EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
**Risk assessment**

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

## 4TH PLENARY MEETING

*Held on 23 September 2009*
*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.

### 2. ADOPTION OF THE DRAFT AGENDA

The draft agenda was adopted as written, with a few changes in the order of points under discussion.

### 3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

The Chair of the SCENIHR Working Group (WG) on Tobacco Additives informed the Committee that several of the invited external experts had declared an interest in view of their affiliations.

For the sake of transparency, the SCENIHR recommended that one expert should provide more detail on one activity in the written declaration.

However, taking into account the nature of all the declarations, the Committee decided that they did not constitute a conflict of interest and that the external experts could participate in the discussions on those matters.

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

The draft minutes of the 3rd plenary meeting were adopted with one minor modification. The minutes are available at:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_mi_031.pdf

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

The Chairman and Secretariat provided feedback on the Scientific Hearing on Nanotechnologies (Brussels, 10 September 2009). The meeting was considered a useful exchange of views, even though little new scientific insights, beyond the comments made during the related public consultation, were gained.

The work on terminology as part of the follow-up to the 1st International Conference on Risk Assessment is ongoing and a meeting of the WG was foreseen in October. The SCENIHR would contribute to the discussions.

Prof. M.-O. Mattsson informed members about a meeting in Austria and one organized by the German Radiation Protection Board, where he presented the work on EMF carried out by the SCENIHR and, in particular, the methodologies used.

## 6. ONGOING REQUESTS

### 6.1. Mercury Sphygmomanometers (for adoption)

The Chairperson of the WG presented the draft opinion to the plenary followed by a discussion. The draft was slightly modified to enhance clarity. The opinion was adopted. Following final editing, the opinion would be published at the following webpage:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_025.pdf

Representatives from DG Enterprise and Industry (ENTR) expressed their appreciation for the work carried out by the SCENIHR.

### 6.2. Tobacco Additives (for discussion)

The Chairperson of the WG informed the Committee about the ongoing work. Upon suggestion of the WG, the Terms of Reference had been slightly modified to enhance clarity of the mandate and to focus the request on the key areas of interest. The WG had further revised the structure of the opinion and had prepared a first draft. The need for a call for information would be further discussed at the next meeting. An additional expert would join the WG.

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

### 7.1. Antimicrobial resistance - zoonotic infections

The Chairperson of the SCENIHR WG on this issue informed the Committee about the ongoing work, the discussions in the overarching WG (OWG) and in the SCENIHR WG. The chairperson presented the latest draft version of the report to members, followed by a discussion. It would be further discussed in upcoming meetings of the SCENIHR WG and the OWG. The report would be adopted by written procedure in October.

### 7.2. Guidance document on antimicrobials used in food decontamination (EFSA)

A member representing the SCENIHR in the WG of the European Food Safety Authority (EFSA), which is preparing the guidance document on behalf of the EFSA-BIOHAZ panel informed the Committee about the ongoing work. The draft document was briefly discussed. Members suggested several scientific issues that would be communicated to EFSA and to the BIOHAZ panel in preparation for the next WG-meeting and the next plenary meeting of the BIOHAZ panel. It was foreseen that the document would enter public consultation at the end of October.

### 7.3. Other

**Nanomaterials in Cosmetics**

A member participating in the WG organized by the Scientific Committee on Consumer Safety (SCCS) informed the Committee about the ongoing work and the dossiers to be evaluated. Several additional meetings had been scheduled.

**Triclosan**

A member participating in the WG organized by the Scientific Committee on Consumer Safety (SCCS) informed the Committee about the ongoing work.

**Threshold of Toxicological Concern (TTC) Approach for Safety Assessment of Chemical Substances**

The Secretariat confirmed that the hearing on TTC would take place on 24 September 2009, followed by a WG-meeting on the next day. Aside from Commission services it would involve the WG on TTC and the stakeholders who contributed to the public consultation as well as other interested members of the three non-food Scientific Committees.

