8th Plenary Meeting of the

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

20 November 2014

Minutes

1. Welcome and apologies

The Head of Unit and the Deputy HoU (DHoU) welcomed the participants and gave the floor to the Chair of SCENIHR. Three apologies were received. Representatives from SANCO B3 joined the meeting by audio for the new mandate on sunbeds.

2. Adoption of the agenda

The agenda was amended, including the following items:

- Easier access and improvement of the visibility of the Opinions.
- Publication of the Opinions.
- An update on the status for replacing one SCENIHR member.

These items have been 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.

One member declared that she is going to be reviewing grants for the European Science Foundation and will be collaborating in a new Working Group (WG) of the European Food Safety Authority (EFSA) that will be responsible for drafting supplementary guidelines for the allergenicity assessment of genetically modified (GM) plants. The Secretariat and the Committee considered that there is no conflict of interest in relation to these declared interests.

No declaration of potential conflict of interest was made by the rest of members.

4. New mandates

Adoption of the mandate on sunbeds: a new DRAFT mandate on sun beds was received from SANCO B3. The representative of SANCO B3 joined the plenary by audio so as to answer the questions and address the comments from SCENIHR. The mandate was adopted. An initial Working group was established and 5 members have volunteered to join it. SCCS and SCHER will be asked for their interest to join the WG.

5. Chair's / member's report

The Chair gave the floor to SCENIHR members on activities they carried out in collaboration with other SC and other Agencies.

ICCG meeting on 16 October

The Chair briefed the plenary on the following issues discussed during the ICCG mentioning the following:

- **Promotion of opinions in scientific journals:** it was discussed and agreed to publish not the opinion as such but an abstract/executive summary in scientific journals, according to the indications of the journal. A trainee is in contact with each SC to negotiate with a few journals how to deal with this matter (layout, abstract, etc).

  Coherence and improvement in structure and content of opinions (public consultation, commenting period, tables with comments). According to the rules of procedures, it is not mandatory to have both abstract and executive summary. It was discussed the commenting period on a preliminary or final opinions. The SCCS has a commenting period after the adoption of opinions, while SCENIHR opinions often go to through public consultation of draft document. It should be decided case by case taking into consideration the sensitivity of the opinion and the need to involve stakeholder in the improvement of the scientific basis.

- **Selection of experts –** any specific need to be identified. SCs were invited to inform the Secretariat about any specific needs, ASAP. The same for any specific call for documents/information.

- **Rapid risk assessment in the context of the cross-border health threats decision.** Involvement of the Scientific Committees. The Decision 1082/2013/EU on serious cross border threats to health covers preparedness planning, risk assessment, risk management and risk communication aspects of all serious cross-border threats to health. According to Article 10.2, risk assessments for threats that are not communicable diseases and for which no EU Agency is in charge should be provided by the Commission (which will use the existing expertise within scientific committees). Concerning SCs, the key element is to provide such a risk assessment for chemical or environmental threats keeping independence of the experts. The Commission, together with Public Health England, prepared the Quicksilver exercise (on 24 – 25 September) to test the capacity and capability of SCs to implement the Decision. COM would like to develop a method for assessment of "chemical and environmental health risks" together with SCHER (and other SCs should they wish so) involving as well as people who're already taking part in this project (from MSs, laboratories etc.). Ideas are welcome. There will be a meeting with Member States on 19-20/11 on the evaluation of the exercise and the final report of PHA should be available in December 2015.

GLORE meeting:

- The Chair briefed the plenary on the main outcomes of the first day of GLORE meeting which was very well perceived by the audience.

ERaSynBio workshop:

- The Chair gave the floor to the chair of the WG on SynBio who attended the first day (19/11) of ERASynBio's workshop on exchange of synthetic biology and RRI projects.

ECHA meeting:

- The Chair gave the floor to the member of SCENIHR, who attended the meeting together with the representatives of SCHER and SCCS.

6. Communication by Commission Departments

New term of the Commission

The members have been updated by the DHoU with regards to the expected changes due to the new term of the Commission.

New opinions/mandates from other Scientific Committees (printed lists will be distributed during the meeting)

The list with new opinions and mandates published by the SCs between the plenaries in September and November was made available to committee members.

News from other EU risk assessment bodies

- The Chair mentioned the targeted consultation launched by EFSA about its activities on increasing robustness, transparency and openness of Scientific Assessments, with the deadline on 15/12. The SCENIHR members have been asked to provide their input to Secretariat which will forward them to EFSA. The SCENIHR suggested Emanuela Testai to represent the committee at the workshop EFSA will organize late spring 2015 so as to discuss the contributions received during this exercise.
- The Chair mentioned the Call of Expression of Interest for Membership of the Scientific Committee on Occupational Exposure Limits (SCOEL) with the deadline on 15/12/2014.

