



5th 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

26 February 2014, 9:00-16:00

Minutes

1. Welcome and apologies

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

No absences. One member attended the plenary by audio (see annex 1). Two representatives of SANCO B2 attended the meeting by audio.

2. Adoption of the agenda

- The agenda was amended, including one member's proposal, namely, "workflow and responsibilities", in order to analyse the experience gained so far concerning the efficiency of existing SCENIHR procedures in comparison to structures and examples of comparable committees, national and/or international.
- This new item was 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. It was reminded that these declarations have to be made orally at each plenary meeting as well as at the start of each working group meeting and are noted on the minutes.
- It was mentioned that members must declare any activity that might be seen as an interest to SCENIHR's opinions.
- A member declared as being partner in an FP7 project, in which partners participate that are small and medium sized enterprises. It was clarified that participation in research project funded by the EU generally does not constitute a conflict of interest. And in this case no conflict of interest was found.
- 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 are carrying out in collaboration with other SC and other Agencies.

One member mentioned her participation in the discussions on the dental Amalgam Opinion of SCHER.

- The Chair mentioned the *Workshop on integrated assessment of emerging science and technologies, in Brussels, on March 28*, which is part of the work in the FP7 research project EST-Frame, on integrated assessment of emerging science and technologies. The participation from a SCENIHR representative had been requested. The SCENIHR agreed with the participation of the Chair of Synthetic Biology WG as a representative of the committee.

5. Communication by Commission Departments

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

- Replacement of a member. He resigned in September 2013 and his replacement should be appointed, if needed, by the Commission by means of a Decision. SCENIHR members agreed that there is a need of filling in the vacancy with a scientist with experience in risk assessment, toxicology and medical devices. The secretariat will check the pool of advisors and make a short list with potential candidates and then those candidates will be asked for their availability and interest in becoming members of SCENIHR. Their DoIs will be requested so as to check them at a very first stage.
- Annual COI/DOI forms for 2014 requested by email of 5 February 2014 had been filled in and sent by 12 members. The rest of 2 members have been reminded to submit their DoIs as soon as possible. It was stressed that no opinions can be published in 2014 without publishing the DOI.
- EMF Conference under EL Presidency on SCENIHR opinion and hearing: the committee was updated on SCENIHR representation to these events. The Chair of SCENIHR, the Chair of WG on EMF and one member of the committee will attend both events.

6. New mandates:

Safety of surgical meshes used in urogynecological surgery."

- The new mandate was briefly introduced during the plenary in December.
- The Chair gave the floor to the representative of SANCO B2 who had revised the mandate based on the discussion held in December and invited SCENIHR to comment on the text.
- SCENIHR members proposed some changes in the text, then adopted a new amended text which has to be sent to SANCO B2 for their consideration and approval.
- The Committee discussed the composition of the relevant working group. Four members of the SCENIHR volunteered to become members of this WG and the Chair was appointed.
- To select further experts it was decided to examine the 80 CVs retrieved from the data base of experts and pool of advisors and to launch the call of expression of interest for experts in surgical meshes as soon as possible, to have candidatures at the first meeting.
- Secretariat will launch a doodle so as to establish the date of the first meeting of the WG.

7. On-going work

For approval/adoption:

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 to report on the progress of work for this preliminary opinion
- The opinion was sent to SCENIHR for adoption by written procedure
- Comments submitted by SCENIHR members have been revised by the Chair of the WG and the rapporteurs and the last version of the preliminary opinion was presented at the plenary.
- There were some comments related to the need to reformulate some sentences from the risk assessment perspective.
- The Chair of the WG will prepare a new version of the opinion to be circulated to SCENIHR for approval for public consultation which is expected to be launched in the first half of March.

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 meetings of the WG. A revised version was sent to SCENIHR; but the document was still not ready to be approved for public consultation.
- Then, the Chair gave the floor to SANCO B2 representative to introduce their comments on the opinion
- Secretariat should launch a doodle so as to establish the date of an additional meeting of the WG to deal with new wording of specific sections for which comments were raised
- The adoption of the opinion was postponed to the next plenary in June.

