



**2ND PLENARY MEETING OF THE
SCIENTIFIC COMMITTEES ON HEALTH, ENVIRONMENTAL AND EMERGING RISKS (SCHEER)**

Venue: HTC building
11, rue Eugène Ruppert, L-2557 Luxembourg

5-6 July 2016

Minutes

5 July 2016:

1. Welcome and apologies

The Chair welcomed the participants, including the Vice Chair of the SCCS, to meeting and announced that two apologies had been received. Two members joined the plenary meeting by audio.

Colleagues from DG SANTE B2 joined the plenary by audio for the discussion on the preliminary Opinion on tobacco additives on 6 July.

2. Adoption of the agenda

The agenda was adopted as presented.

3. Declaration of interests on matters in the agenda

The Chair requested participants to declare any interest on the matters on the agenda. None of the participants made a declaration of any conflict of interest.

4. Communication by Commission Departments

The Chair gave the floor to the Secretariat for an update on the state of play on the following issues:

• **Information on lifecycle of Opinions: the aim is to explain (especially to the newcomers) the path from a mandate to the final Opinion.**

– A presentation was made by the Secretariat explaining the following steps:

- Request for a mandate by customer DG
- Public consultation on the mandate
- Approval of the mandate by the SCHEER in plenary meeting
- Formation of a working group composed by SCHEER members and external experts (selected from the reserve list, database experts, specific call for experts)
- Info gathering: Call for information, literature search
- Preparation of a draft preliminary Opinion
- Approval of the preliminary Opinion for public consultation (SCHEER plenary).

- Public consultation/commenting period as part of the stakeholders dialogue, held to improve the scientific basis of the Opinion
 - Possibility of hearings with stakeholders
 - Preparation of draft final Opinion
 - Adoption of the final Opinion (SCHEER plenary)
 - Publication of the final Opinion (incl. table of comments and replies)
- **Follow-up of work with scientific journals** to promote the dissemination of the SCs Opinions. The secretariat informed the members about the status of the publication of different Opinions in relevant scientific journals.
- **List of mandates/ Opinions of the two scientific committees** was distributed to SCHEER members illustrating the ongoing work in the SCCS.
- **The Deputy Head of Unit informed the members about the adoption on 30 May 2016 of a Commission Decision establishing horizontal rules on the creation and operation of Commission expert groups.** Rules of Procedure of SCs will be aligned with this decision and the declaration of interest DOI form will be changed.
- **The Deputy Head of Unit informed the members about the knowledge hour organised on 8 June 2016 in Brussels,** which was followed by a meeting with SANTE units interested in the activities of the SCs. Both the Chair of the SCCS and of the SCHEER gave a short presentation on the activities of the Committees. Similar events will be organised in Brussels in DG GROW and JUST (Consumers) after the summer.
- **The Deputy Head of Unit informed the committee about the annual visit to EFSA and JRC:** in the period 28-30 June 2016. The aim of the visit was to get updated information about the specific areas of work for both institutions and to identify possibilities for future cooperation between the Scientific Committees and EFSA and JRC. The following points were discussed with **EFSA**:
 - Mutual exchange of information on the work programme of the Scientific Committee and the on-going activities of the Emerging risks and non-food Committees Update on the WG Weight of Evidence (expected to be finished in Q3 2017) and the WG Biological Relevance (expected to be finished in Q1 2017). These WG have just started, but their content could be of interest for SCHEER.
 - Update of the work programme of the WG on Uncertainty in Risk Assessment. There is a one-year trial phase (until March 2017) to be finalised Dec 2017. After this, it will be mandatory for each EFSA Opinion. SCs members can participate in the training this coming October if they are interested.
 - WG on benchmark dose (public consultation to be launched soon), nanotechnology in food, chemical mixtures, RRA. Synergies could be created..
 - Trainings on uncertainty provided by EFSA may be of interest to SCmembers.
 - Use of JRC reports as scientific basis for Opinions.

5. Chair's / member's report

The Secretariat reported on the participation of members in the following meetings:

- WHO Meeting on UV on 1-2 June 2016
- IARC 50th anniversary conference on 7-10 June:
<http://www.iarc-conference2016.com/index.php?langue=en&onglet=12>

6. EFSA for the WG on mixture on 27-28 June. New mandates

- No new mandates have been submitted for adoption by the SCHEER.
- The Secretariat informed the members about the state of play of the SCHER Mandate on the development of minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge in the EU. The mandate was adopted by the SCHER in October 2015. The mandate asks the SCHER to evaluate the consolidated technical report which was due in June 2016 but which was delayed.

