





Λευκωσία, 2 Μαρτίου 2015

ΠΡΟΣ: Όλους τους ενδιαφερόμενους

ΑΠΟ: Γενικό Γραμματέα

ΘΕΜΑ: Προσχέδιο Ευρωπαϊκής Συμβουλευτικής Επιτροπής για

ασφάλεια και υγεία για τη θέσπιση του 4ου καταλόγου

Ενδεικτικών Οριακών Τιμών Επαγγελματικής Έκθεσης.

Κυρίες / Κύριοι

Επισυνάπτεται η γνωμοδότηση της Ευρωπαϊκής Συμβουλευτικής Επιτροπής για ασφάλεια και υγεία στη εργασία σχετικά με τον 4^{ον} κατάλογο Ενδεικτικών Οριακών Τιμών Επαγγελματικής Έκθεσης (Indicative Occupational Exposure Limit Values – IOELVs).

Αν έχετε οποιαδήποτε σχόλια παρακαλώ όπως μας τα αποστείλετε στο email: freedom@ccci.org.cy ή στο φαξ: 22665685 το αργότερο μέχρι τις 30 Μαρτίου 2015.

Με εκτίμηση,

Παναγιώτης Παναγής, Λειτουργός Τμήματος Εργασιακών Σχέσεων.

/EΞ



The Advisory Committee on Safety and Health at Work

DRAFT Supplementary Opinion

Supplementary 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

Doc. XXXX/15

Adopted on XX/05/2015

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

This opinion has been prepared by the Working Party on Chemicals (WPC). It supplements the one adopted by the Advisory Committee on Safety and Health at Work (ACSH) the 27/11/2014 (Doc. 1893/14) 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/EC¹. The WPC invites the Plenary of the Advisory Committee on Safety and Health at Work (ACSH) to adopt this supplementary Opinion.

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, or groups of substances, have been adopted up to now (Directives 2000/39/EC², 2006/15/EC³, 2009/161/EC⁴). Directive 91/322/EEC⁵, derived from the repealed Directive 80/1107/EEC⁶, 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 prepared an opinion on the preparation of a Directive establishing a 4th list of IOELVs which was endorsed by the Plenary of the ACSH on the 27/11/2014 (Doc. 1893/14).

Further to that, the WPC has continued to work on the candidate substances included in their work plan for which more discussion was needed at the time of drafting the referred Opinion (Doc. 1893/14). These substances could also be part of the proposal of a Commission Directive establishing a 4th list of IOELVs and therefore the WPC has decided to draft this Supplementary Opinion.

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

2. SUMMARY OF THE DISCUSSIONS IN THE WPC

In the meeting of the WPC in February 2015, it was finalised the discussion on a number of substances to be proposed for an IOELV at EU level.

A summary of the discussions, focused on the workability 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.

White Spirit

General Remarks

The SCOEL Recommendation SUM 87 (2007) proposes the following limits:

8h - TWA: 116 mg/m³ (20 ppm)

15 min - STEL: 290 mg/m³ (50 ppm)

The WPC notes that since the date of adoption of the SCOEL Recommendation there have been significant changes to the definition and certain other aspects relating to how commercial white spirit is placed on the market. These changes reflect the requirements of CLP and REACH Regulations. As such the definition used in the existing SCOEL Recommendation is no longer in line with current commercial practices and this may create confusion in the interpretation and use of the limit values recommended by SCOEL.

For the above reason the WPC suggests SCOEL to review itsthe Recommendation.

Workers Interest Group comments

Employers Interest Group comments

Governments Interest Group comments

Diphenylether octabromoderivative (DPBDE), commercial mixture (CAS No. 32536-52-0)

General Remarks

The SCOEL Recommendation SUM 148, adopted in 2012, proposes the following limit:

8h – TWA: 0,2 mg/m³ DPBDE (commercial mixture)

Some concern was expressed on the need and utility of setting a limit value for a substance which is already restricted at EU level (entry 45, annex XVII REACH), and for which the occupational exposure is expected to be very limited, mainly, but not only, in the waste treatment sector.

In addition the SCOEL Recommendation applies to the commercial mixture that can no longer be placed on the EU market. The WPC noted that it may be more appropriate to have an OEL for the specific chemical, and that this could be addressed via a more general consideration of bromine compounds.

For all the above reasons, the WPC concluded not to support the inclusion of this substance in the proposal for a 4th list of IOELVs.

Workers Interest Group comments

Employers Interest Group comments

Governments Interest Group comments

Bisphenol A (CAS No. 80-05-7)

General Remarks

The proposal is based on SCOEL Recommendation SUM 113, revised in 2012:

8h – TWA: 2 mg/m³ (inhalable dust)

An Indicative Occupational limit value is already set at EU level for this substance in Directive 2009/161/EU (8h – TWA: 10 mg/m³), following the SCOEL Recommendation first adopted in 2004.

All interest groups agree with the proposed value.

Workers Interest Group comments

Employers Interest Group comments

Governments Interest Group comments

Nickel metallic (CAS No. 7440-02-0)

General Remarks

The SCOEL SUM 85, adopted in 2011, recommends the following values:

8h-TWA: 0.005 mg/m³ (respirable fraction)

There are three key issues that were identified as being critical to the development of an IOELV for this substance, these are:

- The availability of new scientific data since the adoption of the SCOEL Recommendation.
- The ability to measure the substance at the level suggested for the IOELV and
- The ability to comply with the suggested value.

DG EMPL has requested SCOEL to assess the impact of recent scientific studies on the existing Recommendation.

