



3rd Plenary Meeting of the

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

Meeting room: HTC 02/280

25 -26 September 2013, 9:00-16:00

Minutes

1. Welcome and apologies

Deputy HoU **welcomed the participants** and a tour the table was made to introduce new members regarding their professional background, affiliations and areas of scientific expertise.

Absences: 3 members of SCENIHR excused. One of the Vice chairs joined the second day of the plenary meeting by audio.

2. Adoption of the agenda

Agenda was adopted as presented.

3. Declaration of interests on matters on the agenda

The Chair asked the committee members to inform of any conflict of interest to be acted in the minutes of the plenary. No declaration of potential conflict of interest was made.

4. Chair's / member's report

The Chair briefly informed participants on the EFSA initiative on environmental risk assessment (ERA) and informed that one of the Vice chairs of SCHER expressed her interest to be part of this EFSA WG. A further member expressed his interest. Their names will be passed to EFSA.

The European Food Safety Authority requested the participation of experts of the non-food scientific committees in this new working group(s) with the scope to better harmonise the approach to some elements of environmental risk assessment (ERA). Other European agencies and bodies are involved as well in this exercise.

The Chair also informed the members of the committee about the WHO/IPCS Workshop on Uncertainty in Hazard Assessment on 19-20 November 2013 in the Netherlands. One member of each committee will attend the workshop.

One of the vice chairs informed the plenary about the participation in the Conference of 'Nanoforum', organised between 19-20 September 2013 at the Faculty of Civil and Industrial Engineering, 'La Sapienza' University of Rome representing the SCENIHR activities in the area of nanotechnology.

5. Feedback by Commission Services

The DHoU informed the members about the resignation of Prof Dr Dekant. The Secretariat had received his official letter announcing his resignation due to his restriction of time availability. It was mentioned that, depending on the needs of the SCENIHR a replacement could be sought among the pool of advisors. This could take some time depending on the appointment procedure the Secretariat has to follow. It was suggested by the majority of the members that the person to replace Prof Dr Dekant should be of the same or similar scientific discipline/specialty.

Two colleagues from SANCO B2 attended the plenary by audio and stressed the importance of receiving the opinions well in advance of the plenary meetings so as to be able to provide a substantial feedback to the text, taking into account the quality of the output.

6. On-going work

Adopted Opinions:

- ***Preliminary Opinion on the safety of Poly Implant Prothèse (PIP) Silicone Breast Implants (2013 update)***

This opinion was sent to be adopted by written procedure last August. However, due to many substantial comments received from the members of SCENIHR the Secretariat had to go back to the WG who had worked intensively to consider all comments. As the final version was received only on 19/9 this opinion was submitted for adoption during the plenary.

The Chair of SCENIHR made a detailed presentation of the opinion. It was stressed from the beginning that the mandate was very difficult and the topic is a very sensitive one.

Some SCENIHR members underlined the fact that they are risk assessors and the statements in the opinions (including this one) should be focused on risk assessment, so it was recommended to avoid risk management formulation in the text.

The Chair gave the floor to Paul Piscoi for B2 comments on the PIP II Opinion. The colleagues from SANCO B2 presented their comments to the opinion and underlined the sensitivity of the topic. They underlined the need for clarification and coherence within the text.

The Preliminary Opinion was adopted with the condition to make the editorial changes and suggestions received from SCENIHR's members, Secretariat and SANCO B2.

The document is going to be circulated again, after integration of comments from the chair of the WG, for information to SCENIHR before sending it for publication and public consultation.

Draft Opinions:

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

The draft of the preliminary opinion was discussed. Few comments were raised to be passed on to the WG members. Further work is still needed. The opinion will be discussed for adoption during SCENIHR next plenary (11/12/2013).

– ***The safety of the use of Bisphenol A in medical devices - Update:***

The draft of the preliminary opinion was discussed. Few comments were raised to be passed on to the WG members. The opinion will be discussed for adoption during SCENIHR next plenary (11/12/2013)

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

The draft of the preliminary opinion was discussed thoroughly. The text of the opinion is almost finalised. The opinion will be sent for adoption by written procedure before the next plenary meeting.

– ***Potential health effects of exposure to electromagnetic fields (EMF)***

The progress of this opinion was presented. Few meetings are still needed to finalise this very comprehensive opinion. The Opinion is due to be discussed for adoption during next plenary of SCENIHR.

