



10th 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

29 April 2015 (starting at 9:00)

Minutes

1. Welcome and apologies

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

Jan Linders, the Vice Chair of SCHER attended the plenary.

Representatives of DG GROW I4, DG GROW I 5, 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.

One member declared a request his/her department has recently received from the Director General of his/her Institute responding to a request by the Ministry of Health to carry out a toxicological risk assessment of a tobacco device for national regulatory purposes.

The SCENIHR and the Secretariat concluded that there is no conflict of interest because this was an institutional work for regulatory purposes carried out in the public interest.

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

4. Adoption of new mandate

The Chair gave the floor to the representative of DG GROW I5 to introduce the request for a scientific opinion on Biological effects of UV-C radiation relevant to health with particular reference to UV-C lamps.

An expert from the Centre for product safety and hazardous materials of the Kassel Regional Council (DE) joined the meeting by audio to answer technical questions from the committee.

The mandate was adopted; 5 members of the SCENIHR and one from SCHER volunteered to join the WG.

5. Chair's / member's report

The Chair gave the floor to those members of the committee who attended the following meetings:

- EMF Meeting with some stakeholders organised on 25 February 2015 in Luxembourg
- ICCG Meeting organised on 24 March
- GSMA Europe Workshop on EMF organised on 22 April 2015 in Brussels.

6. On-going work:

This point was put forward in order to meet the time schedule and discuss the opinions with the rapporteur and Commission departments joining by audio.

<u>For approval/adoption:</u>

- **The preliminary opinion on Safety of surgical meshes used in urogynecological surgery** (due by January 2015)

The rapporteur presented the preliminary opinion at the plenary to be approved for public consultation. The representative of DG Grow, I4 was present by audio.

The preliminary opinion was thoroughly debated. As there were several comments from the members and some suggestions for changing parts of the text, a period of one week was agreed by the Committee to receive these in written form. Based on the comments received the Chair of the WG together with the rapporteurs will prepare a new draft which may be discussed by the WG during an audio conference. Then the amended preliminary opinion will be sent to the SCENIHR to be adopted by written procedure.

- **Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users**

The Vice chair of the SCENIHR, made a presentation of the final opinion explaining the main changes included in the text as consequence of comments received during the public consultation.

After discussion and changing of some parts, the final opinion was adopted by the SCENIHR.

The Commission informed the plenary about the Ombudsman inquiry on dental amalgam preliminary opinion, in particular about the composition of the working group and the alleged conflict of interest of some of its members. The report on this inquiry is pending.

- **The final opinion on Synthetic Biology II and the replies to comments received during the PC**

The Chair of the WG, presented the content of the opinion. After discussion among the members of the Committee, the final opinion was adopted by the SCENIHR with the condition that the comments received from a member of the SCENIHR should be taken into account by the members of the WG when finalising the opinion.

The opinion shall now be adopted by SCHER and SCCS by written procedure with the deadline of 04/05.

<u>Update:</u>

➤ **Final Opinion on DEHP on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk (2015 update)**

The Chair and rapporteur of the WG updated the plenary on the state of play of this opinion. The Chair and the co-rapporteur are still working on the replies to contributions received during the public consultation which ended last November. The finalisation of this opinion has been delayed due to the illness of the Chair/rapporteur and the workload of the other rapporteur who was working also at other opinions.

Taking into account that DG GROW expressed the need of having the opinion finalised and published before the summer break, the Secretariat may consider the possibility of organising an additional audio meeting with the WG to finalise the text of the opinion.

➤ **Preliminary Opinion on Synbio III**

The Chair of the WG updated the plenary on the state of play of this opinion. Next meeting of the WG is scheduled on 17-18 May. One member of SCENIHR confirmed his availability to contribute to this opinion on waste management at the section on mitigation.

