



14th 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

16 February 2016 (starting at 9:00)

Minutes

Welcome and apologies

The Chair welcomed the participants and announced the apologies received (one).

The Vice Chair of the SCCS attended the meeting.

Representative of DG GROW attended the meeting by audio.

Adoption of the agenda

The agenda was adopted as it was presented.

Declaration of interests on matters in the agenda

The Chair requested participants to declare any potential conflicts of interest regarding the subject matters on the agenda. No declarations of any conflict of interest were made.

Communication by Commission Departments

The Chair gave the floor to the Deputy Head of Unit (DHoU), Mrs. Donata Meroni, for an update on the state of play of the following issues:

- Update on the Call for applications

The Evaluation Panel met last month and produced a list of suitable candidates. Pursuant to provisions of Decision C (2015) 5383, the members of the new Committees will be appointed by the Director General of the DG SANTE from the list of suitable candidates. Candidates not appointed as members stay on the reserve list. The new Committees will enter into service in April 2016.

- Ongoing evaluation of the Scientific Committees (2009-2014)

A progress report has been produced based on interviews carried out with stakeholders and members/experts of the SCs. A survey targeting members and experts was launched.

-New opinions/mandates from other Scientific Committees. The members received printed copies of the list with mandates and new Opinions.

- Follow-up of work with **scientific journals** to promote the dissemination of the SCs opinion. The DHoU informed the members about the publication of different Opinions in the following scientific journals:

- o Journal of Regulatory Toxicology and Pharmacology - article on Dental amalgam

- Journal of Regulatory Toxicology and Pharmacology - articles on BPA and DEHP
- Journal of Medical Devices Regulation (February issue) - short article about the Opinion on surgical meshes
- Journal Mechanics of Time Dependent Materials - article on surgical meshes is currently being prepared by the Secretariat to be submitted to the journal.
- **The members were informed about new Science Factsheets prepared by the Secretariat:**
 - Tobacco additives: publication foreseen on 29 January 2016, together with the final Opinion
 - Sun beds: Writing of the draft text has started.
- **The DHoU informed the plenary about some future events:**
 - 19th Annual Conference of the European Biosafety Association, 20-22 April – Opinions on Synbio will be presented by the rapporteur.
 - EFSA Plenary, 21 April – SynBio Opinions will be presented by the Chair of the WG.
 - Joint plenary meeting of the new Scientific Committees on 28-29 April 2016.

Chair's / member's report

The Chair asked the members who attended various events to briefly inform the members about the outcomes of discussions:

- Society of Toxicology Webinar, 21 January 2016, to present the Opinion on Nanomaterials in Medical Devices

The webinar was a success: 227 people were in attendance at one point. A summary will be made by the Society of Toxicology and this summary, an audio recording of the presentation and the presentation itself will be available shortly on the SOT website under the Medical Device and Combination Product Specialty section.

- Synthetic Biology Expert Meeting, 11 February 2016, Brussels

The Chair of the WG on Synbio made a short presentation of the meeting and a list of all dissemination activities related to Synbio Opinions was shared with the members. The Expert Meeting on Synthetic Biology was organised by the European Commission under the auspices of the Netherlands Presidency of the European Union. Among the participants were the members of the Council Working Parties on International Environmental Affairs on Biodiversity and Biosafety and the meeting was in preparation for COP13 to the Convention on Biological Diversity in December 2016.

New mandates:

The request for a scientific Opinion regarding the health effects of Light Emitting Diodes (LEDs) radiation, received from DG GROW, was discussed during the meeting and a number of changes were made. The mandate was not adopted: further modifications are needed by DG GROW. It was decided that after modification by GROW, the mandate will be submitted to the new SCHEER at the first plenary.

On-going work:

Adoption/Approval of the preliminary Opinion for public consultation:

- **Biological effects of UV-C radiation relevant to health with particular reference to UV-C lamps**

The Chair gave the floor to the chair of the WG, Lesley Rushton, to present the preliminary Opinion. The text of the Opinion was broadly discussed among members and several comments were made. The Opinion was not approved; instead, an additional WG meeting will be organised in March to address the points raised by the members.

Progress of preliminary opinions on:

- **Guidance on the structure and content of SCHEER opinions**

The Chair gave the floor to the chair of the WG, Ana Proykova, who presented the state of play of this Opinion. The next meeting of the WG is scheduled on 17 February.

- **Revision of the 'Memorandum on weight of evidence and uncertainties**

The Chair gave the floor to the chair of the WG, who briefed the plenary about the state of play of this Opinion. The next meeting of the WG is scheduled on 17 February.

- **The second opinion on tobacco additives**

The Chair gave the floor to the chair of the WG, who presented the state of play of this opinion. The next audio meeting of the WG is scheduled on 18 February 2016.

- **Sunbeds Opinion**

The DHoU informed the plenary that, at the request of DG JUST and DG GROW, a public hearing will be organised in April on the Opinion on sunbeds. The dates will be confirmed shortly.

Follow-up of Opinions:

Opinion on nanomaterials in medical devices

SCENIHR Opinions (2009 and 2015) are extensively cited and 2 tables are reproduced (with Commission permission) in the recently published RIVM Report on Nanotechnologies in Medical Devices (17 December 2015). This is further proof of the uptake of the scientific committee's work.

http://www.rivm.nl/en/Documents_and_publications/Common_and_Present/Newsmessages/2015/Nanotechnology_increasingly_used_in_medical_devices

Farewell

The DHoU presented the main achievements of the term and invited members to comment on them.

Any other business:

None

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, Prof Dr Proykova Ana (vice-Chair), Prof Eduardo Rodriguez Farre, Dr Rushton Lesley, Prof Dr Rydzynski Konrad, Dr Rizzo Luigi, Prof Theodoros Samaras, Dr Testai Emanuela (vice-Chair) and Dr Theodorus Vermeire.

Absences:

Dr Martinez-Martinez Luis

SCENIHR Secretariat (DG SANTE)

Mrs Donata Meroni, DHoU

Mrs Mihaela Haratau

DG GROW, D4, Unit C3

Mrs Victoria Piedrafita