



Minutes of the Plenary Meeting of the Scientific Committee on Occupational Exposure Limits

10-11 June 2015

June 10 (10:00 – 18:30 h)

June 11 (09:00 – 17:30 h)

**JMO – Kirchberg
Jean Monnet Building,
Rue Alcide De Gasperi, L-2920 Luxembourg
Room C4/44
Luxembourg**


**2015-07-06
adopted by written procedure**

	AGENDA POINTS	RELATED DOCUMENTS
1.	Opening of meeting	
1.1	Adoption of the agenda The agenda of the meeting was adopted without changes.	<i>SCOEL draft agenda June 2015</i>
1.2	Welcome and introduction European Commission, DG Employment B.3 Health and Safety at Work Teresa MOITINHO DE ALMEIDA, Head of Unit Ms Moitinho welcomed the SCOEL Members for the new term of office and the very first term of office as under Commission Decision 2014/113/EU. Ms. Moitinho provided an overview of the underlying principles of EU worker protection legislation and its basis in the treaty of the functioning of the European Union, i.e. article 153. The legal basis of Occupational Exposure Limits at the EU level was explained being Directives 98/24/EC and 2004/37/EC. Practical benefits of EU OELs were presented as well as roles and responsibilities regarding compliance and enforcement. Ms. Moitinho raised the importance of SCOEL and its Members that all are appointed in a personal capacity and provide science- and technology-based advice to the European Commission on request. The meeting was further chaired by the Scientific Secretary to the Committee, Dr. Christoph Klein.	
1.5	The Commission services have invited experts for agenda items on Working Group (WG) Cooperation and WG Quality: Prof. Hermann Bolt, Dortmund Prof. Helmut Greim, München Both were present during the entire meeting, because the issues of these horizontal WGs were addressed throughout the agenda. Mr. Tim Bowmer from the European Chemicals Agency attended the meeting on request and in support to the Commission services at DG ENV and DG GROW. A tour de table was performed including the establishment of a table showing the fields of specialisation and experience of the individual members. <i>In order to further enhance readability, the abbreviation WG and WGs for the plural will be used throughout SCOEL documents: 'WG' for 'Working Group' and WGs for 'Working Groups'. In documents shared with the public, the term will normally be introduced once and when first used in the document.</i>	

1.3	<p>Conflicts of interest (COI) – Declaration of Interest (DOI)</p> <p>All appointed Members have provided signed declarations of interest to the Secretariat of SCOEL. The Commission services have assessed the declarations of the Members. An overview was provided about the outcome of analysis and mitigation measures proposed, which were accepted by the Members and experts. All obligations of the Members apply and especially the ethical principles addressed in article 9 of the Rules of Procedure and the Commission Decision 2014/113/EU.</p> <p>The mitigation measures comprise:</p> <ol style="list-style-type: none">1. Members that are designated 'industry' will not act as chair, co-chair or rapporteur for a project. In addition, such Members will only participate in a project up to and including level stage 30. A Member can participate to a project at stage 40 and/or stage 50, for both on request and if a declaration of absence of a conflict of interest is provided regarding the project.2. Members that are marked 'industry funding' will not act as chair, co-chair or rapporteur for a project unless a declaration of absence of a conflict of interest is provided regarding the project. In addition, the members will only participate in a project up to and including level stage 30. A Member can participate to a project at stage 40 and/or stage 50, for both on request and if declaration of absence of a conflict of interest is provided regarding the project.3. Members marked 'Member State' will not participate in projects that are related to a specific file, dossier, request brought forward by the Member State that she/he has an affiliation with.	DOI forms
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Expert Name	Conflict of Interest
Boogaard, Pieter Johannes	Industry
Cocker, John	Member State, funding by industry
Hartwig, Andrea	NONE
Heederik, Dick	Funding by industry and Member State
Hoffmann, Sebastian	NONE
Johanson, Gunnar	Member State, funding by industry
Kromhout, Hans	Funding by industry
Landsiedel, Robert	Industry
Leibold, Edgar	Industry
Levy, Len	Funding by industry
Manno, Maurizio	NONE
Moretto, Angelo	Funding by industry
Nemery de Bellevaux, Benoit	NONE
Nielsen, Gunnar	Member State
Pospischil, Erich	NONE
Rietjens, Ivonne	Funding by industry and Member State
Santonen, Tiina	Member State, funding by industry
Seaton, Anthony	NONE
Simonnard, Alain	NONE
Van Loveren, Hendrik	Member State
Van Tongeren, Martie	Funding by industry and Member State
Greim, Helmut	NONE
Bolt, Hermann	NONE