➤ **Preliminary opinion on tobacco additives**

The Chair of the WG updated the plenary on the state of play of this opinion. The next meeting of the WG (audio) will take place on 30 April. The representative of DG SANTE, D4 joined the plenary by audio and informed the members about an ongoing project on composition of tobacco and related products and its impact on human health. It aims to assess data submitted by the industry in the context of reporting obligations introduced by Directive 2001/37/ related to toxicity, addictiveness and attractiveness of ingredients contained in tobacco.

It was discussed and agreed with SANTE D4 to split the mandate into two opinions: one on the list of additives - to be delivered by the end of June 2015 (preliminary) and mid-October 2015 (final) and the second on experimental strategy (Question 3 of the mandate) – providing a guideline with description on what experiments at what conditions should be requested from the tobacco industry – to be delivered by May 2016.

➤ **Preliminary opinion on sunbeds**

The Chair of the WG updated the plenary on the state of play of this opinion. The results of the literature search have been forwarded to the WG for their review and consideration. Next meeting of the WG is scheduled on 24/06.

The Chair of the WG informed the Committee about his/her participation in the WHO Intersun programme meeting on 5-6 May 2015 in Geneva to present the mandate and the progress of this opinion.

7. Communication by Commission Departments

This point was postponed to give priority to the discussion of the opinions.

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

- New Decision setting up Scientific Committees
- Next term 2016-2021
- The DHoU informed the SCENIHR about the **European Ombudsman inspections** on 2 files: PIP and EMF and about 2 more inquiries on dental amalgam and EMF. All of these cases concern mainly the composition of WG and conflicts of interest alleged by the complainants.
- **Cooperation with other DGs**: DG ENV asked the Secretariat of the SCs to cooperate for organising a lunchtime conference on 27 May with the title: "Emerging environmental and health risks: the role of the scientific committees".
- A printed list of **new opinions/mandates from other Scientific Committees** was distributed during the meeting.
- Follow-up of work with **scientific journals** to promote the dissemination of the SCs opinions: The Committee was informed that several scientific journals published already the executive summaries of different opinions, as follows: two executive summaries were sent to the Journal of Medical Device Regulation. One covers the 'guidance on the determination of potential health effects of nanomaterials used in medical devices' and the other one is about the 'safety of metal-on-metal joint replacements with a particular focus on hip implants'; one comment was sent to Materials Today on 'Nanosilver: safety, health and environmental effects and role in antimicrobial resistance'; an article providing an overview of the activities carried out by the European Commission related to electromagnetic fields was sent for publication in a special issue of Electromagnetic Biology and Medicine which will appear in April.
- Communication activities:

The committee was informed about the communication materials currently under preparation concerning Synthetic biology and dental amalgam.

- Next meetings:

The committee was informed about the forthcoming meetings, as follows:

- o WHO- 20th International Advisory Committee (IAC) meeting and 4th InterSun programme Advisory meeting, 4-6 May 2015 – Geneva, Switzerland

EFSA guidance on uncertainties in risk assessment

EFSA is launching a public consultation on this guidance and plans a workshop in June. Input from members of the three non-food Scientific Committees is expected after the launch of the public consultation.

Any other business

- Dates of next plenary meetings:

25 June 2015 (AUDIO)
24 September 2015
3 December 2015

Annex 1

List of Participants

Members of the SCENIHR

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

Members of other Scientific Committees:

Jan Linders, Vice Chair of SCHER

Absences:

Prof Dr Rydzynski Konrad,

SCENIHR Secretariat (DG SANTE)

Mrs Donata Meroni
Mrs Mihaela Haratau
Mrs Silvia Hrubanova

DG GROW, I4

Mr Paul Piscoi

DG GROW, I5

Mrs. Victoria Piedrafita (DG for Internal Market, Industry, Entrepreneurship and SMEs, Unit I5 Engineering Industries)

Other participants (attending by audio)

Mr Thomas Apel, the Centre for product safety and hazardous materials of the Kassel Regional Council (DE) to answer technical questions from the committee on the new mandate on UVC lamps.