

EUROPEAN COMMISSION
Employment, Social Affairs and Inclusion DG

Employment and Social Legislation, Social Dialogue
Health, Safety and Hygiene at Work

Luxembourg,
EMPL B3/AMo/zp (2013)

SCOEL Contact Points

Dear Sir or Madam,

**Subject: Activities of the Scientific Committee on Occupational Exposure
Limits (SCOEL)**

In the context of cooperation and transparency concerning the Commission's activities in the establishment of Occupational Exposure Limits, I send you the adopted note of the 85th meeting of the Scientific Committee on Occupational Exposure Limits (SCOEL) held in Luxembourg on 26th – 27th September 2012.

Yours faithfully,

Maria-Teresa Moitinho de Almeida
Acting Head of Unit

C.c.: SCOEL Members
 Members of ACSH Working Party on Chemicals



NOTE on the 85th MEETING of the Scientific Committee on Occupational Exposure Limits

**26-27 September 2012
EUFO - Conference Room
L-2920 Luxembourg
(Gasperich)**

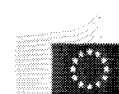
1.	Opening of the meeting by the Chair (Prof. Hermann Bolt)
1.1	Adoption of the agenda The agenda was adopted.
1.2	Conflicts of interest The chairman requested members to indicate whether any of the agenda items presented a conflict of interest. No conflicts of interest were reported.
1.3	Adoption of the draft note of the 84th meeting The minutes of the 84 th SCOEL meeting were adopted without changes and will be published on the SCOEL website, which from now on will be the normal procedure.
2.	General information on the Commission's activities relevant to the work of SCOEL
2.1	Suspended adoption of amended SCOEL Decision The adoption of an amended SCOEL Decision (intended to deal with allowances together with aspects of transparency and ethics) was suspended due to financial aspects at the very last minute. Alternative approaches are under consideration. This includes, e.g., a Commission Decision from 5 December 2007 (<i>Rules on the reimbursement of expenses incurred by people from outside the Commission invited to attend meetings in an expert capacity</i>) can be applied for SCOEL, which allows an up to 50 % increase in allowances to "working groups of high level experts".
2.2	JRC Scientific support
2.2a	<i>3rd TWG Meeting, 13 June 2012</i> The minutes are available on CIRCA (post-meeting: transferred to CIRCABC).
2.2b	<i>4th TWG Meeting, 9 September 2012 (via teleconference)</i> This teleconference was a review of the criteria documents presented under item 2.2d. It was agreed that the documents could be submitted to SCOEL for further review.
2.2c	<i>New administrative arrangement</i> DG EMPL is in the process of signing the 2 nd administrative arrangement, which will last for a period of 24 months. A continuation of the work on the rubber industry will be added to the draft arrangement (item 2.2.e4).
2.2d	<i>JRC criteria document drafts for discussion (structure/content, how to proceed):</i> Generally, it was agreed to use the JRC criteria documents (CDs) as a basis for Recommendations like SCOEL has done in the past with CDs produced by other bodies. SCOEL will make an independent evaluation of the data and consult also other sources as needed. Critical issues should be discussed in more detail, as is the normal procedure, but for non-critical issues a reference to the CD was considered adequate. For transparency, the CDs have to be published and made publicly available. It should be clear that the CDs have been prepared for SCOEL by a third party. The JRC <i>summaries</i> can be used as a starting point for a Recommendation, but should be taken out of the CDs and handled over to SCOEL separately. It was further requested that reference lists in such summaries should cover only studies referenced in the summaries and not include what is only cited in the more comprehensive CDs. As regards requests from the outside to include new (non-critical) data in Recommendations based on CDs, a modification of the key methodology document may be needed and also a revision of the standard letter accompanying

