



6th Plenary Meeting of the

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

Eugène Ruppert Street 11, L-2453 Luxembourg

10-11 June 2014

Minutes

1. Welcome and apologies

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

Representatives of SANCO B2, SANCO E1, DG ENV attended the meeting by audio.

Representatives of SANCO D4 joined the first day of the plenary by videoconference to introduce the new mandate on tobacco additives.

2. Adoption of the agenda

- The agenda was amended, including one member's proposal, namely, request to add the following items:
 - How to improve working methods concerning collation of comments from committee members on draft opinions/reports.
 - Discussion on how to respond to members of the public who contact members of the committee about issues. These new items have been included at AOB.

3. Declaration of interests on matters in the agenda

- The Chair asked the members to declare any conflict of interest they might have with the matters to be discussed in the plenary as indicated on the agenda. No declaration of potential conflict of interest was made by members.

4. Chair's / member's report

- The Chair gave the floor to SCENIHR members to briefly report on activities they are carrying out in collaboration with other SC and other Agencies.
 - Workshop on integrated assessment of emerging science and technologies, Brussels, on March 28;
 - ECR 2014 - 09 March 2014 , Vienna;
 - EFSA Worksop on BPA, on 23 April, Brussels;
 - EMF Workshop.

Presentations were delivered by relevant members of SCENIHR.

5. Communication by Commission Departments

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

- Annual COI/DOI forms for 2014 have been requested by email of 5 February 2014. Each member provided this DOI. No conflicts of interests have been

spotted out in these declarations which are now posted on the website of the Scientific Committees.

- EMF Conference under EL Presidency on SCENIHR opinion and hearing: SCENIHR representation consisted of the Chair, Theodoros Samaras (Chair of the WG), Norbert Leitgeb.
- In September a preparedness exercise is scheduled involving SCHER to test its promptness to react in case of chemical accidents under the Decision on serious cross border health threats (2013).

6. New requests/mandates:

New request for a scientific opinion on tobacco additives

The new mandate was introduced by representatives of SANCO D4 who attended the plenary by video conference.

- SCENIHR members proposed some changes in the text of the mandate and requested some more clarifications

7. On-going work

For approval/adoption:

- **Guidance on the determination of Potential Health Effects of Nanomaterials Used in Medical Devices.**

The Chair gave the floor to the Chair of the WG for an update on the state of play.

- The opinion was sent to SCENIHR for adoption by WP with deadline 07 April 2014.
- There is still some cleaning up to do regarding the formatting, references, and annexes. The Secretariat will do the editing.
- SANCO B2 requested the WG to elaborate a diagram to explain and synthesize the risk assessment approach for nanomaterials used in medical devices.
- The opinion will be integrated with this diagram, and after approval will undergo for public consultation by the end of July.

- **Preliminary Opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users**

The Chair gave the floor to the Chair of the WG for an update on the opinion

- The opinion has been revised and updated during the last meeting of the WG on 07/05 when 2 members of SCENIHR joined the meeting by audio. A revised version was sent to SCENIHR.
- The opinion is delayed due to further work to be done in the WG. The abstract should be revised.
- The Chair gave the floor to the representative of SANCO B2 who made some comments to make the opinion addressing properly the mandate. B2 will send specific comments after the plenary.
- The opinion is expected to be published before the summer break.
- **The safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk (2013 update)**

The Chair gave the floor to the Chair of the WG for an update on the opinion:

- There are some parts that need to be revised; the abstract should be changed.
 - SANCO B2 mentioned that the opinion should be adopted during the next plenary
 - A second rapporteur was identified, who will work together with the existing rapporteur in order to finalise the opinion by the next plenary in September 24/09.
- **Final Opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance**

This opinion was adopted. It will be published after the plenary.

Updates

Synthetic Biology

The Chair gave the floor to the Chair of the WG for an update on the state of play on this opinion and the following points were addressed:

- The first opinion was published for public consultation with deadline 21/07. SCCS expressed a minority opinion and the DHoU informed the plenary about the next steps
- SCENIHR and SCCS would work over the summer to try to overcome their differences on the definition considering contributions received via the public consultation and try to seek a common position
- SCCS will be asked to nominate more than 1 member for this opinion
- The 2nd opinion on methodology for risk assessment should be finalised by 1st of October and the 3rd one by the end of January 2015.

Safety of surgical meshes used in urogynecological surgery.

The Chair updated the plenary on the state of play of this opinion. External members have been selected for the WG and assessment of their DOI is on-going. Some issues envisaged with regard to the DOIs. Next meeting is scheduled on 30/06.

The safety of the use of Bisphenol A in medical devices

The Chair reminded that this preliminary opinion was published on 29/01/2014 (the public consultation was open until 26/03/2014). 121 comments received and addressed by the WG. SCENIHR is in favour to wait EFSA to finalise their opinions and to publish them in the same time. A coordination meeting should be envisaged so as to be aware and discuss the replies to the comments received during the public consultations by EFSA and SCENIHR. These aspects should be further discussed by the Secretariat with EFSA.

The Potential health effects of exposure to electromagnetic fields (EMF)

The Chair reminded that this preliminary opinion was published on 04/02/2014 and the public consultation is open until 16/04/2014. 200 comments received during the public consultation and submitted to the WG. Next WG is scheduled on 1-2 July to deal with contributions received via public consultation.

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

The Chair gave the floor to the chair of the WG who updated the plenary on the status of the opinion. 51 comments received during the public consultation have been forwarded to the chair and the rapporteurs of the WG who will review and address them during the summer break. The final opinion is expected to be finalised by the next plenary on 24-25/09.

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

The DHoU informed the plenary about a number of letters and requests of information received from journalists and from an association who challenged the content of the opinion and the independence of external experts involved in the WG. Currently, the secretariat is drafting replies in collaboration with the chair, vice-chairs of SCENIHR and different units.

8. Brainstorming session

- SCENIHR discussed a list of emerging issues for drawing Commission's attention on the actual and potential risks (to consumer safety, public health and environment). When finalised, SCENIHR will officially submit the list to the Secretariat to be sent to relevant Commission Departments.
- The document containing the proposal for emerging issues should be finalised by the next plenary in September and submitted to the Secretariat

9. Any other business

- The Chair addressed one member's request to add the 2 additional items on the agenda:
 - How to improve working methods concerning collation of comments from committee members on draft opinions/reports.
 - Discussion on how to respond to members of the public who contact members of the committee about issues. These new items have been included at AOB.

The Secretariat will explore IT tools to obviate to facilitate this task.

The decision was not to enter into dialogue directly but to go through the committee who can if appropriate, suggest a response to the secretariat.

Follow up of the opinions: SCENIHR will be very much interested in being informed about the final use of the opinions. This issue to be further explored by the Secretariat.

Next plenary meetings:

- 24-25 September, starting at 13:00 on 24/09
- 19 November between 9:00-17:00. The members should fly in on 18/11.

Annex 1

List of Participants

Members of the SCENIHR

Prof Igor Emri, Dr Epstein Michelle, Prof Dr Hartemann Philippe (Chair), Prof Dr Hoet Peter (attended the second day), 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 Testai Emanuela (vice-Chair) and Dr Theo Vermeire.

Absences:

Dr Samaras Theodoros

SCENIHR Secretariat (DG SANCO)

Mrs Donata Meroni
Mrs Mihaela Haratau
Mr Giulio Gallo (for item 6 and 7)

DG SANCO B2

Mrs Federica de Gaetano (by audio)
Dr Paul Piscoi (by audio)

DG SANCO E1

Mrs Ilaria Ciabatti

DG ENV

Julie Raynal