



12th Plenary Meeting of the

SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR)

Venue: HTC 02/280 Luxembourg

Eugène Ruppert Street 11, L-2453 Luxembourg

24 September 2015

Minutes

1. Welcome and apologies

The Deputy HoU (DHoU) welcomed the participants and gave the floor to the Chair of SCENIHR. Two apologies received. Six members joined the meeting by audio.

Qasim Chaudhry, the Vice Chair of SCCS, attended the plenary.

Representatives of DG GROW D4, DG GROW I5 and DG SANTE D4 attended the meeting by audio.

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 conflict of interest regarding matters on the agenda.

Michelle Epstein declared as an interest to be a member, in her personal capacity, of the research project FA 1402 Imparas: <http://imparas.eu> COST Action. This was not considered being a conflict of interest as this project relates to Improving Allergy Risk Assessment Strategy for new food proteins and the SCENIHR has not a mandate on this topic, therefore the interest is not specific. Moreover, the project is co-funded by the European Commission and it is considered of public interest.

It was reminded that these declarations have to be made orally at each plenary meeting and are noted on the minutes.

4. New mandates:

No new mandates have been adopted by the plenary.

5. Chair's / member's report

The Chair gave the floor to those members who attended the following meetings in representation of the committee, to report on it:

- 05 May WHO Workshop 4th InterSun programme – Theodoros Samaras
- 05-06 May 2015 - WHO Workshop 4th InterSun programme – Lesley Rushton
- 28 May 2015: ICNIRP/WHO Workshop, Istanbul – Theodoros Samaras
- 24-25 June 2015: WHO/Europe meeting on implementation of the Minamata Convention on mercury – The Secretariat for Arne Hensten

- 29-30 June: EFSA Workshop on Increasing Robustness, Transparency and Openness of Scientific Assessments in Brussels – Emanuela Testai
- 09 July 2015: Council working Party on International Environment Issues Workshop in Brussels – Theo Vermeire
- 18/09/2015: Meeting on electro hypersensitivity with stakeholders in DG SANTE – Norbert Leitgeb
- 19-21/09/2015: Conference organized by the Technical University in Sofia, Sozopol – Ana Proykova.

6. Communication by Commission Departments

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

- New Commission Decision C(2015)5383 on establishing Scientific Committees in the field of public health, consumer safety and the environment¹ adopted on 7th August 2015.

The major changes compared to the previous organisation of the Committees consist in the merge of SCHER and SCENIHR Committees to constitute the SCHEER (Scientific Committee on Health, Environmental and Emerging Risks), the abolition of the pool of advisors and the creation of a reserve list of members, the prolongation of the duration of the term (from 3 to 5 years) and the transposition of Commission Decision on expert groups rules concerning special allowances.

- As the terms of office of the current Committees expire beginning of April 2016 a call for membership was published on 14th August 2015 on DG SANTE and Scientific Committees websites². The deadline for applications is 2nd of November 2015.

Members of the new Committees will be appointed by the Director General of the DG SANTE from a list of suitable candidates. Candidates not appointed as members will stay on the list as a reserve, to replace members who resign.

- Ongoing external evaluation of the Scientific Committees (2009-2014): The functioning of the scientific committees is to be evaluated in order to assess the value of their advice in the Commission decision-making process. This evaluation will also guide the services for the renewal of the mandate of the Scientific Committees in 2016 in support of the update of the Commission Decision. Members and experts may be contacted by the external contractor (Economisti Associati) managing the evaluation.
- Feedback from Secretariat on JRC/EFSA visits, including public consultation of EFSA on Guidance on Uncertainty (deadline 10 September). ICCG prepared a common answer and one of the Vice-chairs of the SCENIHR was appointed on the field' as the Rapporteur.
- New opinions/mandates from other Scientific Committees adopted during the period April-September 2015: printed lists have been distributed during the meeting.
- Follow-up of work with scientific journals to promote the dissemination of the SCs opinion. The committee was informed about the articles published

¹ http://ec.europa.eu/health/scientific_committees/docs/call_2015_5383_decision_with_annexes_en.pdf

² http://ec.europa.eu/health/scientific_committees/docs/call_experts_2015_en.pdf

http://ec.europa.eu/health/scientific_committees/call_experts/call_exp_2015_en.htm

- in August 2015 by the Journal of Medical Device Regulation (Final Opinion on the safety of medical devices containing phthalates (DEHP), Preliminary Opinion on safety of surgical meshes used in urogynaecological surgery, Final Opinion on Dental Amalgam (news).
 - in September 2015 by "Bioelectromagnetics" journal (the whole executive summary of the EMF opinion).
- The committee was informed about the risk communication materials currently under preparation concerning surgical meshes and tobacco additives opinions. Printed copies of various factsheet recently produced were distributed during the meeting.
- The committee was informed about the forthcoming meetings, as follows:
- **28 September 2015:** Workshop in Athens on EMF organised by Greek Mobile Operators Association;
 - **14-16 October 2015:** conference 'Shaping the future of food safety, together'(www.efsaexpo2015.eu) organised by the EFSA in Milan;
 - **6 October 2015:** LEXNET (www.lexnet-project.eu) workshop to present the results of the project;
 - **20-21 October 2015:** The 2nd Synthetic Biology Congress in London;
 - **10 December 2015: Workshop on synthetic biology** – From Science to Policy and Societal Challenges organised by Commission and SCs.

