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The Advisory Committee on Safety and Health at Work

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

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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)

This Supplementary 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) on the 27/11/2014 (Doc. 1893/14) on a proposed list of substances for which an Indicative Occupational Exposure Limit Value (IOELV) could be set under a Commission Directive, pursuant to Directive 98/24/EC[1]. The WPC invites the Plenary of the 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/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 Directive 91/322/EEC[5], derived from the repealed Directive 80/1107/EEC[6], is still in force and establishes limit values for another 10 chemical substances.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 2014-2016 (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 in its work plan, including substances for which more discussion was needed at the time of drafting the above Opinion (Doc. 1893/14). These substances could also be part of the proposal for a Commission Directive establishing a 4th list of IOELVs, and therefore the WPC has drafted 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 discussions were finalised on proposals for IOELVs at EU level for a number of substances.

A summary of the discussions, focusing on the workability of the values recommended by SCOEL, and the conclusions reached, follows for each substance or group of substances.

Biological limit values do not form part of this proposal. However, the ACSH recognises the possible importance of such values for some substances and encourages the WPC and the Commission services to continue to discuss this issue.

White Spirit

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 the 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 reviews its Recommendation and does not support the inclusion of this substance in the proposal for a 4th list of IOELVs.

Employers Interest Group comments

Employers Interest Group confirms that the Hydrocarbon Solvent Producers Association (HSPA) has developed a “naming convention”, under which hydrocarbon solvents were registered under REACH. The naming convention brings clarity and specificity on solvent composition and differentiation. SCOEL would benefit by evaluating “white spirit” under this nomenclature.

By following the “naming convention” the IOELV could be aligned with the recent RAC decision to differentiate the aliphatic/aromatic solvents from the de-aromatised grades. HSPA can provide information specific to hydrocarbon solvents in general and specifically those substances most similar to the now-classified substances.

By bringing clarity to solvent composition, occupational studies of 1960-1980 relevant to “white spirit”, (i.e., a primarily C9-C11 aliphatic solvent with 15%-20% aromatic) will become more meaningful. Employers strongly support the proposal to bring the discussion back to SCOEL. SCOEL might then also take into account limit values for hydrocarbon solvents obtained through other methodologies used for regulatory purpose (e.g. EH40/2005, TRGS900) in order to avoid confusion.

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

General Remarks

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.

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

General Remarks

The proposal is based on SCOEL Recommendation SUM 113, revised in 2014:

8h – TWA: 2 mg/m^3 (inhalable dust)

An IOELV is already set at EU level for this substance in Directive 2009/161/EU (8h – TWA: 10 mg/m^3), following the SCOEL Recommendation first adopted in 2004.

All interest groups agree with the proposed revised value.

Workers Interest Group comments

Although the WIG agrees with the proposed revised value for BPA, the WIG notes that an increasing number of scientific papers identify BPA as an endocrine disruptor chemical for which no safe threshold can be derived. Should this be confirmed by new long-term toxicity study, the WIG is of the opinion that BPA should be removed from the list of IOELVs under the Chemical Agents Directive, with the view to laying down a binding occupational exposure limit value in the then appropriate legal instrument.

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/m^3 (respirable fraction)

Three key issues 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 metallic nickel at the level recommended by SCOEL may pose some technical challenges and this needs to be further assessed.

Workers Interest Group comments

The WIG agrees with the proposed value unless the current review by SCOEL will result in a revised recommendation.

The ability to measure the substance is not an issue, given the method described in "BGI 505-10" as "Verfahren 3" with a level of determination of 0,47 µg/m³, published by the German Mandatory Accident Insurance Schemes (DGUV, "Berufsgenossenschaften") in 2007, electronically available at: http://publikationen.dguv.de/dguv/pdf/10002/i-505-10.pdf

Since indicative OELVs are to be based solely on health effects and the availability of measurement techniques, the inclusion of a feasibility factor is not a legal option.