A discussion around the issue of COI as such addressed items of what has to be regarded as a COI and in how far a Committee can still work at all, when being confronted with a request for declarations and explanations that sometimes can be perceived as overwhelming and inhibiting progress regarding the tasks. Several academic Members reiterated the importance of the contributions from Members with industrial experiences and views as this expertise and experience is crucial in understanding the relevance of the analysis for the occupational setting. In general, the mitigation measures introduced

	by the Commission services were accepted. Based on the additional information from the discussions, Members shall re-edit the respective declarations of interest and submit an updated version by 2015-07-02 at the latest, if deemed necessary. Otherwise, the signed version will be used and made publically available on the web as discussed.	
1.4	The Minutes of the SCOEL meeting 2015-03-18 and 19 had been adopted by written procedure earlier and were distributed for information. There were no further comments or discussion.	<i>published</i>
2. General information: Commission services and SCOEL		
2.1	<p>Overview of achievements made and documents issued: Recommendations released (CIRCABC public) Status of ongoing files (H. Bolt/Secretariat)</p> <p>In order to have and gain a full updated overview, the tables of existing recommendations as published as 'summary' documents' or 'SUM' were updated and the published versions have been uploaded on the public site of CIRCABC 'SCOEL public'. The tables are sorted by SUM number or chemical agent's name or year of adoption. Documents in the spaces are readily accessible. The content will be regularly updated as documents become available.</p> 	<p>Tables: released-Status of Recommendatio ns SUM documents published</p>
2.2	<p>New term of office: Commission Decision 2014/113/EU and standard rules of the Commission expert groups</p> <p>Needs to address Scheme of SCOEL</p> <p>Organisational frame: Plenary, horizontal and vertical Working Groups-</p>	<p>Commission Decision 2014/113/EU C2010_7649_en</p>

the Matrix

The Secretariat explained the new working structure of SCOEL along the matrix diagram as presented below. The work is organised and shared between the layers of WGs and the plenary. The role of the already established horizontal WGs was explained:

1. Working Group Cooperation

The 'WG Cooperation' shall support the effective cooperation of SCOEL with other Scientific Committees and Union agencies or other bodies established regarding specific issues identified and on request by the Commission services, the Secretariat as related to the Rules of procedure Article 5 paragraph 4.

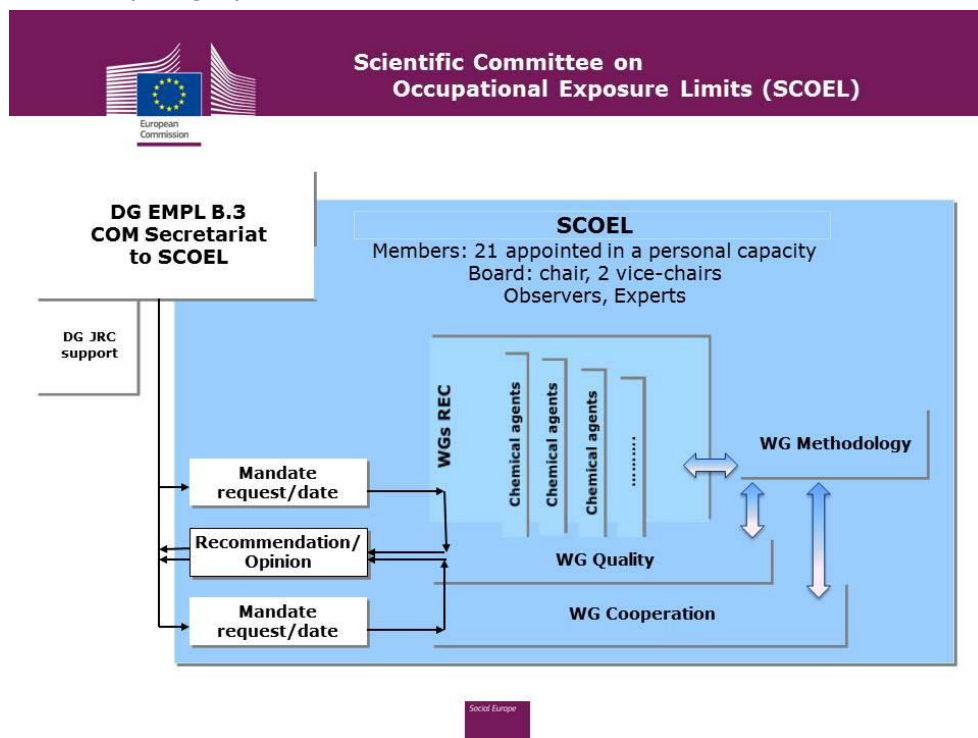
2. Working Group Methodology

The 'WG Methodology' shall ensure in close collaboration with the Secretariat that the SCOEL methodology reflects the latest scientific standards and that it is implemented. It addresses specifically the items explained in the Rules of procedure Article 8 paragraph 4.

