# EUROPEAN COMMISSION HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products **Risk assessment** 

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

### **16<sup>TH</sup> PLENARY MEETING**

Held on 30 November 2011 in Brussels

### Minutes

### 1. WELCOME AND APOLOGIES

The Chairman, Prof. J. Bridges, opened the meeting and welcomed the participants. Apologies were received from Prof. K. Dawson, Prof. K. Schulze-Osthoff, Dr T. Vermeire and Dr. J. Schüz.

# 2. ADOPTION OF THE DRAFT AGENDA

The order of points under discussion in the draft agenda was slightly modified to accommodate the availability of participants in the meeting.

# 3. DECLARATION OF INTERESTS ON MATTERS ON THE AGENDA

No new declarations of interest were made.

# 4. APPROVAL OF THE MINUTES OF THE PREVIOUS PLENARY MEETING

The draft minutes of the 15<sup>th</sup> plenary meeting were adopted without modifications. The minutes are available at:

http://ec.europa.eu/health/scientific committees/emerging/docs/scenihr mi 043.pdf

### 5. CHAIR'S/MEMBERS' REPORT

# 5.1. Scientific conference on EMF

M.-O. Mattsson provided a summary of the 2011 International Scientific Conference on EMF and Health, organized by the Commission and the SCENIHR on 16-17 November, 2011. The conference gathered close to 300 participants from 34 countries representing a wide range of stakeholders: industry, regulators, civil society, researchers... Concerned citizens animated the debate in the discussion sessions, but most questions and remarks were formulated against a perceived bias of the speakers on the programme and did not address issues that were within the scope of the event, such as questions of scientific methodology. The members of the SCENIHR recognized that it is important to maintain a dialogue with all stakeholders and that some reject the scientific method. The members also welcomed the current trend towards more transparency in the provision of scientific advice and recognized that there is currently a political aim to put pressure on the scientific committees. The members welcomed the idea that controversial scientists should apply to participate in the EU scientific advisory bodies and abide by the same criteria as all other applicants. Regarding transparency, members supported the practice of public consultation. They called for a clearer expression of uncertainty in scientific opinions and recognized the need to explain better how scientific publications and received comments were taken into account. However, it is crucial for scientific committees not to deviate from science.

### 5.2. Other issues

W. De Jong provided a short update of the SCCS work on nanomaterials in cosmetics. A first opinion was adopted. Work on ZnO and  $TiO_2$  is continuing. The committee is still waiting for some data. The work on the guidance document on risk assessment of nanomaterials is also still ongoing.

J.-M. Pagès presented briefly the 6<sup>th</sup> Management Committee meeting of COST Action BM 0701 on *Antibiotic Transport and Efflux: New Strategies to combat bacterial resistance*.

# 6. Presentation on REACH restrictions for measuring devices

A representative from DG ENTR presented to the SCENIHR the restrictions laid on Hg in measuring devices under REACH and explained how the SCENIHR work on sphygmomanometers was taken into account. The SCENIHR expressed its gratitude.

### 7. OPINIONS FOR FINAL ADOPTION

# 7.1. Artificial Light

M.-O. Mattsson provided a short overview of the 10 October scientific hearing. The 11 attendees to the hearing represented patient groups, regulators and industry. In the very constructive discussion, they reiterated the main points that were submitted online at the occasion of the public consultation. The public consultation did not lead to modifications in substance of the conclusions of the opinion but the WG will rephrase and clarify a number of points to address the comments. The WG will add to the opinion a short section describing the outcome of the public consultation. Following a discussion in the plenary meeting, the SCENIHR asked the WG to adjust some assumptions made in the worst case scenario under question C and to redo the calculation on the number of squamous cell carcinomas. The opinion will be adopted via written procedure as soon as the agreed modifications are made.

# 7.2. Combination effects of chemicals

The joint (SCHER, SCCS, SCENIHR) opinion on the toxicity of mixtures was adopted. Editorial comments could be communicated to the SCHER secretariat until December  $6^{\text{th}}$ .

### 8. OPINION FOR ADOPTION IN VIEW OF PUBLIC CONSULTATION

# 8.1. Improvements of Risk Assessment (SCHER, SCCS, SCENIHR)

The preliminary joint (SCHER, SCCS, SCENIHR) opinion on improvements in risk assessment approaches was adopted. Editorial comments could be communicated to the SCHER secretariat until December 6<sup>th</sup>. There is broad agreement that the usefulness of risk assessments must be improved. Questions on how to address the socio-economic issues were raised. It is understood that the public consultation will lead to changes in substance to the opinion.

### 9. ONGOING WORK

### **9.1. OWN WORK**

# Methodology / Weight of Evidence Approach

Minor editorial improvements are still needed. The Chair agreed to take care of them.

# 9.2. JOINT OPINIONS / PARTICIPATION OF MEMBERS IN ACTIVITIES OF OTHER SCIENTIFIC BODIES

• New Challenges for Risk Assessment (SCENIHR, SCHER, SCCS)

The WG is meeting on December 2 and agreed to send the next draft opinion to the SCENIHR for comments and written contributions.

 Threshold of Toxicological Concern (TTC) Approach for Safety Assessment of Chemical Substances (SCCS, SCHER, SCENIHR)

This work is still ongoing

Other

Nothing to report.

### 10. FEEDBACK BY COMMISSION SERVICES ON FOLLOW-UP TO OPINIONS

No additional feedback.

### 11. NEW REQUESTS

### 11.1. Bisphenol A in medical devices

Representatives from the Commission services working on medical devices presented a new request for a scientific opinion on the safety of the use of Bisphenol A in medical devices. The SCENIHR accepted the request.

# 11.2. Potential health effects of exposure to EMF - update

L. Bontoux presented a new mandate on the potential health effects of EMF to update the 2009 SCENIHR opinion, as announced previously to the November scientific conference. The SCENIHR accepted the request which will be submitted to public consultation.

# 11.3. Nanosilver – Safety, health and environmental effects and role in antimicrobial resistance

A representative from the Commission services in charge of the safety of consumer products presented a new request for a scientific opinion on nanosilver: safety, health and environmental effects and role in antimicrobial resistance. The SCENIHR accepted the request. The SCENIHR will associate experts from the SCHER to this opinion.

### 12. EMERGING ISSUES

Members did not have any new topic to discuss.

### 13. ANY OTHER BUSINESS

Two new dates were chosen for plenary meetings in 2012: 24 February and 19 March.

### **Annex I:** List of Participants.

### **Annex I**

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Held on 30 November 2011 in Brussels

# **LIST OF PARTICIPANTS**

### MEMBERS OF THE SCENIHR:

Prof. A. AUVINEN, Prof. J. BRIDGES (Chair), Dr. W. DE JONG (Vice chair), Prof. P. HARTEMANN (Vice chair), Prof. A. HENSTEN, Dr. T. JUNG, Prof. M.-O. MATTSSON, Dr. H. NORPPA, Dr. J.-M. PAGÈS, Prof. A. PROYKOVA, Prof. E. RODRÍGUEZ-FARRÉ, Dr. M. THOMSEN, Dr. T. VERMEIRE

### **EUROPEAN COMMISSION:**

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

Dr. L. BONTOUX, Dr. V. GARKOV, Dr. P. MARTIN, Dr T. DASKALEROS

# **Other Commission staff:**

Ms. A. GIRAL-ROEBLING (ENTR), Mr. J. VOGELGESANG (SANCO), Mr A. PEREZ (SANCO), Ms F. DE GAETANO (SANCO),