



## **13<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**

**03 December 2015**

#### **Minutes**

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

The Deputy HoU (DHoU) welcomed the participants and gave the floor to the Chair of SCENIHR. One apology received. Three members joined the meeting by audio.

The Vice chair of SCHER, attended the meeting.

Representatives of DG GROW D4, DG SANTE D4, DG JUST E3 and DG RTD D2 attended the meeting by video conference.

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

The agenda was adopted with two amendments: the discussion on the final opinion on surgical meshes was postponed until 10:35. A new item was included under 'on-going work: update', namely the one regarding the comments received from PVC med and the impact these may have on the final opinion on DEHP.

### **3. Declaration of interests on matters in the agenda**

The Chair requested to participants to declare any interest on the matters on the agenda. No declarations of any conflict of interest were made by participants.

It was reminded that these declarations have to be made orally at each plenary meeting and are noted on the minutes.

### **4. Adoption of the opinions**

#### **➤ The final Opinion on Synbio III – Research Priorities**

The Chair gave the floor to the chair of the working group on Synbio who presented the final Opinion and the results of the public consultation. The SCENIHR adopted the final opinion agreeing with the comments received from SCHER and DG RTD.

A number of the SCCS members attended the presentation and agreed with the opinion.

#### **➤ The final opinion on tobacco additives**

The Chair gave the floor to the chair of the working group on tobacco additives who presented the opinion and the results of the public consultation. It was proposed to

elaborate an executive summary using the actual abstract in the opinion and to rewrite the abstract. A discussion followed.

The representatives of DG SANTE D4 who joined the meeting by video conference asked the committee to prioritize the substances using the information already included in the text of the opinion such as the table from the annex.

The SCENIHR decided that further work is still needed to finalise the Opinion. Therefore an extra meeting of the Working Group should be convened to address the comments expressed by SCENIHR members. Then the Opinion will be finalised and adopted by written procedure.

➤ **The final opinion on Safety of surgical meshes used in urogynecological surgery**

The Chair gave the floor to the rapporteur of the opinion who presented the results of the public consultation and the final opinion. The representatives of DG GROW, D4 joined the meeting by video conference and provided their comments which were discussed by the committee.

The final opinion was adopted, to be published after quality check controls, before Christmas.

**Adoption of the preliminary opinion:**

➤ **Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes**

The Chair gave the floor to the chair of the WG who presented the preliminary opinion. Then, a discussion followed and comments were made from members and also from DG JUST.

Some changes were made to the draft text of the preliminary Opinion, according to these comments. Finally, the preliminary opinion was adopted by the SCENIHR for public consultation with the exception of one member of the SCENIHR, Norbert Leitgeb, who voted against the adoption of the preliminary opinion because of, in his opinion, there were editorial inaccuracies and the part concerning research needs was inadequate.

The publication of the Opinion is foreseen after Christmas, due to quality checks to be performed. The SCENIHR asked the Secretariat to start drafting an easy to read fact sheet to disseminate this opinion, once finalised, in a layman language. The SCENIHR asked the Secretariat to start drafting an easy to read fact sheet to disseminate this opinion, once finalised, in a layman language.

**On-going work: update**

➤ **Biological effects of UVC radiation relevant to health with particular reference to UVC lamps**

The Chair gave the floor to the chair of the WG who updated the plenary on the state of play of this opinion. Some discussion followed.

The Committee was explained that there is still some work to be done to prepare the draft of the preliminary Opinion which should be ready for adoption during the plenary meeting on 16 February 2016.

## ➤ **The second opinion on tobacco additives**

The same WG which elaborated the first opinion on tobacco additives will start working on the second opinion immediately after its adoption. The second opinion will focus on the type and criteria for comprehensive studies that should be requested from manufacturers to assess the relevance of the individual additives. It should be finalised before the end of the term of the current SCENIHR.

## ➤ **DEHP final opinion**

In October 2015, the Secretariat received a communication about the final opinion on DEHP from PVCmed, an organization that comprises the whole medical device value chain. They enumerated factual errors they had found in the opinion.

SCENIHR members, who were also members of the working group went through the document and formulated replies to the comments. Consequently, some text of the Opinion was changed but these changes did not result in modification of the conclusions or the 'opinion part' itself.

The Committee approved these changes and discussed the procedure to be used in similar situations. Even if the public consultation time was ended, and the Opinion already finalised, due to the fact that the comments provided by PVCmed were judged to be useful information, and they did not alter the conclusions of the Opinion, it was agreed that a corrigendum to the opinion should be published.