3. Working Group Quality

The 'WG Quality' shall support the Board in close coordination with the Secretariat regarding coherence, conclusiveness, conciseness and quality of Recommendations, Opinions, and supporting reasoning. It addresses specifically the items explained in the Rules of procedure Article 9 paragraph 2.

Framework for
Commission
Expert Groups-
Horizontal Rules
and Public
Register
C2010_7649 EN
acc. document



2.3	<p>Rules of Procedure. Outline and practical considerations, guidance, questions and answers</p> <p>The rules of procedure were presented, discussed and questions were answered. The stage codes were explained and discussed. On request by a Member, further clarification regarding the consultation period has been given and was agreed on by SCOEL:</p> <p>The consultation of documents is performed at stage 40 and more specifically, if a project is promoted to stage 40.20. The consultation period will normally be three months. The period can be extended by SCOEL, if justified.</p>	<p>Rules of Procedure International harmonised stage codes Published</p>
2.4	<p>Practical introduction to using CIRCABC with special emphasis on the handover phase (Secretariat)</p> <p>There was a hands-on training performed regarding the sharing of documents and cooperation. The cooperation of team Members, when working on a shared document shall be organised within the project working groups under the responsibility of the co-chairs. A guidance document, "How to work in CIRCABC" has been uploaded to the SCOEL space. Further guidance is provided by the Secretariat team on request.</p>	<p>CIRCABC instruction note</p>
2.5	<p>Mandates received from the Commission services</p> <p>The Mandates issued were introduced. Issued mandates are published in the SCOEL public CIRCABC space.</p>	<p>Mandate(s), issued Published</p>
2B.	Election of the Board Members	
	<p>(Morning session of 2nd day of the plenary meeting)</p> <p>2B.1 Election of the Board Members</p> <p>Outline of the procedure by the secretariat</p> <p>2B.1.1 Election of the chairperson</p> <p>2B.1.2 Election of the vice-chairperson</p> <p>2B.1.3 Election of the second vice-chairperson</p> <p>The Committee elected the board Members on the basis of the election procedure:</p> <ol style="list-style-type: none"> 1. The election of the Chair and of each of the Vice-Chairs shall be held separately. Members present at the meeting have the right to vote. 2. The Secretariat shall be notified of those wishing to stand as candidates before the meeting, or their names announced at the meeting. Members may present themselves as candidates or be proposed by another Member. 	<p>Commission Decision 2014/113/EU Rules of Procedure</p>

	<ol style="list-style-type: none"> 3. The candidates must be present at the meeting and, prior to the vote, declare that they are prepared to accept the post of Chair (or Vice-Chair) of the Committee concerned and be prepared to assist the Commission on matters relating to the coordination of the work of the Committee and its working groups, including if necessary participating in co-ordination meetings organised and chaired by the Commission. 4. The candidate receiving the majority of the votes from the Members of the Committees shall be elected. 5. If none of the candidates receives an absolute majority, a second ballot shall be held between the two candidates with the highest individual totals of votes in the first ballot. The procedure shall be repeated until one candidate obtains the majority of the votes of the Members of the Committee. 6. Candidates may withdraw their candidature at any time during the procedure. 7. Where there is, or remains a single candidate, that candidate shall be elected provided that she/he receives the majority of votes cast. <p>The board Members elected are: Prof. Len Levy (chair) Prof. Maurizio Manno (vice-chair) Prof. Gunnar Johanson (vice-chair)</p>	
3. SCOEL Recommendations or Opinions		
3.1	<p>WG Cooperation</p> <p>3.1.1 Assign/confirm co-chairs The co-chairs were assigned.</p> <p>3.1.2 Chemical agent 1-methyl-2-pyrrolidone (NMP) and occupational exposure limit value; REACH-OSH interface with ECHA: Content, timelines, resources.</p> <p>The issue was discussed and a team was formed. The timing is critical. SCOEL will immediately commence to perform the work as outlined in the mandate. The available information shall be reviewed in order to generate a fully updated revision of the SCOEL recommendation. Further internal analysis will comprise a detailed presentation and analysis of the evaluation process and the individual steps taken. Also</p>	Mandate, issued published

