxide	1 ⁽⁸⁾	---	4 ⁽⁸⁾	---	---
1305-78-8	Calcium oxide	1 ⁽⁸⁾	---	4 ⁽⁸⁾	---	---
7446-09-5	Sulphur dioxide	1,3	0,5	2,7	1	---
7580-67-8	Lithium hydride	---	---	0,02 ⁽⁷⁾	---	---
61788-32-7	Hydrogenated terphenyl	19	2	48	5	---