	<p>Recommendations sent for consultation.</p> <p>DG EMPL and SCOEL expressed their gratitude and appreciation of the work performed by the JRC.</p>
	<p>1. TiO₂ (incl. nanosized particles)</p> <p>It was agreed to prepare a Recommendation based on the JRC document (and with the proposed summary used as starting point) with one key issue being the differentiation between respirable and ultrafine particles. This Recommendation could also serve as a model regarding the general procedure aspect and how to proceed.</p> <p>ACTION: Prepare a draft Recommendation to be discussed at the December meeting.</p>
	<p>2. Zinc and its inorganic compounds</p> <p>Some key points to be addressed are a more thorough discussion on particle size and that effects of both particle toxicity and zinc toxicity have to be considered. It was considered essential to recommend an OEL that prevents zinc overload (leading to copper deficiency). It was agreed to draft a SCOEL Recommendation based on the JRC documentation and other material as needed and to have a first discussion at the December meeting.</p> <p>ACTION: Prepare a draft Recommendation to be discussed at the December meeting.</p>
	<p>3. Hexachlorobenzene</p> <p>It was agreed that the best approach would be to propose a BLV in light of the long half time and limited use of the compound, and to base a SCOEL Recommendation on the JRC documentation and other material as needed and to have a first discussion at the December meeting.</p> <p>ACTION: Prepare a draft Recommendation to be discussed at the December meeting.</p>
	<p>4. Beryllium and compounds</p> <p>Questions raised were if grouping according to solubility is needed and how to interpret exposure level data (median or mean levels). Possible measurement difficulties at a recommended OEL may need to be addressed. It was further pointed out that sensitisation, and not chronic beryllium disease, is the critical effect. The relevance of skin exposure and need for a skin notation was emphasised. It was agreed to draft a SCOEL Recommendation based on the JRC documentation and other material as needed and to have a first discussion at the December meeting.</p> <p>ACTION: Prepare a draft Recommendation to be discussed at the December meeting.</p>
	<p>5–6. Diethyl phthalate and dimethyl phthalate</p> <p>The toxicological data base was considered limited. The available inhalation DNEL for dimethyl phthalate seems to be based on a study that is accessible to SCOEL. If BGVs are to be proposed, it was considered important to carefully evaluate the methodology for urinary sampling. If the excretion is biphasic, sampling type and time will highly affect the results and measures should be taken not to miss a possible 2nd peak of excretion. It was agreed to base a SCOEL Recommendation on the JRC documentation and other material as needed and to have a first discussion at the December meeting.</p>

	ACTION: Prepare a draft Recommendation to be discussed at the December meeting.
	<p>7. Carbon nanotubes</p> <p>The overall complexity of the topic was discussed. Key issues included the characteristics of workplace exposure, e.g. single fibres vs. agglomerates, the stability of agglomerates, and the variability/complexity in surface properties, and how to handle the CNTs, on a case by case basis or as groups according to some common criteria. It was agreed to draft a SCOEL Recommendation based on the JRC documentation and other material as needed (e.g. the draft NEG document should be consulted) and to have a first discussion at the next meeting. At that stage, a compilation of arguments and suggestions on how to proceed and handle this topic was considered most important.</p> <p>ACTION: Prepare a draft Recommendation to be discussed at the December meeting.</p>
2.2e	<i>JRC scoping study drafts for discussion:</i>
	<p>1. Aviation engine oils/hydraulic fluids (incl. cabin air contamination)</p> <p>At present, this was not considered an issue for setting an OEL and therefore there is no immediate necessity for SCOEL involvement or action. However, the report highlights the possibilities for risk management. The procedural issues or how to handle the final report was postponed for a future meeting.</p> <p>ACTION: Put on the agenda for a future meeting for a SCOEL endorsement or statement.</p>
	<p>2. Aviation fuels</p> <p>In the JRC scoping study it was concluded that this is an area for which a derivation of OELs may be feasible. It has been agreed that the JRC, within the 2nd administrative arrangement (funded by DG EMPL), will prepare a criteria document on this topic for future SCOEL involvement.</p> <p>ACTION: No immediate action (await JRC criteria document).</p>
	<p>3. Combustion products from aviation fuels</p> <p>Issues raised for future work were harmonisation of analytical procedures (what is measured and how) and the assessment of individual exposure. A small expert workshop (presumably with participation from SCOEL) could address these issues.</p> <p>It has been agreed that the JRC, within the 2nd administrative arrangement (funded by DG EMPL), should take this work forward. The JRC will update routinely to give SCOEL a possibility to interact and help steer the work. The end product will be handed over to SCOEL to give an expert judgement.</p> <p>ACTION: No immediate action (await continued JRC feedback).</p>
	<p>4. Occupational exposures in the rubber industry</p> <p>The complexity of the problem was acknowledged. As rubber dust/fumes cannot be easily generated and studied in animal experiments, epidemiological data are the key to information, but the latency between exposure and onset of disease (cancer) is problematic as is the variability in exposures over time and between processes/sectors. It was mentioned that there is research going on in the UK, and publications already available, on projections on cancer burden based on current exposures. The nitrosamines should be at focus of future work, whereas <i>most</i> of the</p>