	<p>methodological and procedural aspects shall be described as relevant for the outcome. WG Cooperation shall meet by end of July to discuss the progress made and organise the follow up.</p> <p>The chairperson of the ECHA Risk Assessment Committee, Mr. Tim Bowmer, was present during this plenary meeting. It was suggested that several Members of RAC and SCOEL would meet in October possibly in Helsinki in order to discussing the development of a possible joint document. Mr. Bowmer would invite SCOEL Members to such meeting to Helsinki. DG EMPL indicated its willingness to host a meeting in Luxembourg or Brussels as most appropriate to make progress.</p> <p>3.1.3 General mandate regarding the REACH-OSH interface (Mandate at draft stage): Preliminary information, if available.</p> <p>There were general points mentioned by the Commission services that would most probably be part of a general mandate to SCOEL to address the REACH-OSH interface. This may include work regarding the methodology and description.</p>																																																																	
<p>3.2</p>	<p>WG Quality</p> <p>3.2.1 Assign/confirm co-chairs</p> <p>Recommendations at stages 50-60</p> <p>Chemical agents:</p> <table border="1" data-bbox="236 1137 1233 1440"> <thead> <tr> <th>WG</th> <th>Review Stage code</th> <th>Stage code</th> <th>COM Mandate</th> <th>COM target date</th> <th>NAME</th> <th>CAS</th> <th>SUM/REC No</th> </tr> </thead> <tbody> <tr> <td>Quality</td> <td>90.92</td> <td>50.99</td> <td>2015-05-04</td> <td>2015-09-30</td> <td>4-Aminotoluene</td> <td>106-49-0</td> <td>145</td> </tr> <tr> <td>Quality</td> <td>90.92</td> <td>50.99</td> <td>2015-05-04</td> <td>2015-09-30</td> <td>Aniline</td> <td>62-53-3</td> <td>153</td> </tr> <tr> <td>Quality</td> <td></td> <td>50.99</td> <td>2015-05-04</td> <td>2015-09-30</td> <td>Isoamyl alcohol</td> <td>123-51-3</td> <td>177</td> </tr> <tr> <td>Quality</td> <td></td> <td>50.99</td> <td>2015-05-04</td> <td>2015-09-30</td> <td>Hexachlorobenzene</td> <td>118-74-1</td> <td>188</td> </tr> <tr> <td>Quality</td> <td></td> <td>50.99</td> <td>2015-05-04</td> <td>2015-09-30</td> <td>Chloromethane</td> <td>118-74-1</td> <td>191</td> </tr> <tr> <td>Quality</td> <td></td> <td>50.99</td> <td>2015-05-04</td> <td>2015-09-30</td> <td>Di-n-butyl-phthalate</td> <td>84-74-2</td> <td>143</td> </tr> <tr> <td>Quality</td> <td>90.92</td> <td>50.99</td> <td>2015-05-04</td> <td>2015-12-20</td> <td>Cumene</td> <td>98-82-8</td> <td>29</td> </tr> </tbody> </table> <p>3.2.2 Per chemical agent:</p> <p>Responsibilities, content, timelines, resources.</p> <p>Per project file, draft Recommendation, a responsible Member for the finalisation of the work was identified. Progress is on track. The draft documents are uploaded in CIRCABC.</p> <p>3.2.3 Support by the JRC to the Secretariat for filling (eventual) gaps.</p> <p>The JRC supports the Secretariat in the different development phases of the project. The JRC provides contributions to the drafting of SCOEL recommendations based on the revised template for Recommendations (2015 April 17) in particular regarding chapters 2 to 6, for chemical agents, for which the Commission services have given a mandate to</p>	WG	Review Stage code	Stage code	COM Mandate	COM target date	NAME	CAS	SUM/REC No	Quality	90.92	50.99	2015-05-04	2015-09-30	4-Aminotoluene	106-49-0	145	Quality	90.92	50.99	2015-05-04	2015-09-30	Aniline	62-53-3	153	Quality		50.99	2015-05-04	2015-09-30	Isoamyl alcohol	123-51-3	177	Quality		50.99	2015-05-04	2015-09-30	Hexachlorobenzene	118-74-1	188	Quality		50.99	2015-05-04	2015-09-30	Chloromethane	118-74-1	191	Quality		50.99	2015-05-04	2015-09-30	Di-n-butyl-phthalate	84-74-2	143	Quality	90.92	50.99	2015-05-04	2015-12-20	Cumene	98-82-8	29	<p>Mandate(s), issued published</p>
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SCOEL. The JRC provides the support under an administrative arrangement agreed on by the Commission services. Where required and requested, the JRC provides also systematic information search and pre- or meta-analysis to further enhance efficiency and quality of the work of SCOEL. This may be of special importance in the early stage of project development and in the phase of identifying needs for a possible review.