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

The progress of this opinion was presented. Few comments were raised to be passed on to the WG members. The opinion will be discussed for adoption during the next plenary of SCENIHR (11/12/2013)

– ***Health Effects of Nanomaterials Used in Medical Devices***

The progress of this opinion was presented. The WG held the last meeting on 17 September. Following the discussion among the WG members it was decided to reformulate the text of the mandate. The mandate was discussed and reformulated taking into account the proposals received from unit B2. During the Plenary, unit B2 asked the Secretariat to send the new text of the mandate by e-mail. This opinion is expected to be finalised by the end of December and possibly adopted at the plenary meeting in February.

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

The progress of this opinion was presented. The text is almost finalised. The opinion is expected to be approved during the Plenary on 11 December 2013.

– ***Synthetic Biology***

The Chair of the WG updated the plenary about the stage of the work of this WG. The mandate is a joint one for all 3 SCs and it was decided that SCENIHR will coordinate this WG. Each SC has representatives in the WG. The WG is now complete with 8 additional members who have been selected in July 2013. The first physical meeting of the WG will be organised on 15 October. The opinion is expected to be finalised by October 2014.

7. Brainstorming session

– *How to improve the efficiency of the work of the Committee/ working groups?*

The Chair started the discussion underlining some of the lessons learnt from past experience.

- It is advisable to have two different people nominated as Chair of the WG and as the rapporteurs because these have distinct roles in the functioning of the WGs and to avoid creating burdensome work on them.
- According to the rules of procedures chairs of the WGs have to be members of SCENIHR. Their roles are:
 - To ensure the management of the WG
 - To facilitate relations and dialogue between the members of the WGs
 - To distribute the tasks and responsibilities among the WG members
- Role of the rapporteur (who can be external expert to the Committee) and is paid with an additional indemnity (see Commission Decision 2008/721/EC) is clear stated in the Rules of Procedure (page 13 art 66-69). **This role is very important for collecting the different contributions of the WG members and harmonizing these contributions because of the actual impossibility for the scientific officer to do it alone for multiple on-going opinions.**
- A planning table for the on-going opinions was distributed, setting milestones for the preparation of the opinion.
- Outsourcing some of the work (e.g. literature review, references check)
- Better formulation of the mandates, the mandates should be manageable by the WGs
- Establishing a template for the structure of the opinions which have to be followed/used by each WG
- Establishing a clear cut-off date of literature review
- Strict timeframe for the work
- Adequate information to the external members about their responsibilities when joining a WG and time/work availability requested
- Rethinking the structure and length of the documents/opinions (should be better to keep them around 50 pages otherwise there is a difficulty of reading/following the text; the opinion itself and the answer to the questions from the ToR should be placed at the beginning of the document)
- Better interaction between the WGs and SCENIHR Committee
- The opinions should be sent to SCENIHR with at least 2 weeks prior to the plenary meetings.

The Secretariat and the Chair of SCENIHR will elaborate a document including the proposal for the new working procedures and this will be circulated to SCENIHR members before the next plenary meeting.

– *Listing of emerging issues for drawing Commission's attention on the actual and potential risks (to consumer safety , public health and environment)*

Some proposals have been received from members of SCENIHR covering the following topics:

- Looking at 3D movies/images for a prolonged period of time (several hours), may be associated with reported health symptoms
- 3-D printers
- E-cigarette as consumer product
- The use of nanomaterials for medical imaging and drug delivery

The members have discussed the proposals received and it was agreed to send their further proposals to Secretariat so as to be compiled in a document to be discussed during the next plenary meeting on 11-12 December 2013.

8. Any other business

- Next plenary meeting 11-12 December 2013
- Calendar of meetings in 2014 – to be established after the meeting. Doodle to be launched to set up dates in one of the following weeks:
 - One day plenary meeting in the last week of February or the first week in March
 - One day plenary meeting in the second or third week of June
 - One day plenary meeting in the 3rd or 4th week of September

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 Dr Rizzo Luigi, Dr Rushton Lesley, Dr Rydzynsky Konrad, Dr Samaras Theodoros, Dr Testai Emanuela (vice-Chair) – by audio on 26/09 and Dr Theo Vermeire.

Apologies

Prof Igor Emri
Prof Eduardo Rodriguez Farre.
Prof Wolfgang Dekant - resigned

SCENIHR Secretariat (DG SANCO)

Mrs Donata Meroni
Mr Giulio Gallo
Mrs Mihaela Haratau

DG SANCO B2

Mrs Federica de Gaetano
Dr Paul Piscoi