	<p>problems with aromatic amines were considered to be historical.</p> <p>It was decided to add <i>Occupational exposures in the rubber industry</i> to the 2nd administrative arrangement with the JRC, to outline a strategic approach for the future and to identify key areas (e.g. chemical agents, or processes/sectors) and presumably with a special focus on the nitrosamines.</p> <p>ACTION: No immediate action (await continued JRC feedback).</p>
2.3	<p>SCOEL – Renewal of term of office</p> <p>DG EMPL has received a number of nominations for the 6th term of office (2013-15). However, SCOEL members not yet nominated who wish to continue for the next term of office were encouraged to contact their relevant national authorities to ensure that appropriate actions are being taken. Based on nominations received, an evaluation committee will appoint SCOEL members for the 6th term of office (first meeting scheduled at 13 November). Hopefully, the new panel will assemble for the first time in March 2013. It was regarded essential to finish as many open files/documents as possible before the end of this year. At the end of this year, a quality check of the JRC documents will also be needed and a discussion about procedures regarding them.</p>
2.4	<p>Migration from CIRCA to CIRCABC</p> <p>The migration to the new information portal will take place at the beginning of October and SCOEL will be informed when the new system is operational. All historical documents will be available on CIRCABC.</p>
2.5	<p>ECHA Workshop on REACH and OSH</p> <p>SCOEL will be represented by G. Johanson (giving an oral presentation on the relation between OELs and DNELs), H. Bolt (round table discussion) and some additional members. It was argued that (although DNELs can usually be found) access for SCOEL to the REACH data is a problem that needs to be addressed at ECHA and should be a major point at the discussion.</p>
2.6	<p>Formaldehyde (SCOEL/SUM/125) (CAS No: 50-00-0)</p> <p>There is a need, and an expectation from stakeholders, that SCOEL re-opens this issue to clarify if the present SCOEL Recommendation from 2008 needs to be revised based on new studies. It was therefore suggested to have a brief up-to-date presentation of the scientific data by the rapporteur and short discussion at the December meeting. However, the main discussion will be postponed till the SCOEL members appointed for the 6th term of office meet in 2013.</p> <p>ACTION: Prepare brief presentation of the new scientific data for the December meeting (item 8).</p>
3.	Final adoption/editing of SCOEL Recommendations
3.1	<p>Nitroethane (SCOEL/SUM/183) (CAS No: 79-24-3)</p> <p>The Recommendation and draft reply were adopted.</p> <p>ACTION: Send reply letter and publish the adopted Recommendation on the website after technical editing.</p>

4.	Review of methodological issues
4.1	<p>Notation for hearing impairment ("noise notation") The draft addition to the SCOEL Methodology document (new Chapter 11. Strategy for assigning a noise notation) was accepted.</p> <p>ACTION: Publish the updated SCOEL Methodology document.</p>
5.	SCOEL draft Recommendations: after consultation with the contact points
5.1	<p>2-Phenylpropane (Cumene) (SCOEL/SUM/29) (CAS No: 98-82-8) The key issue is whether or not it is possible to recommend an OEL for this threshold carcinogen, based on a 3-month study when the NTP long-term cancer study did not provide a NOAEL. It was decided to re-consult the studies on cancer mechanisms to check the argumentation and to ensure consistency in Section 2.7.3 and Chapter 3. The discussion will be continued at the next meeting.</p> <p>ACTION: Revise the draft Recommendation and prepare a draft reply for the December meeting.</p>
5.2	<p>Nitrogen dioxide (SCOEL/SUM/53) (CAS No: 10102-44-0) The consultation period has been extended (originally July–September). In light of comments already received, it was requested to have a detailed presentation and discussion of the Morfeld data/methodology (including sub-group with higher exposure) at the next SCOEL meeting. By that time, the consultation period will have ended and all comments received.</p> <p>ACTION: Explore the possibilities and make arrangements for Dr Morfeld to attend the December meeting.</p>
5.3	<p>BGV addendum MOCA (Annex to SCOEL/SUM/174) (CAS No: 101-14-4) The consultation period has been extended. In response to comments already received, it was agreed to revise the definition of a BGV in the key methodology document to include cases like this when there is no background exposure. The discussion will be continued at the next meeting when the consultation period is closed.</p> <p>ACTION: Revise the definition of BGV in the key methodology document and circulate for comments/approval. Make amendments of the draft Recommendation and reply to be considered at the December meeting (item 5).</p>
5.4	<p>Diphenyl ether (SCOEL/SUM/182) (CAS No: 101-84-8) Comments received from the contact points were discussed and amendments in response to these were suggested.</p> <p>ACTION: Make amendments of the draft Recommendation and reply for final adoption (item 3) at the December meeting.</p>
5.5	<p>Annex to Acrylamide (SCOEL/SUM/139) (CAS No: 79-06-1) Comments received from the contact points were discussed and amendments in response to these were suggested. It was clarified that the recommended biological guidance value is for non-smokers.</p> <p>ACTION: Make amendments of the draft Recommendation and reply for final adoption (item 3) at the December meeting.</p>