## **5. Lunch break**

## **6. New mandates:**

The Secretariat, as requested by SCENIHR, drafted two new mandates on:

- **Guidance on the structure and content of SCHEER opinions**
- **Revision of the 'Memorandum on weight of evidence and uncertainties**

The aim of these mandates is to facilitate the transfer of knowledge and expertise from the current SCs to the new one and to foster the integrated approach which should regulate the new Committee SCHEER.

The SCENIHR discussed and then adopted the two mandates.

A joint WG with members from the SCHER and SCENIHR was formed and the date for the first physical meeting was agreed, namely, the 21<sup>st</sup> of January 2016.

## **7. Chair's / member's report:**

The Chair gave the floor to those members of the committee who attended the following events:

- Workshop in Athens on EMF organised by Greek Mobile Operators Association on 28 September 2015;
- Glore Meeting organised on 19-20/11 in Seoul;
- Conference 'Shaping the future of food safety, together'(www.efsaexpo2015.eu) organised on 14-16 October;
- 2nd Synthetic biology congress in London organised on 21 October;
- Meeting of the group of experts on Tobacco Policy organised in Brussels on 15/10/2015

## 8. Communication by Commission Departments:

The Chair gave the floor to DHoU for an update on the state of play of the following issues:

### ➤ **Update on the Call for applications**

353 applications were received for membership in the two committees: SCCS and SCHEER.

The Evaluation Panel has met this month and will produce a list of suitable candidates by the end of January. According to the provisions of Decision C (2015) 5383, the members of the new Committees will be appointed by the Director General of the DG SANTE from a list of suitable candidates.

Candidates not appointed as members stay on the list as a reserve. The new Committees will enter into service in April 2016.

### ➤ **Ongoing evaluation of the Scientific Committees (2009-2014)**

An intermediate report has been produced based on interviews carried out with stakeholders and members/experts of the SCs. The contributions provided through the 'lessons learnt' section will be forwarded to the contractor to feed the evaluation report.

### ➤ **Feedback from the EFSA concerning uncertainties and weight of evidence**

Representatives of the SCENIHR, SCHER and SCCS coordinated the reply to EFSA on uncertainties. EFSA is currently assessing the contributions received under public consultation.

➤ **New opinions/mandates** from other Scientific Committees (*Printed copies were distributed to the members*)

➤ Follow-up of work with **scientific journals** to promote the dissemination of the SCs opinion:

- Draft articles on DEHP, Dental Amalgam and BPA were prepared by the Secretariat and sent to the WG for their feedback.

➤ **Future events:** the members have been informed about the future events to be organised in December and January:

- **10 December 2015: Workshop on synthetic biology – From Science to Policy and Societal Challenges** organised by Commission and SCs.
- **Conference on synbio:** IRGC Meeting on January 7-8 - Theo Vermeire was invited as a speaker.

## 9. SCENIHR term 2013-2016: Lessons learnt (second session)

A second discussion on lessons learned was held during the plenary so as to share suggestions and experiences concerning the functioning of the Scientific Committees during the term 2013-2016. In this second session, the aim was to discuss the Rules of procedure, especially the sections on:

- Stakeholders dialogue
- Functioning of the committees (establishment of WG, role and tasks of the chair/rapporteur of the WG, selection of experts)

## 10. Any other business

Dates for next meetings:

- WG on UVC lamps: first or second week of January
- WG on Guidance: 21 January
- 14<sup>th</sup> Plenary meeting: 16 February.

## **Annex 1**

### **List of Participants**

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

Dr Epstein Michelle, Prof Igor Emri, Prof Dr Hartemann Philippe (Chair), Prof Dr Peter Hoet (by audio), Dr Martinez-Martinez Luis, Prof Dr Leitgeb Norbert, Prof Dr Proykova Ana (vice-Chair), Prof Eduardo Rodriguez Farre, Dr Rushton Lesley, Prof Dr Rydzynski Konrad, Prof Theodoros Samaras (by audio), Dr Theo Vermeire, and Dr Testai Emanuela (by audio)

#### **Absences:**

Dr Rizzo Luigi

#### **SCENIHR Secretariat (DG SANTE)**

Mrs Donata Meroni  
Mrs Mihaela Haratau  
Mrs Silvia Hrubanova

#### **DG GROW, D4**

Mr Paul Piscoi

#### **DG SANTE, D4**

Mrs Katja BROMEN  
Mr

#### **DG JUST, E3**

Mrs Ana Maria Blass Rico

#### **DG RTD, D2**

Mrs. Carmen Coll de Vicente