6 July 2016

1. Adoption/approval for public consultations of the preliminary Opinions on:

Biological effects of UV-C radiation relevant to health with particular reference to UV-C lamps

The Chair gave the floor to the Chair of the WG who presented the preliminary Opinion. The SCHEER approved the preliminary Opinion for public consultation. The working group was asked to take into consideration all comments and changes discussed and agreed during the plenary meeting. The preliminary Opinion should be published for public consultation by the end of July.

Tobacco additives – Opinion II

The Chair gave the floor to the Chair of the WG to present the preliminary Opinion on tobacco additives II. Colleagues from the tobacco unit joined the meeting by audio.

The preliminary Opinion was approved for public consultation provided that the WG will address a number of issues discussed during the meeting. The preliminary Opinion should be published for public consultation by the end of July.

Guidance on the structure and content of SCHEER Opinions

The Chair gave the floor to the Chair of the WG who presented the proposed structure, agreed by the WG in the last meeting on 17 June. The SCHEER concluded that more discussion is needed to conclude the guidance document. The SCHEER concluded that only an extended abstract would be used in the Opinions, instead of an abstract and an executive summary.

2. Ongoing work:

Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes

The Chair gave the floor to the Chair of the WG who presented the state of play of this Opinion. The WG met on 4-5 July to discuss the replies to comments received during the public consultation. The Opinion should be ready for adoption during the next plenary meeting scheduled on 17 November.

Rapid risk assessment

The Chair gave the floor to the Chair of the WG who presented the guidance document and outcomes of the WG meeting that took place the day before. The call for experts to create the pool of experts, able to provide RRA assessment in case of need, will be reopened.

Update to an earlier Opinion published by SCHER concerning the need for the use of non-human primates in biomedical research, safety and efficacy testing

The Chair gave the floor to the secretariat to summarise the results of the Call for information and Call for experts (the deadline was 3 July). 36 experts applied and 7 experts from the reserve list expressed their interest to join the WG. In addition, the SCHEER secretariat asked the European Medicines Agency to nominate an expert; this request was accepted and an EMA expert was appointed. Concerning the Call for information, since 1 January 2009, interested parties have been invited to submit relevant information concerning new technologies used to replace, reduce and refine the use of non-human primates in biomedical research, production and testing of products and devices. 18 organisations or individuals provide their contributions. The next WG meeting is scheduled for 14 July. The deadline for preliminary Opinion is December 2016.

Opinion on the potential risks to human health of Light Emitting Diodes (LEDs)

The Chair gave the floor to the Chair of the WG who presented the state of play of this Opinion. The work is at the very beginning. A Call for experts was published in June and will remain open until the end of July. A call for information may be published in order to get information regarding the market penetration of the LED-containing products.

Scientific advice regarding a call for data and literature review concerning the safety of PIP silicone breast implants and a possible Opinion on connection between breast implants and anaplastic large cell lymphoma

The Chair gave the floor to the Chair of the working group for an update. The work on this Opinion is at the very beginning, two calls for information were published in June (they will be open until 4 September). The Secretariat will support the working group with two literature searches.

Revision of the 'Memorandum on weight of evidence and uncertainties'

The Chair gave the floor to the Chair of the WG, who presented the state of play of this memorandum. Two members of the SCHEER volunteered to join the WG.

3. Any other business

Emerging risks

The Chair of the SCHEER asked members to read the Position Statement on emerging and newly identified health risks to be drawn to the attention of the European Commission, which was published by the former SCENIHR in 2014. The members were asked to send their views about how and when to restart the discussion on a possible update of this document and who should take action.

The next SCHEER plenary meeting will take place on **17 November 2016**.

The dates of the following SCHEER plenary meetings have been set up as follows:

2 February 2017
18 May 2017

Annex 1

List of Participants

Members of the SCHEER

Roberto Bertollini, Teresa Borges, Pim de Voogt, Raquel Duarte-Davidson, Rodica Mariana Ion, Renate Krätke, Demosthenes Panagiotakos, Ana Proykova, Theo Samaras, Marian Scott, Emanuela Testai, Theo Vermeire, Marco Vighi, Sergej Zacharov

Apologies received:

Wim de Jong, Remy Slama,

SCHEER secretariat

Donata Meroni
Silvia Hrubanova
Mihaela Haratau

Other Commission departments

DG SANTE (Unit B2)

Katja Broman
Matus Ferech