Regarding the ability to comply with the proposed value, the WIG wants to highlight the fact that neither for tasks with nor for uses of nickel metal any exposure data have been presented to the WPC as yet which might indicate that compliance with the proposed value would constitute an issue. Furthermore, no details about the state of technology of both operational conditions and control measures of such tasks and uses have been made available to the WPC which might corroborate the suggestion of difficulties complying with the proposed value.

Employers Interest Group comments

The review of SCOEL's proposal for the metallic Nickel OEL value has highlighted significant technical and analytical feasibility challenges which need to be further discussed. Similarly, new scientific information is being reviewed by SCOEL; in that context, Employers request to await its opinion in view of its potential implications on the SCOEL Recommendation and the proposed OEL. Metallic nickel OEL values (respirable and inhalable) somewhat higher than the one currently proposed by the SCOEL could be derived when refinements to the OEL calculations are considered. These values would be equally health protective but easier to measure and comply with. In light of the key critical issues and uncertainties identified, the Employers group considers that the OEL currently proposed for metallic Nickel should be further assessed.

For some uses, the level of containment required for achieving the proposed OEL is not technically feasible and may require permanent wearing of PPE which is not recommended for long term tasks.

In addition, in some countries the regulatory level of acceptability requires to be able to measure concentration below 1/10 of the OEL which is not compatible with the Limit of Quantification (LoQ) of existing analytical methods.

Governments Interest Group comments

The Government Interest Group supports the request by DG EMPL that SCOEL considers whether new scientific studies impact on SCOEL's existing recommendation for nickel metal. The GIG also notes that achieving compliance with a respirable limit of 0,005 mg/m^3 for metallic nickel is unrealistic in some fields of industry such as nickel refineries, even where standards of occupational health are good. Such a low value would lead to constant use of personal protective equipment when such measures should be reserved as a last resort.

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 preliminary legal assessment carried out by EMPL.B3, OELs for substances classified under the CLP Regulation as Carcinogen or Mutagen 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 SUM 85, adopted in 2011.

Therefore, depending on the outcome of the legal assessment by the Legal Service of the Commission, EMPL B3 should 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/m^3 (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 (NO_2) is based on SCOEL Recommendation SUM 53, revised in 2014:

8h – TWA: 0,995 mg/m^3 (0,5 ppm)

15 min – STEL: 1,91 mg/m^3 (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 depend on local details of the process, equipment and mine or tunnel design/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 encourages the Standing Working Party for the Extractive Industry (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 NO_2 in mining and tunnelling environments and is checking the suitability of available approaches.

Workers Interest Group comments

The WIG notes that these substances have been under discussion in the WPC for almost 10 years (second IOELVs list) with repeated postponements for IOELVs adoption due to ongoing studies and new data awaited from industry. The WIG is therefore of the opinion that the proposed IOELVs should now be adopted without further delay.

Employers Interest Group comments

As the practical problems of the proposed limits for NO and NO_2 for the underground mining and tunnelling sectors are very evident, these activities should be exempted from the execution of the indicative limit values. Instead the Standing Working Party for the Extractive Industry (SWP) should be encouraged to prepare a report on the technical feasibility of achieving the proposed limit values for NO and NO_2 in underground mining and tunnelling taking into account best practices and available technologies. Employers suggest that the situation of underground mining and tunnelling activities should be reassessed within 5 years after entering into force of the fourth list of indicative limit values taking account of the conclusions of the SWP report.

In addition, in some countries the regulatory level of acceptability requires to be able to measure concentration below 1/10 of the OEL which is not compatible with the Limit of Detection (LoQ) of existing analytical methods.

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.

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/m^3

All the interest groups agree with the proposed value.

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/m^3)

All the interest groups agree with the proposed value.

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/m^3)

A *skin notation* is also proposed.

All the interest groups agree with the proposed value.

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/m^3)

15 min – STEL: 10 ppm (60 mg/m^3)

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 is not in scope of Directive 2004/37/EC.

All the interest groups agree with the proposed value.

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/m³ ([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	-

[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 hours 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