



4th Plenary Meeting of the

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

Venue: HTC 03/383 – Luxembourg

Eugène Ruppert Street 11, L-2453 Luxembourg

11-12 December 2013, starting at 12:00

Minutes

1. Welcome and apologies

The Deputy HoU (DHoU) welcomed the participants and gave the floor to the Chair of SCENIHR.

Absences: 1 member excused and one attended the plenary by audio (see annex 1).

Rapporteurs' attendance: The rapporteur of the WG on BPA opinion attended the plenary by audio and the rapporteur of the WG on EMF Opinion attended the second day of the plenary in the absence of the chair of the WG.

A representative of SANCO B2 attended the meeting and another was connected by audio during the discussion of the opinions of their interest. A representative of SANCO B3 joined the plenary by audio.

2. Adoption of the agenda

The agenda was amended so as to enable the preliminary discussion on the new mandate received from SANCO B2 one day before the plenary. The new point included on the agenda was *point 6. New mandates: "Request for a scientific opinion on "The Safety of surgical meshes used in urogynecological surgery"*

3. Declaration of interests on matters in the agenda

At this point, the DHoU explained the aim and the guidelines concerning the declaration of interests. It was mentioned that members must declare any activity that might be seen as an interest to SCENIHR's opinions.

The Chair asked the committee members to inform of any conflict of interest to be acted in the minutes of the plenary.

At this point, Prof. Theodoros Samaras in relation to the discussion on electromagnetic fields (EMF) declared an ongoing collaboration on EMF with a research public organisation. This was not considered to represent a conflict of interest by the SCENIHR and he could participate in the discussions on those matters.

Prof. Michelle Epstein declared the collaboration with an industrial partner on a drug discovery project with her University, but this was not considered by the SCENIHR to

represent a conflict of interest on matters in the agenda and she could participate in the discussions on those matters.

No other declaration of potential conflict of interest was made by the rest of the members.

4. Chair's / member's report

The Chair gave the floor to SCENIHR members to report on activities they were involved in and on collaboration with other SCs and EU risk assessment agencies:

- One member reported the participation in EFSA WG on ERA on 28-29 November 2013, Italy, together with a member from SCHER
- One member reported on the results of WHO/IPCS Workshop on Uncertainty in Hazard Assessment on 19-20 November 2013 in the Netherlands.

The Chair underlined the importance of having a good collaboration with other committees and risk assessment agencies to harmonise procedures, share scientific information and be informed on on-going activities of mutual interest.

5. Communication by Commission Departments

The chair, gave the floor to DHoU, to inform the members on the following:

- Annual COI/DOI forms for 2014 will be requested before the next plenary in February
 - Internal survey on the functioning of the SCs will be launched early 2014 to report by the next plenary. Members are invited to suggest points to be evaluated.
 - EMF Conference under EL Presidency on SCENIHR opinion and hearing on 27/28 March 2014 in Athens: SCENIHR representation to be discussed
 - Booking of tickets should be done as soon as the invitation is received, to limit costs. The secretariat will pass this message also to WG experts.
6. New mandates:
- Request for a scientific opinion on "The Safety of surgical meshes used in urogynecological surgery."

At this point, the Chair gave the floor to the representative of SANCO B2 to briefly introduce the new mandate. The Chair mentioned that the members had received the mandate by email only one day before the plenary, therefore no extensive discussion could be initiated as the members needed more time to reflect on the content. The mandate was presented and a detailed discussion is foreseen for the plenary on 26/02/2014. SANCO B2 will provide SCENIHR with more information about the topic.

7. On-going work

For approval/adoption:

The safety of the use of Bisphenol A in medical devices

The Chair gave the floor to the Chair and the rapporteur of the WG (by audio) to report on the Opinion.

EFSA, in their BPA opinion in preparation, has proposed a new t-TDI of 5 microgram/kg bw/day, which is ten-fold lower than the previous TDI (being 50 microgram). SCENIHR supports the outcome and on this basis, it is necessary to review the SCENIHR opinion taking into consideration the new EFSA health-based reference value.