Guidelines on handling of conflict of interest

The Chair gave the floor to DHoU for an update on the state of play of this issue. It was mentioned that the document is almost finalised and will be sent for intra SANCO consultation.

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

The Chair gave the floor to the trainee, Petronille Bogaert, for an update on this issue.

Synbio (workshop)

The Chair gave the floor to DHoU who informed the committee about the intention to organise a workshop on this topic in the second semester of 2015.

Editorial newsletter and communication initiatives

The Chair gave the floor to DHoU who informed the committee that the next issue of the newsletter will be dedicated to the SCENIHR and its work on Synthetic Biology and has asked the members to recommend a member to sign the editorial. The Chair of the WG on Synbio was nominated for this.

7. On-going work:

For approval/adoption:

- **Synthetic Biology Preliminary Opinion II (preliminary opinion)**

The Chair gave the floor to the Chair of the WG to present the preliminary Opinion on SynBio II. SCENIHR approved the preliminary opinion for public consultation with a few amendments. The Secretariat was requested to send the opinion to the other Committees for approval during their plenaries: SCHER plenary on 28/11 and SCCS on 16/12. After the approval a public consultation will be launched for a period of 6 weeks.

- **Final Opinion on the Guidance on the determination of Potential Health Effects of Nanomaterials Used in Medical Devices**

The Chair of the WG presented the final text of the opinion after taking into consideration the comments received during the public consultation. The opinion was discussed in detail and SCENIHR members asked for additional time to provide their comments. The opinion together with the document containing the replies to contributions received during public consultation will be sent for adoption by written procedure by mid-December.

Update:

- **The safety of the use of Bisphenol A in medical devices (Final opinion)**

The members discussed the status of this opinion in the absence of the Chair of the WG. The EFSA is going to adopt their opinion by the end of November and to publish it at the beginning of January. The SCENIHR decided to publish the opinions at the same time. Adoption by written procedure could be necessary.

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

The Chair of the WG Theo Samaras updated the members on the progress of the opinion. On 10/11 the experts on epidemiology had a meeting to discuss the particular aspects raised during the public consultation. The WG will have the last meeting on 10/12. The opinion is expected to be adopted during the plenary on 27/01/2015.

- **Synthetic Biology III:**

The Chair of the WG briefed the plenary on the stage of this opinion. An audio meeting will be organised on 10/12 so as to start the discussions on this opinion.

- **Safety of surgical meshes used in urogynecological surgery (due by January 2015)**

The Chair briefed the members on the progress of this opinion. Next meeting is scheduled on 02/12/2014. The opinion is expected to be ready for approval during the plenary on 27/01.

- **Tobacco additives (due to June 2015)**

The Secretariat informed the members on the progress of this opinion. One member of SCENIHR expressed her intention to abstain from the vote of this opinion due to personal reasons.

Update on the public consultation:

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

Public consultation was closed on 16/11/2014. 101 comments have been received during the PC and will be forwarded to the Chair and the rapporteur of the WG to finalise the opinion.

- **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)**

Public consultation is open until 30/11/2014.

8. Any other business

- **Position Statement on Emerging risks:** A new version of the document was disseminated before the plenary with the introduction part. The SCENIHR approved it. The Secretariat will do the follow up with COM departments.

- **Structure of the opinions**: some members proposed to rethink the way opinions are structured. These should not be longer than 50 pages, with an executive summary of 3 pages maximum and/or an abstract of 1 page. The SCENIHR stressed that the Opinion on Synbio I goes already in this direction and decided to implement this new proposal starting with the mandates received in the current term (synbio, surgical meshes, tobacco additives and sunbeds).
- It was stressed to pay more attention on the way to formulate the replies to the contributions received during the public consultation. The responses should be assertive but not offensive. The Secretariat could provide a template for replies.

The meeting was closed with the Chair and Secretariat formulating the best wishes of a Merry Christmas and a happy new year to all members.

Dates of next plenary meetings
27 January 2015
29 April 2015
24 September 2015
3 December 2015

Annex 1

List of Participants

Members of the SCENIHR

Dr Epstein Michelle, Prof Dr Hartemann Philippe (Chair), 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 and Dr Theo Vermeire (by audio).

Absences:

Prof Igor Emri, Prof Dr Hoet Peter and Dr Testai Emanuela

SCENIHR Secretariat (DG SANCO)

Mrs Donata Meroni
Mrs Mihaela Haratau
Mrs Silvia Hrubanova
Mrs Petronille Bogaert

DG SANCO B3

Mr Vasile Octavian