



## **7<sup>th</sup> 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**

**24-25 September 2014 (starting at 13:00 on 24 of September)**

### **Minutes to be published**

#### **1. Welcome and apologies**

The Deputy Head of Unit (DHoU) welcomed the participants and gave the floor to the Chair of SCENIHR. Three apologies were received. Three members joined the plenary by audio.

Representatives of SANCO B2 and D4 attended the meeting by audio.

#### **2. Adoption of the agenda**

- The agenda was amended, including the following items:
  - the issue of coherence and improvement in structure and content of the opinions (abstract, executive summary and opinion itself)
  - the promotion and dissemination of opinions, in particular by means of publications on scientific journals.

These items have been included under AoB point.

#### **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 mentioned that members must declare any activity that might be seen as an interest to SCENIHR's opinions.
- No declaration of potential conflict of interest was made by members.

#### **4. New mandates:**

##### **Tobacco additives:**

- Representatives of SANCO D4 joined the plenary by audio so as to introduce the new version of the mandate on tobacco additives and to answer to questions raised by SCENIHR. D4 provided SCENIHR with a number of background documents and an initial list of additives reported to MS by the tobacco industry. All these documents will be made available for the WG.
- A member volunteered to join the WG.
- The mandate was adopted by SCENIHR.
- The deadline for the preliminary opinion was set for June 2015.

### **Sun beds:**

- The DHoU mentioned that in the past this mandate was under the remit of SCCS.
- The mandate will be discussed during the ICCG meeting on 16/10 together with the possibility of having a joint opinion with the other SCs.

### **5. Chair's / member's report**

- The Chair gave the floor to SCENIHR members to report on activities they carried out in collaboration with other SCs and Agencies.
- SCENIHR members have attended the following events between the 6th and the 7th plenary:
  - ✓ AMS Workshop on pelvic surgery on 03/07/2014 in Paris;
  - ✓ The 8th International Workshop on Biological Effects of EMF, in Varna, on 22/09/2014. DG SANCO and SCENIHR participated in a special session during the first day of the workshop with presentations on EMF responsibilities in the Commission and on the preliminary opinion on possible health effects of EMF and risks' communication. A lot of interest was raised around the opinion.

### **6. Communication by Commission Departments**

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

- 24-25/09: 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);
- New Guidelines on how to evaluate the declaration of interest form of the experts of Scientific Committees;
- The ICCG meeting on 16/10;
- A session of the European Health Forum in GASTEIN devoted to the Scientific Committees on 2 October. See the programme on <http://www.ehfg.org/detailevent.html?eid=88>;
- IDEA Workshop on 17 December. The IDEA annual meeting (IFRA) is planned to be organised back to back to SCCS Plenary meeting;
- Participation of one SCENIHR member at an upcoming nanonetwork meeting at EFSA, on 21-22 October to present the opinion on NanoSilver;
- Public hearing on Dental Amalgam scheduled on 27/10;
- GLORE meeting on 19/11 and the representation of SCENIHR;
- The representation of SCENIHR to ERASynBio's workshop on exchange of synthetic biology and RRI projects, in Brussels, on 19/11.

### **7. On-going work:**

For approval/adoption:
------------------------

#### **Final Opinion on 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 informed the plenary about the last changes in the opinion, in the abstract and executive summary. The SCENIHR adopted the opinion which is going to be published soon after the meeting together with the document containing replies to contributions received during the public consultation.

## **Final Opinion on Synthetic Biology I – Definition and replies formulated by SCENIHR to the contributions received during the public consultation**

The Chair gave the floor to the chair of the WG who informed the plenary about the last changes in the opinion and in the abstract. The SCENIHR adopted the opinion which is going to be published soon after the meeting together with the document containing replies to contributions received during the public consultation.

## **Preliminary Opinion on 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 abstract and a number of paragraphs in the opinion have been changed;
- A quality check should be performed by Secretariat throughout the document to ensure consistency with the changes discussed in the plenary. The reference list has to be completed;
- The opinion was approved for public consultation.

Update:

## **Synthetic Biology – Opinion II**

The Chair gave the floor to the Chair of the WG for an update on the state of play on this opinion. The opinion is progressing well, it is expected to be finalised and discussed at next Plenary late November. Next audio meeting of the WG is scheduled on 03/10/2014.

## **Safety of surgical meshes used in urogynecological surgery**

The Chair has updated the plenary on the state of play on this opinion. The WG has selected two rapporteurs who will present the preliminary version of the opinion by the end of January 2015. Next meetings scheduled on 4/11/2014 (audio) and 02/12/2014.

## **The safety of the use of Bisphenol A in medical devices**

The Chair gave the floor to the Chair of the WG for an update on the state of play on this opinion. An audio meeting with EFSA was organised one day before the plenary when it was agreed that SCENIHR opinion should be published at the same time as the EFSA one.

Update on the public consultation:

The Chair has updated the members on the stage of the following opinions during or after the public consultations:

## **Preliminary Opinion on the Guidance on the determination of Potential Health Effects of Nanomaterials Used in Medical Devices**

The public consultation is open until 3 October.

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

The public consultation is open until 16 November.

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

The Chair gave the floor to the Chair of the WG for an update on the progress of the opinion. The WG met on 1-2 July 2014. The date of the literature to be analysed has been extended to 30 June 2014. Consequently, the text has to be updated to include new possible evidence. Next meetings are scheduled on 9-10 October 2014.

### **Emerging issues for drawing Commission's attention on the actual and potential risks ( to consumer safety , public health and environment )**

The SCENIHR discussed a new proposal: the risk for the workers in charge to control (customs) and handle containers because of previous biocidal fumigations or chemical reactions involving different goods during travel to be included in the list of emerging issues for drawing Commission's attention on the actual and potential risks. After discussion, it was concluded that the topic does not fall in the remit of SCENIHR. The document was adopted by SCENIHR. The Secretariat was asked to distribute it to relevant Commission Departments.

### **Any other business**

#### **Structure of the opinions**

- It was agreed that the structure of the opinion should follow the Rules of Procedure, some elements can be omitted if not appropriate and the order changed. As an example:
  - Abstract (Executive summary optional)
  - ToR and background information
  - Opinion (this could include executive summary)
  - Rationale
  - Bibliography
  - Annexes

#### **Promotion of opinions in scientific journals:**

- It was discussed the possibility to increase the visibility of SCENIHR and to broadly disseminate the opinions in the scientific community. In this respect it was proposed to publish an abstract of the opinion (maybe in an editorial format) in different scientific journals the members have been asked to identify journals of interest.

#### **Next plenary meetings:**

- 20/11/2014 (starting at 9:00)
- 27/01/2015 (starting at 9:00)
- 29/04/2015 (starting at 9:00)
- 24/09/2015 (starting at 9:00)
- 3/12/2015 (starting at 9:00)

## **Annex 1**

### **List of Participants**

#### **Members of the SCENIHR**

Prof Igor Emri, Dr Epstein Michelle (by audio 1<sup>st</sup> day), 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 Testai Emanuela (vice-Chair, by audio) and Dr Theo Vermeire (by audio).

#### **Absences:**

Igor Emri, Luigi Rizzo, Michelle Epstein (2<sup>nd</sup> day)

#### **SCENIHR Secretariat (DG SANCO)**

Mrs Donata Meroni  
Mrs Mihaela Haratau

#### **DG SANCO B2**

Mrs Federica de Gaetano

#### **DG SANCO D4**

Mrs Katja Broman