7. On-going work:

Update on public consultations and finalization of the opinions

- **The final opinion on Safety of surgical meshes used in urogynecological surgery**

The Chair updated the plenary on the state of play of this opinion. 87 comments were received during the public consultation and have been sent to the WG. Two audio meetings will be scheduled shortly to discuss and agree with the WG the answers to comments received during the public consultation to finalize the opinion. It is expected to adopt the final opinion by the **end of November**. The representative of DG GROW, D4 was present by audio.

- **The final Opinion on Synbio III**

The Chair gave the floor to the chair of the WG, for an update on the state of play of this opinion. The preliminary opinion was published for public consultation between 15 July and 16 September. 61 comments have been received from 12 organizations. The opinion will be finalised by mid-November to be adopted by the three Committees by written procedure or at the meeting depending on the date of the plenaries.

- **The final opinion on tobacco additives**

The Chair gave the floor to the chair of the WG, to update the plenary on the state of play of this opinion. The opinion was published for public consultation between 22 July and 06 September 2015. The public consultation was afterwards reopened on the request of the SANTE until 23 September. The secretariat however stressed that the prolongation would cause a delay of the final opinion. Approximately 260 comments

were received with more than 1500 attachments. A date will be set up for the next audio meeting to discuss how to address the comments received and to allocate tasks to different members. The final opinion is expected to be adopted during the plenary in December.

➤ **Preliminary opinion on sunbeds**

The Chair gave the floor to the chair of the WG who gave a thorough presentation of the draft opinion. The members of the SCENIHR were asked to send their comments on the draft opinion to the Secretariat by October 15th. Next meeting of the WG is scheduled on **10 November 2015**. The preliminary opinion expected to be ready for adoption for public consultation during the plenary on 03/12.

➤ **Preliminary opinion on UVC-lamps**

The representative of DG GROW C3 joined the plenary by audio.

The Chair gave the floor to the chair of the WG, who updated on the state of play of this opinion. Next meeting of the WG is scheduled on **22 October 2015**. The preliminary opinion is expected to be ready for adoption for public consultation during the plenary on 03/12/2015.

➤ **Lessons learnt**

At this point members were asked to share their suggestions based on experience gained during the term 2013-2016 concerning the functioning of the Scientific Committees. A set of questions was provided to help the reflection process. It consists of three parts:

- Brainstorming on positive, negative aspects and improvement needed.
- Specific questions mirroring those used in the evaluation on the Scientific Committees. In this way all members have the opportunity to contribute to the evaluation.
- Contributions concerning working methods which will be reflected in the Rules of Procedure.

The discussion will continue in the next two plenary meetings.

As an immediate action the SCENIHR decided to explore the possibility with SCHER to have a joint mandate on 'Guidance on the structure and content of opinions and statements'. A working group should be formed comprising members of both Committees.

The Memorandum on weight of evidence and uncertainties needs to be reviewed in the light of the new EFSA Guidance to better serve the needs of the future SCHEER committee. The SCENIHR decided to explore the possibility with SCHER to have a joint mandate. A working group should be formed comprising members of both Committees.

Any other business

A doodle will be launched to set up the date for plenary meeting in February 2016.

Annex 1

List of Participants

Members of the SCENIHR

Dr Epstein Michelle, , Prof Dr Hartemann Philippe (Chair), Prof Dr Peter Hoet (by audio), Prof Dr Leitgeb Norbert, Dr Rizzo Luigi, Prof Dr Proykova Ana (vice-Chair), Prof Eduardo Rodriguez Farre, Dr Rushton Lesley, Prof Dr Rydzynski Konrad (by audio), Prof Theodoros Samaras (by audio), Dr Theo Vermeire (by audio), and Dr Testai Emanuela (by audio)

Absences:

Prof Igor Emri, Dr Martinez-Martinez Luis

SCENIHR Secretariat (DG SANTE)

Mrs Donata Meroni
Mrs Mihaela Haratau

DG GROW, D4

Mr Paul Piscoi

DG GROW, C3

Mrs Victoria Piedrafita