At the request of the Members of SCOEL, a new horizontal Working Group was set up regarding exposure and toxicokinetics. The Working Group shall be named 'WG Exposure and Toxicokinetics'. The two co-chairs were assigned and agreed on by the Committee.

Working Group Exposure and Toxicokinetics

The 'WG Exposure and Toxicokinetics' shall support the work of the vertical working groups and in close coordination with the co-chairs of the respective vertical WGs regarding contributions on the specific fields of exposure and toxicokinetics. This comprises firstly exposure, exposure monitoring and its relation to the use of a chemical agent and occupational exposure scenarios. Secondly, it includes toxicokinetics and its relevance for the interpretation of adverse health effect endpoints addressed, its contribution to derivation of corresponding dose descriptors and consideration of a role for biomonitoring. It addresses specifically the development of the Recommendations and Opinions with respect to the specific fields as explained in the Rules of procedure Article 6 paragraph 3.

3.3

WG REC: Vertical working groups

Mandate(s),
issued
CIRCABC public

3.3.1 Progress per chemical agent/group of chemical agents:
Establish vertical WG as appropriate, assign/confirm co-chairs
Commitments for contribution/ teams of 4-5

Per chemical agent:

Responsibilities, content, timelines, resources.

For each chemical agent with a single identifier of the REC Number, one vertical WG was formed and agreed on by SCOEL.

The co-chairs of each WG REC for these WG RECs were assigned. The project status and stage code were re-confirmed.

WG	Review Stage code	Stage code	COM Mandate	COM target date	NAME	CAS	SUM/REC No
REC	90.92	20.00	2015-03-26	2015-11-30	Man Made Vitreous Fibres	MMVF10	108
REC	90.92	20.00	2015-03-26	2015-11-30	Man Made Mineral Fibres	MMMF	88
REC		50.00	2015-05-04	2015-12-20	n-Butyl acetate	123-86-4	184
REC		50.00	2015-05-04	2015-12-20	sec-Butyl acetate	105-46-4	184
REC		50.00	2015-05-04	2015-12-20	Isobutyl acetate	110-19-0	184
REC	90.92	40.00	2015-05-04	2015-12-20	Formaldehyde	50-00-0	125
REC	90.92	20.00	2015-06-03	2015-12-20	Silica crystalline (Cristobalite)	14464-46-1	94
REC	90.92	20.00	2015-06-03	2015-12-20	Silica crystalline (Quartz)	14808-60-7	94
REC	90.92	20.00	2015-06-03	2015-12-20	Silica crystalline (Tridymite)	15468-32-3	94
REC	90.92	20.00	2015-06-03	2015-12-20	Hydrazine	302-01-2	164
REC	90.92	20.00	2015-06-03	2015-12-20	Chromium (VI) compounds	EC 606-053-1	86
REC		20.00	2015-06-03	2015-12-20	2-Nitropropane	79-46-9	300
REC		20.00	2015-06-03	2015-12-20	o-Toluidine, 2-methylaniline	95-53-4	301
REC		50.99	2015-05-04	2016-01-20	Phosphoryl trichloride	10025-87-3	181
REC		30.00	2015-05-04	2016-01-20	Trimethylamine	75-50-3	179

3.3.2 Identify/propose chemical agents for COM to issue a mandate

A list of chemical agents was established, for which SCOEL proposes and would be willing to receive a mandate from the Commission services as shown below. There are further chemical agents under discussion for possible finalisation and for which intense data searches and pre-evaluations were already performed. However, the Commission services will launch mandates corresponding to the needs identified and the priorities set. Work will be performed on chemical agents, for which a mandate has been launched by the Commission and received by SCOEL.

