



EUROPEAN COMMISSION  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products  
**Risk assessment**

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

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

*Held on 19 September 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. P. Hoet, Prof. M.-O. Mattsson, Dr. H. Norppa, and Dr. J. Schüz.

#### **2. ADOPTION OF THE DRAFT AGENDA**

The draft agenda was slightly modified, including a few changes in the order of points under discussion. Additional items were discussed under item 11 of the agenda.

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

Prof. Ken Dawson declared that he had been invited by FoodDrinkEurope, a representation of the European food and drink industry (see <http://www.fooddrinkeurope.eu/>) to give an overview on the knowledge gaps related to the safety evaluation of nanomaterials at the 4th Nanotechnology Stakeholder Dialogue Day on 5 October in Brussels (see <http://fooddrinkeurope.newsweaver.co.uk/flyer/14zeuyzjeew>, programme: [http://www.fooddrinkeurope.eu/uploads/events\\_documents/Nanotechnology\\_Day - Draft Programme 27.9.2011bk.doc.pdf](http://www.fooddrinkeurope.eu/uploads/events_documents/Nanotechnology_Day_-_Draft_Programme_27.9.2011bk.doc.pdf)). His expenses for travel and accommodation would be paid by the organizers.

Taking into account the nature of the declaration, the Committee decided that they did not constitute a conflict of interest and that Prof. Dawson could participate in the discussions on those matters.

The Chair of the joint working group (WG) on New Challenges to Risk Assessment informed the Committee that three of the external experts invited to the WG on an ad-hoc basis and for an exchange on particular questions had declared an interest in view of their affiliations.

Taking into account the declarations provided, the Committee decided that two of the experts could be asked to continue supporting the WG on an ad-hoc basis as considered necessary, e.g. by providing information on specific issues and comments on the draft opinion. For the other expert, a further involvement beyond the presentation of information was not foreseen, due to his activities for industry in a related subject area.

As always, all declarations of interests of external experts and contributors will be accessible to SCENIHR-members via the CIRCA-site of the respective WG.

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

The draft minutes of the 14<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\\_042.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_mi_042.pdf)

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

Prof. Ph. Hartemann reported about his involvement in investigating the recent outbreak of enterohemorrhagic *E. coli* (EHEC) and the challenges that such events pose to the Member States and the European Union.

#### **6. ONGOING WORK**

##### **6.1. Methodology / Weight of Evidence Approach (for discussion)**

Members discussed and finalized the draft memorandum to clarify how expert judgement is used in their risk assessments. The memorandum covers the identification and selection of relevant publications for analysis, weighing the data, and its application for risk assessment purposes.

Furthermore, the SCENIHR drafted a proposal to develop a common procedure of SCENIHR, SCHER and the SCCS for the weighing of scientific evidence that will form the basis for a joint mandate of the three non-food scientific committees. This should help to improve consistency of the risk assessment approaches used over time and across committees and could influence thinking at international level.

SCENIHR adopted the document. Following an editorial revision, the document will be accessible via the following webpage:

[http://ec.europa.eu/health/scientific\\_committees/emerging/statements/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/emerging/statements/index_en.htm)

##### **6.2. Artificial Light (for information)**

The Secretariat provided a short overview about the upcoming hearing on 10 October and future meetings of the WG. The opinion had been approved for public consultation by written procedure on 18 July 2011. The public consultation would be open until 30 September.

Link to public consultation:

[http://ec.europa.eu/health/scientific\\_committees/consultations/public\\_consultations/scenihr\\_consultation\\_14\\_en.htm](http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_consultation_14_en.htm)

Link to registration for hearing:

[http://ec.europa.eu/health/scientific\\_committees/events/ev\\_20111010\\_en.htm](http://ec.europa.eu/health/scientific_committees/events/ev_20111010_en.htm)

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

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

The Chairperson of the cross-committee WG informed members about the ongoing work and about a recent WG-meeting. SCENIHR-members were reminded to contribute to the ongoing work in line with the assignments agreed at the earlier plenary meetings.