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
- The opinion was already discussed during the last plenary in December but it is still far from finalisation.
- The representatives of SANCO B2 expressed their interest in the timeline of this opinion.
- Some comments were expressed by members: some of the text should be revised in the light of new literature recently available, the bio monitoring part should be updated; one member of the committee offered to work on this
- The abstract, executive summary, the opinion and the conclusions should be written in the same consistent style
- There is a need to clarify some points related to the sub-chronic / sub-acute exposure
- The opinion should be finalised in 1-2 months and sent to SCENIHR for adoption by written procedure.

Health Effects of Nanomaterials Used in Medical Devices

- The Chair gave the floor to the Chair of the WG for an update on the opinion
- Comments were expressed by members on the draft opinion presented:
 - there is still some cleaning up to do regarding the formatting, references, and annexes before the document can be considered final
 - the toxicokinetics part should be re-written in a way to differentiate the methods applicable for bulk and for nano materials
 - it is important to underline in what respect the present testing used for risk assessment of medical devices are or are not suitable for the case of nano materials.
- A new version of the opinion should be sent to SCENIHR for adoption by written procedure during the month of March.

Update

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 mandate has been split into 3, with the first one being the definition.
- There is a need to have the opinion on definition adopted by June 2014 for the EC to use it at a meeting in Montreal (the SBSTTA-18th meeting of the Convention of Biodiversity, on 23 - 28 June 2014)
- The first opinion on definition was sent to the members of SCENIHR the week before the plenary and also to the other committees for comments, as this is a joint opinion. The Secretariat will collect the comments from all committees and circulated to the WG members.
- The comments SCENIHR members might have need to be sent to Secretariat within 2 weeks. No comments by this date mean that the member agreed
- The opinion on definition will be sent for adoption by written procedure in April.

Update on the public consultation:

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 is open until 26/03/2014).

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.

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

The Chair updated the plenary with the progress of the work.

- The public consultation was closed on 02/01/2014
- 19 organisations/individuals participated in the public consultation delivering comments

- All the comments were discussed in one audio meeting with the WG. A letter was sent to Swedish authorities asking them to provide with scientific papers they mention in their contribution. The reply was received and circulated to the WG.
- The opinion is planned to be finalised and published by mid-May.
- It was mentioned that the comments received during the public consultation will be published in a form of a table and replies to all senders to be prepared and sent individually (Chair and secretariat).

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

- The preliminary opinion was published for public consultation until 02/02/2014
- 31 comments were received from organizations and individuals
- One request was received after the closure of the public consultation from the European Precious Metals Federation (EPMF), a member of Eurométaux (the home to the Consortium of companies preparing and keeping up to date the REACH Registration Dossier for Silver in its various forms: massive, powder, and nano)
- SCENIHR decided to take into account these comments as well

8. Brainstorming session

- Prioritization of the emerging issues for drawing Commission's attention on the actual and potential risks (to consumer safety, public health and environment). *This item was postponed for June, to be discussed as a half day point.*

9. Any other business

Internal survey:

- Internal survey on the functioning of the SCs has been launched early 2014.
- The results of the survey were briefly presented by the Secretariat

"Workflow and responsibilities"

- At this point the Chair mentioned the request from one member of the committee proposing to include this point into the agenda. This was proposed with the aim to analyse the experience made so far and the efficiency of existing SCENIHR procedures in comparison to structures and examples of comparable committees, national and/or international ones.
- It was agreed that the discussion should continue during the next plenary
- Some concrete proposals were made: to speed up the process of issuing the scientific opinions, to inform the WGs that, once the opinion is approved by the plenary, then the WGs should conclude the work on the documents very quickly.

Next plenary meeting:

The Chair suggested having 1½ day meeting to properly discuss the brainstorming session. Next plenary will be organised on 10-11 June 2014.

Annex 1

List of Participants

Members of the SCENIHR

Prof Igor Emri, 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 (by audio), Dr Samaras Theodoros, Dr Testai Emanuela (vice-Chair) and Dr Theo Vermeire.

SCENIHR Secretariat (DG SANCO)

Mrs Donata Meroni
Mrs Mihaela Haratau

DG SANCO B2

Mrs Federica de Gaetano
Dr Paul Piscoi (by audio)