The WPC notes that the measurement of Nickel metallic may pose some technical challenges and this needs to be further assessed.

Workers Interest Group comments

Employers Interest Group comments

Governments Interest Group comments

Inorganic nickel compounds

Due to their classification under the CLP Regulation these substances are in the scope of Directive 2004/37/EC (CMD). According to the outcome of the preliminary legal assessment carried out by EMPL.B3, OELs for substances classified <u>under</u> the CLP Regulation as Carcinogens or Mutagens 1A or 1B cannot be set under the legal framework of Directive 98/24/EC, even if a practical threshold of exposure can be identified, which is the case for inorganic nickel compounds as stated in the SCOEL Recommendation 85, adopted in 2011.

Therefore, <u>EMPL B3 should</u> consider proposing a Binding OEL under Directive 2004/37/EC for this group of substances.

Nitrogen monoxide (CAS No. 10102-43-9) and Nitrogen dioxide (CAS No. 10102-44-0)

General Remarks

The proposal for nitrogen monoxide (NO) is based on SCOEL Recommendation SUM 89, revised in 2014:

8h – TWA: 2,5 mg/m³ (2 ppm)

This substance has an Indicative Occupational Exposure Limit at EU level set in Directive 91/322/EEC (8h – TWA: 25 ppm).

The proposal for nitrogen dioxide (NO₂) is based on SCOEL Recommendation SUM 53, revised in 2014:

8h – TWA: 0,995 mg/m³ (0,5 ppm) 15 min – STEL: 1,91 mg/m³ (1 ppm)

All the interest groups agree with the proposed values whilst recognising the specific challenges for the sectors detailed below.

The WPC recognises the practical problems the proposed limits for NO and NO_2 pose for the underground mining and tunnelling sectors, which in general depends on local details of the process, equipment and layout. Compliance with the limits for personal exposure should always be the objective, but this may take time in these sectors, depending on the circumstances. The WPC (ACSH) encourages the SWP to provide practical guidance on how the limits can be met to the greatest extent possible, and to report progress.

The Commission has been informed of challenges regarding measurement methodologies for NO₂ and is checking the suitability of available approaches.

Workers Interest Group comments

Employers Interest Group comments

Governments Interest Group comments

2-ethylhexanol (CAS No. 104-76-7)

General Remarks

The proposal is based on SCOEL Recommendation SUM 158, adopted in 2011:

 $8h - TWA: 1 ppm (5.4 mg/m^3)$

All the interest groups agree with the proposed value.

Workers Interest Group comments

Employers Interest Group comments

Governments Interest Group comments

But-2-yne-1,4-diol (CAS No. 110-65-6)

General Remarks

The proposal is based on SCOEL Recommendation SUM 159, adopted in 2011:

8h – TWA: 0.5 mg/m³

All the interest groups agree with the proposed value.

Workers Interest Group comments

Employers Interest Group comments

Governments Interest Group comments

Diphenyl ether (CAS No. 101-84-8)

General Remarks

The proposal is based on SCOEL Recommendation SUM 182, adopted in 2012:

 $8h - TWA: 1 ppm (7 mg/m^3)$

15 min – STEL: 2 ppm (14 mg/m³)

All the interest groups agree with the proposed value.

Workers Interest Group comments

Employers Interest Group comments

Governments Interest Group comments

Nitroethane (CAS No. 79-24-3)

General Remarks

The proposal is based on SCOEL Recommendation SUM 183, adopted in 2012:

 $8h - TWA: 20 ppm (62 mg/m^3)$

15 min – STEL: 100 ppm (312 mg/m³)

A skin notation is also proposed.

All the interest groups agree with the proposed value.
Workers Interest Group comments
Employers Interest Group comments
Governments Interest Group comments
1,4-Dichlorobenzene (CAS No. 106-46-7)
General Remarks
The proposal is based on SCOEL Recommendation SUM 65, revised in 2014:
8h – TWA: 2 ppm (12 mg/m³)
15 min – STEL: 10 ppm (60 mg/m³)
A skin notation is also proposed.
SCOEL categorizes this substance as a carcinogen group D (non-genotoxic carcinogen with a threshold). Under the CLP Regulation this substance is classified as carcinogen 2 and therefore not under the scope of Directive 2004/37/EC.
All the interest groups agree with the proposed value.
Workers Interest Group comments
Employers Interest Group comments

Governments Interest Group comments

3. SUBSTANCES PROPOSED FOR A 4TH LIST OF IOELVs IN THIS SUPPLEMENTARY **OPINION**

CAS(1)	NAME OF AGENT	LIMIT VALUES				Notation(²)
		8 hours (³)		Short-term (⁴)		
		mg/m ³ (⁵)	ppm (⁶)	mg/m³	ppm	
79-24-3	Nitroethane	62	20	312	100	skin
80-05-7	Bisphenol A	2 (7)	-	-	-	-
101-84-8	Diphenyl ether	7	1	14	2	-
104-76-7	2-ethylhexanol	5.4	1	-	-	-
106-46-7	1,4-Dichlorobenzene	12	2	60	10	skin
110-65-6	But-2-yne-1,4-diol	0,5	-	-	-	-
10102-43-9	Nitrogen monoxide	2,5	2	-	-	-
10102-44-0	Nitrogen dioxide	0,995	0,5	1,91	1	-

CAS: Chemical Abstract Service Registry Number
 A skin notation assigned to the occupational exposure limit value indicates the possibility of significant uptake through the skin

through the skin

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

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

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