



**18<sup>th</sup> plenary meeting of the  
Scientific Committee on Emerging and Newly Identified Health Risks  
SCENIHR**

**Meeting date: 7 June 2012**

**Minutes**

**1. WELCOME AND APOLOGIES**

The Chair welcomed the participants and announced the apologies received (please see Annex I)

**2. ADOPTION OF THE DRAFT AGENDA**

The agenda was adopted with the addition of two new mandates submitted by the Commission services (on hip implants and phthalates in medical devices)

**3. DECLARATION OF INTERESTS ON MATTERS ON THE AGENDA**

No declarations were made.

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

The minutes were approved after some editorial changes and after removal of the name of the person who submitted criticism of the dental amalgam opinion.

**5. OPINIONS FOR FINAL ADOPTION**

**5.1. Improvement of Risk Assessment**

The Committee adopted the opinion after some changes in the wording and a re-design of the final figure which reflects the whole process of dialogue between risk assessors, risk managers and socio-economic analysts.

**6. OPINION FOR ADOPTION IN VIEW OF PUBLIC CONSULTATION**

Nothing for this meeting

## **7. ONGOING WORK**

### **7.1. OWN WORK (THE RESPECTIVE CHAIRS TO PROVIDE AN UPDATE)**

#### **▪ EMF**

The Chair of the working group (WG) updated the Committee on the progress of the opinion. New experts have been recruited. Additional expertise may be needed in the areas of neurobehavioral effects and terahertz technology.

#### **▪ PIP2**

The Chair of the WG updated the Committee on the progress of the opinion (the same WG is answering some new questions; a retrospective assessment is to be launched based on a questionnaire to be sent out to Member States and some non-EU countries.) SCENIHR members are encouraged to offer their input on the questionnaire.

#### **▪ BPA in medical devices**

The Chair of the WG updated the Committee on the progress of the opinion. The identification of the alternatives to BPA (as indicated in the terms of reference) would necessitate also evaluation of their safety which will require more time. Since the focus of this opinion is BPA, the text may refer to risk assessments of alternatives done by other jurisdictions (e.g. Japan, Canada). Members of SCENIHR are asked to let the WG know about such assessments.

#### **▪ Nanosilver**

The Chair of the working group updated the Committee on the progress of the opinion. One prospective member of the WG will be contacted by the WG Chair to clarify his participation in view of possible conflict of interest.

#### **▪ Nanomaterials in Medical Devices**

The Chair of the working group updated the Committee on the progress.

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

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

The chair of the WG provided an update and asked for contributions by SCENIHR as a whole and concretely by some Committee members on specific sections of the opinion by the end of June. The expectation is for the opinion to be adopted for public consultation by the end of September. If the human-health part of the opinion is not ready by then, the public consultation on the ecotox part will be launched separately.

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

The opinion was already adopted via written procedure.

WG on Nanomaterials in Cosmetics SCCS

The work is on-going.

**8. FEEDBACK BY COMMISSION SERVICES ON FOLLOW-UP TO OPINIONS**

Discussion on a possible response to the letter sent to Commissioner Dali by NGOs on the Weight-of-Evidence Memorandum.

The Committee decided for the Chair to draft a response which will be circulated for comments.

**9. NEW REQUESTS**

- Phthalates in medical devices.
- Metal-on-metal hip implants.

The Committee accepted both mandates and determined the SCENIHR participants in the respective working groups. The first meeting of the WG on hip implants will be held on July 9<sup>th</sup> while the one of the WG on phthalates on July 10<sup>th</sup>. During these first meetings, the mandates will be reviewed by the respective WGs in view of feasibility of the work and the concrete wording of the submitted draft terms of reference.

**10. EMERGING ISSUES**

None were reported.

**11. ANY OTHER BUSINESS**

- Sponsored journals and how to evaluate papers published there.

This issue could be included as a consideration in the weight-of-evidence approach to evaluation of the literature. The access to journal articles is an issue for the work of the Committee.

## **Annex I**

<p><b>SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR)</b></p>
--

<p><b>18<sup>TH</sup> PLENARY MEETING</b></p>
---

*Held on 7 June 2012  
in Brussels*

### **LIST OF PARTICIPANTS**

#### **MEMBERS OF THE SCENIHR:**

Prof. Anssi AUVINEN - apologies  
Prof. Jim BRIDGES (Chair)  
Prof. Kenneth DAWSON  
Dr. Wim DE JONG (Vice chair)  
Prof. Philippe HARTEMANN (Vice chair)  
Prof. Arne HENSTEN  
Prof. Peter HOET  
Dr. Thomas JUNG  
Prof. Mats.-Olof. MATTSSON  
Dr. Hannu. NORPPA - apologies  
Dr. Jean.-Marie. PAGÈS – apologies  
Prof. Klaus SCHULZE-OSTHOFF  
Prof. Ana PROYKOVA  
Prof. Eduardo RODRÍGUEZ-FARRÉ  
Dr. Joachim SCHÜZ  
Dr. Mogens THOMSEN – apologies  
Dr. Theo VERMEIRE

#### **EUROPEAN COMMISSION:**

Dr. Laurent BONTOUX  
Dr. Vladimir GARKOV  
Dr. Philippe MARTIN