##### **7.2. Improvements in Risk Assessment Approaches (SCHER, SCCS, SCENIHR)**

Members participating in the cross-committee WG informed the Committee about the ongoing work, recent updates on the draft document and an upcoming WG-meeting. A public consultation and a workshop in relation to this topic are foreseen.

### **7.3. Toxicity and Assessment of Mixtures of Chemicals (SCHER, SCCS, SCENIHR) (for approval for public consultation)**

The Secretariat informed the Committees about the results of the public consultation, held from 4 July to 9 September. A total of 40 submissions were received from 29 organizations and 11 individuals, with a majority of participants in the public consultation (33 out of 40) agreeing with the conclusions of the opinion. Two of the contributors were uncertain and five disagreed. The contributions would be assessed at an upcoming WG-meeting.

A member participating in the cross-committee WG informed about his participation in a recent workshop on "Combined Exposure to Chemicals", organized by the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOX) in Berlin (see <http://www.ecetoc.org/index.php?mact=XtendedCalendar,cntnt01,details,0&cntnt01documentid=37&cntnt01returnid=108>). The outcome of that meeting would be considered when finalizing the joint opinion.

An upcoming relevant workshop on the subject would soon be held in the US (see <http://tools.niehs.nih.gov/conferences/dert/mixtures/>).

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

The Secretariat and a member of the joint WG informed members about a future WG-meeting where the opinion would be considered in light of the ongoing work at EFSA.

#### **7.5. Other**

##### **Exposure assessment (SCHER)**

The Secretariat and a member participating in the WG organized by the SCHER informed the Committee about the status of the work.

##### **Expression of uncertainties (SCHER)**

The Secretariat and a member participating in the WG organized by the SCHER informed the Committee about the status of the work.

##### **Nanomaterials in Cosmetics (SCCS)**

Members participating in the WG organized by the SCCS informed the Committee about the ongoing work and the draft opinion on the UV-filter ETH50 that would be proposed for adoption at the upcoming plenary meeting of the SCCS (20 September 2011).

##### **TTC (EFSA)**

A member participating in the WG organized by EFSA informed members about the ongoing work, an upcoming WG-meeting and the public consultation that would be open until 23 September.

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

### **Mercury Sphygmomanometers in Healthcare and the Feasibility of Alternatives**

Dr. Wim de Jong and the Secretariat reported about the Annex XV Restriction Report from the European Chemicals Agency (ECHA), proposing a restriction of mercury in several measuring devices and related opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) (see [http://echa.europa.eu/reach/restriction/restrictions\\_under\\_consideration\\_en.asp](http://echa.europa.eu/reach/restriction/restrictions_under_consideration_en.asp)).

The report and the opinions took account of the recommendations made in the SCENIHR-opinion and in particular to allow the use of mercury sphygmomanometers as reference standards in clinical validation studies of mercury-free blood-pressure measurement devices.

## **9. NEW REQUESTS**

### **Health effects of security scanners for passenger screening (based on X-ray technology)**

A representative from DG MOVE and the Secretariat presented information on the background to the request.

The possibility of introducing security scanners on the list of eligible screening methods and technologies for screening persons was first proposed to the Council and the European Parliament in 2008. Following opposition from the EP, the Commission agreed to review the matter further and withdrew security scanners from its original legislative proposal.

While security scanners are currently not on the list of allowed methods for passenger screening in the EU, they may be deployed under certain conditions. Some EU countries have already introduced them under these rules. In the current context of terrorist fears, such scanners are being deployed at airports worldwide.

Following the Commission Communication COM(2010)311 on the use of security scanners at EU airports, an in-depth impact assessment was carried out by the Commission. It concluded that security scanners are an effective method for the screening of passengers and should be authorised for use at EU airports under certain operational conditions and detection performance standards

Consequently, the Commission has proposed to add security scanners to the list of the method for passenger screening. This proposal was voted favourably in the Aviation Security Regulatory Committee of July 2011 and is now under the scrutiny of the EP and the Council. In order to safeguard citizens' health and safety, the Commission has at this stage proposed to only allow security scanners which do not use ionising radiation.