Contacts were established between SCENIHR and EFSA panel on BPA to ensure that both committees have the same hazard characterization..

To further the progress of the opinion, the following approach was suggested:

- To review the opinion taking into consideration the new t-TDI used as the starting point in the EFSA opinion
- To set up a final meeting of the WG (audio) by the end of December to discuss and agree upon the final modifications of the text
- The final draft of the opinion to be submitted to WG members, for their agreement at the beginning of January
- To launch the written procedure for adoption by SCENIHR in mid-January
- launch of the public consultation is expected by the end of January.

A video conference with EFSA was organised to exchange information about the timelines for the public consultations of both opinions and the changes needed to align the SCENIHR opinion to the new TDI used by EFSA.

Nanosilver: safety, health and environmental effects and role in antimicrobial resistance

The preliminary opinion was adopted. Launch of the public consultation is foreseen on 13 December. The deadline is 2 February 2014.

The safety of metal-on-metal joint replacements with a particular focus on hip implants

SCENIHR members raised quite substantial comments about this opinion, which needed to be further addressed by the WG; therefore, SCENIHR agreed that the MoM preliminary opinion needed more work and could not be adopted as such. Approval by written procedure was envisaged by late January/beginning of February and the launch of the public consultation by the end of January.

Potential health effects of exposure to electromagnetic fields (EMF)

The WG former Chair, then rapporteur attended the plenary and made a detailed presentation of the preliminary opinion. The preliminary opinion was approved for public consultation by a majority. It was agreed that some changes were still needed and would be made prior to the public consultation. The launch of the public consultation is expected in February.

Update:

The safety of dental amalgam and alternative dental restoration materials for patients and users

The Chair of the WG reported on the progress of the opinion. The opinion is still in preparation. The next meeting of the WG is scheduled on 28/01/2014.

The safety of medical devices containing DEHP-plasticised PVC or other plasticisers on neonates and other groups possibly at risk (2013 update)

The rapporteur reported on the progress of the opinion which is still in preparation.

Health Effects of Nanomaterials Used in Medical Devices

The Chair of the WG reported on the progress of the opinion and answered the specific comments and questions received from the representatives of SANCO B2. The opinion is still in preparation. The next meeting of the WG scheduled on 13/12/2013.

Synthetic Biology

The Chair of the WG updated the Committee on the progress of the work. One physical meeting of the WG was organised on 15/10/2013 and another audio one on 26/11/2013. The WG discussed the possibility to split the mandate into 3 parts. A new text of the mandate is expected from the WG and will be discussed with DG ENV and DG RTD. The next physical meeting of the WG is scheduled on 4-5 February 2014.

Update on the public consultation:

- The safety of Poly Implant Prothese (PIP) Silicone Breast Implants (2013 update)

Only two contributions had been received at the time of the plenary. The public consultation will be open until 3 January 2014. After the consultation, all the comments will be submitted to the chair and the rapporteurs of the WG for their consideration and action. A WG meeting is also planned to analyse and process the contributions received and to finalise the opinion for SCENIHR adoption.

8. Brainstorming session

- The discussion on the prioritisation of the emerging issues for drawing the Commission's attention on actual and potential risks (to consumer safety, public health and environment) was postponed to the next plenary meeting.

9. Any other business

- Next plenary is scheduled for 26 February 2014 starting at 9:00 (1 day)

Annex 1

List of Participants

Members of the SCENIHR

Dr Epstein Michelle, Prof Dr Hartemann Philippe (Chair), Prof Dr Hoet Peter, 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 Dr Rydzynski Konrad, Dr Samaras Theodoros (by audio), Dr Testai Emanuela (vice-Chair) and Dr Theo Vermeire.

Apologies

Prof Igor Emri

SCENIHR Secretariat (DG SANCO)

Mrs Donata Meroni
Mr Giulio Gallo
Mrs Mihaela Haratau

DG SANCO B2

Mrs Federica de Gaetano
Dr Paul Piscoi (by audio)

DG SANCO B3

Mrs Ana María BLASS RICO (by audio)