5.6	<p>N-methylaniline (SCOEL/SUM/178) (CAS No: 100-61-8) Comments received from the contact points were discussed and amendments in response to these were suggested.</p> <p>ACTION: Edit and prepare the Recommendation and draft reply for final adoption (item 3) at the December meeting.</p>
6.	<p>SCOEL draft Recommendations: before consultation with the contact points</p>
6.1	<p>Bisphenol A (SCOEL/SUM/113) (CAS No: 80-05-7) It was agreed to propose at biological guidance value based on European data, with support also from Canadian data. The need for a skin notation was discussed. A more detailed description of all studies influencing a possible skin notation was requested together with a calculation of the possible skin uptake as compared to the inhalatory uptake at the proposed OEL.</p> <p>ACTION: Revise according to the discussion and present new draft for the December meeting (item 6).</p>
6.2	<p>Copper and inorganic copper compounds (SCOEL/SUM/171) (CAS-No: 7440-50-8) It was agreed to propose the value of 0.01 mg/m³ for the respirable fraction. Regarding the inhalable fraction, it was concluded not to suggest a value but to keep the proposed explanation, but with the table in an annex. It should also be stated that presumably at least part of the exposure in the human key study was to ultrafine particles in the fume, but that manufactured nanoparticles cannot be assessed and may differ in toxicity.</p> <p>ACTION: Revise accordingly and send the draft Recommendation for a 6-month consultation.</p>
6.3	<p>Iso-Amyl alcohol (SCOEL/SUM/177) (CAS No: 123-51-3) Not discussed.</p> <p>ACTION: Present new draft at the December meeting (item 6).</p>
6.4	<p>Trimethylamine (SCOEL/SUM/179) (CAS No: 75-50-3) The argumentation for an OEL and a STEL was discussed. It was agreed that an OEL of 2 ppm could be derived primarily based on animal data, which are supported by the available human data for the compound itself and for related compounds. A 5-ppm STEL because of the irritancy of the compound would also be in accordance with the available human data. The Kubara <i>et al</i> reference should be omitted in the Recommendation section, but the relationship between OELs and RD₅₀s for sensory irritants kept, with a reference to Schaper. To facilitate the discussion at the next meeting, the revised (primarily the Recommendation section) draft should be circulated among SCOEL beforehand. Written suggestions and comments could then be inserted before the meeting.</p> <p>ACTION: Revise according to the discussion and circulate the draft to SCOEL before the next meeting (item 6).</p>
6.5	<p>Phosphoryl trichloride (SCOEL/SUM/181) (CAS No: 10025-87-3) Due to the primarily irritant properties of this compound, it was decided to propose a STEL only (0.02 ppm), which would then apply to each 15-minute period of an 8-hour exposure period. After revising accordingly and after having updated the reference list, the draft Recommendation will be sent to SCOEL to approve or</p>