While X-ray based security scanners are currently used in the UK and the USA, several Member States (e.g. Italy, France, Germany and Austria) prohibit the use of ionizing radiation for non-medical purposes.

In light of the foreseen revision of Commission Regulation (EC) No 272/2009 regarding the methods for passenger screening allowed in the EU and Commission Regulation (EC) No 185/2010 laying down detailed measures for the implementation of the common basic standards on aviation security, the Commission would like to receive information on the safety of the technologies available on the market and in particular on the X-ray based security scanner technologies.

Therefore, the SCENIHR is asked to assess and quantify the potential health effects related to the use of all types of security scanners used for passenger screening which emit ionizing radiation.

The SCENIHR set up a WG and nominated a Chairperson. A list of expertise needed for this mandate was established and possible candidates identified from the expertise available in the Scientific Committees, Pool of Scientific Advisors, the database of experts and systematic online searches.

Link to Mandate:

[http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenihr\\_q\\_026.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_q_026.pdf)

There are currently no other new requests for the SCENIHR. However, several issues are under discussion at Commission services and the Secretariat will keep members informed of new developments.

## **10. EMERGING ISSUES**

Members briefly discussed some topics listed in the working paper on emerging issues and agreed on particular updates to be done following the meeting.

As a follow up to an earlier workshop, it was suggested to have a discussion on synthetic biology at the next plenary meeting.

## **11. ANY OTHER BUSINESS**

### **International Scientific Conference on electromagnetic fields and health, Brussels, 16-17 November**

The Secretariat informed members about the planning of that meeting for which registration was now open at the following link:

[http://ec.europa.eu/health/electromagnetic\\_fields/events/ev\\_20111116\\_en.htm](http://ec.europa.eu/health/electromagnetic_fields/events/ev_20111116_en.htm)

### **7<sup>th</sup> Meeting of Chairs and Secretariats of the Scientific Committees and Panels of Community bodies involved in risk assessment, Helsinki, 10-11 November 2011**

The Secretariat informed members that the meeting was cancelled.

### **Renewal of the Scientific Committees**

The Secretariat updated members about the renewal of the Scientific Committees foreseen in 2012.

### **New website for the three non-food Scientific Committees**

The Secretariat informed members about the progress on the new website for the three committees. The new website would be published shortly, once testing was completed (link: [www.ec-scientific-committees.eu](http://www.ec-scientific-committees.eu) )

### **Change in the management of SCENIHR**

Katja Bromen would change her position at the end of September 2011 and would be replaced by Laurent Bontoux.

### **Representation of SCENIHR in events**

Following an invitation to the SCENIHR by Michèle Rivasi, Member of the European Parliament, Mats-Olof Mattsson would represent the SCENIHR at a workshop at the EP on 11 October (Title of workshop: "Early warnings : The case of Mobile Phone & Head Tumors")

### **Other**

The Secretariat confirmed that the next plenary meeting would be held on **30 November**.

**Annex I:** List of Participants.

## **Annex I**

<p align="center"><b>SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR)</b></p>
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<p align="center"><b>15<sup>TH</sup> PLENARY MEETING</b></p>
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### **LIST OF PARTICIPANTS**

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

Prof. A. AUVINEN, Prof. J. BRIDGES (Chair), Prof. K. DAWSON, Dr. W. DE JONG (Vice chair), Prof. P. HARTEMANN (Vice chair), Prof. A. HENSTEN, Dr. T. JUNG, Dr. J.-M. PAGES, Prof. A. PROYKOVA, Prof. E. RODRÍGUEZ-FARRÉ, Prof. K. SCHULZE-OSTHOFF, Dr. M. THOMSEN, Dr. T. VERMEIRE

#### **EUROPEAN COMMISSION:**

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

Mr. L. BONTOUX, Ms. K. BROMEN, Mr. V. GARKOV, Ms. K. KILIAN, Mr. P. MARTIN, Mr. W. PENNING, Ms. O. ZIANE

#### **Other Commission staff:**

Ms. C. FUSCO (MOVE), Mr. J. VOGELGESANG (SANCO)