Review Stage code	Stage code	COM Mandate	COM target date	NAME	CAS	SUM/REC No
	30.20	2015-to be issued		Beryllium	7440-41-7	175
	30.20	2015-to be issued		Beryllium fluoride	1304-56-9	175
	30.20	2015-to be issued		Beryllium chloride	7787-47-5	175
	30.20	2015-to be issued		Beryllium hydroxide	7787-49-7	175
	30.20	2015-to be issued		Beryllium nitrate	13327-32-7	175
	30.20	2015-to be issued		Beryllium oxide	13597-99-4	175
	30.20	2015-to be issued		Beryllium sulphate tetrahydrate	7787-56-6	175
90.20	30.00	2015-to be issued		Toluene	108-88-3	18
	30.00	2015-to be issued		Hydrogen peroxide		134
90.20	30.00	2015-to be issued		Naphthalene	91-20-3	90
	30.00	2015-to be issued		Dinitrotoluenes		196
	20.20	2015-to be issued		Diesel engine exhaust		none
	20.00	2015-to be issued		Styrene	100-42-5	none
	20.00	2015-to be issued		Styrene oxide	96-09-3	none

4. Methodology	
<p>WG Methodology</p> <p>WG METH Team membership</p> <p>The list of team members was updated. In general, the teams may re-assemble according to the respective needs and requirements identified. In order to being able to plan and coordinate, the participation will be transparently shown and updated internally in the table SCOEL teams and resources planner.</p> <p>Co-chairs: Assignment</p> <p>The co-chairs were assigned.</p> <p>There was a clear and identified need to review and update the SCOEL methodology document. In particular, the structure and readability should be further enhanced. Schematic illustration regarding steps in the evaluation shall be developed and inserted. The document needs as well updating of the terminology used with special regard to taking into account corresponding changes introduced or induced by REACH. The goal is to enhance clarity. The Secretariat will as a next step and supported by a small team of Members generate a new updated version and call for a meeting of the WG Methodology to distribute tasks and commence the work for updating the different chapters. Working in different chapters will allow for distributions by experts to be made for their specific fields of expertise.</p> <p>JRC support to the SCOEL Secretariat</p> <p>Need for review and filling the gaps: Systematic data review and meta-analysis has been addressed under WG Quality. The corresponding parts and methodology should be taken up in the methodology document.</p>	<p><i>Methodology documents</i></p>

5.	Any other issues	
	<p>5.1 Forward planning:</p> <p>The plenary meetings in general will be held at the Commission premises in Luxembourg. SCOEL following a proposal by the Secretariat expressed the wish to hold full two day plenary meetings, for which the Members would arrive the day/night before. The day before the plenary meeting shall be reserved for meetings of the WGs that may want to use the time to finally edit presentations of the progress for the plenary or coordinate on issues that can be more effectively discussed in a physical meeting. The Commission will reserve meeting rooms for this purpose.</p> <p>The Secretariat will launch doodle calls for identification of the most suitable weeks/dates for the plenary meetings in 2016.</p> <p>5.1.2 Meetings of the Working Groups</p> <p>Process and forecast planning</p> <p>To facilitate the work of the WGs, the Members proposed to call for WG meetings about six weeks before the plenary in order to preparing the contributions for distribution before the plenary in time. The meetings of the WGs shall be convened by the Commission services. The date, place and organisation shall be agreed on by the teams, led by the co-chairs of each WG.</p> <p>The time depends on the decisions regarding the plenary meetings.</p> <p>5.2 Proposal for research project related to OEL derivation and SCOEL by Prof. Henry, Université Paris-Dauphine – PSL, Paris, France</p> <p>A presentation was given by the Secretariat. There was a positive discussion of the issue as such and the need to reflect on how science contributes to policy and policy-making. However, the Members had open questions regarding the methodology applied and the progress made so far. The Secretariat was asked to propose to Prof. Henry to firstly present and summarise possibly the progress made so far and the outcome and result of the studies. Secondly, the Members would like to better understand the methodology used for the analysis. Thirdly, it was of interest how the research could and would contribute to better transparency of the process(es) and decision making by SCOEL.</p>	

6.	Meetings in 2015 / 2016	
	<p>Plenary meetings</p> <p>2015 (22 September WG meeting) 23–24 September 2015 (08 December WG meeting) 9-10 December 2015</p> <p>2016* (<i>*addition by the Secretariat after the dates were selected</i>) 2016 March 07-09 2016 June 08-10 2016 September 12-14 2016 December 12-14</p> <p>Working Groups</p> <p>WG Cooperation: 29-31 July 2015 (confirmed)</p>	