	comment on. After approval by SCOEL, it will be sent for a 6-month consultation. ACTION: Revise according to the discussion and distribute to SCOEL. After approval, send the draft Recommendation for a 6-month consultation.
6.6	<i>n</i>-, <i>iso</i>- and <i>sec</i>-Butyl acetates (SCOEL/SUM/184–186) (CAS No: 123-86-4, 105-46-4, 110-19-0) It was decided to use RD ₅₀ s for scaling only, but to base an OEL and/or STEL on the study by Iregren <i>et al.</i> To assess the adversity of the reported effects, a more full description was requested. The risk of mixing irritation and odour from subjective measurements was mentioned. Therefore, it must be carefully checked if the subjective findings were supported by objective measurements. The Iregren study should be re-uploaded for the next meeting. ACTION: Revise according to the discussion and provide a revised draft for the December meeting (item 6).
6.7	<i>tert</i>-Butyl acetate (SCOEL/SUM/187) (CAS No: 540-88-5) Some new animal inhalation studies need to be incorporated and will be forwarded to the rapporteur. The discussion, including identification of the critical effect, will continue at the next meeting. ACTION: Revise according to the discussion and provide a revised draft for the December meeting (item 6).
6.8	4-Aminotoluene (SCOEL/SUM/145) (CAS No:106-49-0) A provisional OEL has been proposed. The value is linked to that for aniline and the relative potency to cause methemoglobin formation. If new data appear for aniline SCOEL may have to reconsider also the value for 4-aminotoluene. The draft was considered ready to be sent for consultation. ACTION: Send the draft Recommendation for a 6-month consultation.
6.9	Dibutyl phthalate (SCOEL/SUM/143) (CAS No:84-74-2) The argumentation for an OEL was considered sufficient. However, some minor addition/revision was suggested, mainly of the biomonitoring paragraph in the recommendation section and a possible recommendation of a biological guidance value. After revision, the draft should be distributed to SCOEL and, after approval, sent for consultation. ACTION: Revise the draft Recommendation according to the discussion, circulate and send for a 6-month consultation after approval.
6.10	1,3-Propane sultone (SCOEL/SUM/189) (CAS No: 1120-71-4) The draft Recommendation was considered ready to be sent for consultation. ACTION: Send the draft Recommendation for a 6-month consultation.
6.11	Nitrogen monoxide (SCOEL/SUM/89) (CAS No: 10102-43-9) It was decided to postpone the discussion of nitrogen monoxide till the next meeting when the critical data for both NO and NO ₂ can be presented and discussed in detail (see item 5.2). ACTION: None.



7.	SCOEL draft Recommendations: preliminary discussion
7.1	<p>Styrene (SCOEL/SUM/176) (CAS No: 100-42-5) Not discussed. ACTION: Prepare a draft for the December meeting (item 7).</p>
7.2	<p>n-Butanol (No SCOEL/SUM/43) (CAS No: 71-36-3) Not discussed. ACTION: Prepare a draft for the December meeting (item 7).</p>
7.3	<p>1,4-Dichlorobenzene (SEG/SUM/65b outdated) (CAS No: 106-46-7) The present Recommendation is outdated. An outline to an updated draft was briefly presented. A more solid evaluation will be presented at the next meeting ACTION: Prepare a draft for the December meeting (item 6).</p>
8.	SCOEL Recommendations: wrap up issues
8.1	<p>Wood dust (SCOEL/SUM/102) Not discussed. ACTION: Report on the progress Finnish research project at the December meeting.</p>
8.2	<p>Sulphuric acid (SCOEL/SUM/105) (CAS No: 7664-93-9) It was agreed that the preferred sampling fraction is the inhalable and that the rationale for this can be presented in a separate addendum. The overall assessment was considered still valid and the main document will thus stay in its present state. ACTION: Prepare a separate addendum clarifying the preferred sampling fraction and that the overall assessment has been regarded still valid (item 8).</p>
8.3	<p>Diacetyl (SCOEL/SUM/149) (CAS-No:431-03-8) New data have been published. It was decided to revise and update the present Recommendation and to address e.g. the problems concerning airborne measurements performed with different methods, suitable exposure measures and mutagenic effects. ACTION: Prepare a draft for the December-meeting (item 7).</p>
9.	Dates of future SCOEL meetings in 2012/2013
	<p>Dates confirmed: 13-14 December 2012 (EUFO) 20-21 March 2013 (EUFO) 12-13 June 201 (EUFO) 25-26 September 2013 (EUFO) 11-12 December 2013 (EUFO)</p>
10.	Any other business
	None.



LIST OF PARTICIPANTS

Prof. H. M. BOLT
Dr. D. BRUNET
Dr. E. DĂNULESCU
Prof. H. GREIM
Prof. A. HARTWIG
Prof. A. HAY
Dr. M. HORNYCHOVÁ
Dr. A. HUDÁK-DEMETER
Prof. D. LISON
Prof. R. MASSCHELEIN
Dr. G. NIELSEN
Dr. H. NORPPA
Dr. E. POSPISCHIL
Dr. T. SANTONEN
Dr. J. SKOWRON
Dr. J. TEJEDOR
Dr. R. WOUTERSEN

Absent: Prof. G. JOHANSON
Prof. L. LEVY
Dr. E. MIRKOVA

Commission

Dr. J. JÄRNBERG (DG EMPL/B3)
Mr. A. MORRIS (DG EMPL/B3)

Mr. D. PAPAMELETIOU (JRC-ISPRA)

Absent: Mr. A. ANGELIDIS (DG EMPL/B3)

Observers

Prof. S. ØVREBØ (EFTA)
Prof. M. GUILLEMIN (EFTA)