**Depleted uranium**

A member informed about an upcoming WG-meeting of the Scientific Committee on Environment and Health (SCHER).

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

A representative from DG Enterprise and Industry (ENTR) provided a short update on further follow up to the earlier opinions on di(2-ethylhexyl)phthalate (DEHP) and dental amalgam. On **DEHP**[1], the opinion has helped the Commission to communicate risks in the discussion with external parties. Furthermore, specific labelling requirements for certain medical devices containing phthalates will become mandatory as of 21/03/2010. CEN is developing a symbol to that end. In parallel, precautionary measures in relation to the use of such devices in high risk patients group will have to be developed by the manufacturers by the same timeline.

On **dental amalgam**[2], the opinion has facilitated the communication with stakeholders by providing responses to stakeholders' safety concerns. DG ENTR also noted that the SCENIHR opinion is in line with a recent assessment of the US Food and Drug Administration (FDA).

A representative from DG Enterprise provided additional feedback on the earlier opinion on **biocides**[3]. In addition to the new mandate (see Point 9), the opinion had an impact on the proposal for revision of the Biocides Directive and on labelling provisions that are currently discussed. Furthermore, various activities and initiatives of the Commission will address the sustainable and prudent use of biocides.

The Secretariat provided information on an upcoming meeting with colleagues in DG Research to discuss the next work programmes and funding possibilities for research projects in relation to **electromagnetic fields** (EMF) as suggested in the recent SCENIHR opinion[4].

[1] http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_014.pdf

[2] http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_016.pdf

[3] http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_021.pdf

[4] http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_024.pdf

## 9. NEW REQUESTS

### The safety of reprocessed single-use medical devices

Representatives from DG Enterprise and Industry (ENTR) provided information on the background of the request. The development and use of single-use[5] medical devices has been supported by the emergence of blood transmitted diseases and nosocomial infections on one hand and technological developments on the other hand. Triggered by increasing pressure to reduce costs, some single-use medical devices are being reprocessed. The reprocessing practice of single-use medical devices is not regulated at the Community level for the time being and is handled quite differently by the Member States. To address the concerns raised regarding patient safety and to clarify the notion of single-use, Directive 2007/47/EC provided further clarification on the definition of the term 'single use', and introduced new requirements for single-use medical devices. In addition to these requirements and to ensure that the reprocessing does not endanger patients' safety or health, the SCENIHR is asked to assess the potential risk of reprocessed single-use medical devices for patients' health.

Members discussed the mandate and provided feedback to Commission services. The SCENIHR set up a Working Group and appointed a Chairperson and a Rapporteur. Members also identified additional expertise that would be needed for the task. This and the need for a call for information would be further discussed at the first WG-meeting. Given the deadline of the request, it was agreed that no Public Consultation would be carried out.

The final version of the mandate is available at the following webpage:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_021.pdf

### Research strategy to address the knowledge gaps on the antimicrobial resistance effects of biocides

A representative from DG Environment (ENV) provided information on the background of the request. Recent scientific evidence suggests that during the last decade, antibiotic resistance has increased worldwide leading to treatment failures in humans and animals. In its earlier opinion delivered in January 2009[6], the SCENIHR confirmed that at least some resistance mechanisms are common to both biocides and antibiotics. Scientific evidence does indicate that the use of active molecules in biocidal products may contribute to the increased occurrence of antibiotic resistant bacteria. The SCENIHR had also identified a number of data and knowledge gaps to be filled, in particular regarding quantitative exposure data, methods to evaluate the ability of a biocide to induce/select for resistance against biocides and antibiotics, and environmental studies focussing on the identification and characterisation of resistance and cross-resistance to antibiotics following use and misuse of biocides. Antimicrobial resistance remains a sensitive political subject and more research is needed to address the issues identified. To allow the Commission to propose the most relevant research topics on this issue for future funding, the SCENIHR

[5] Directive 2007/47/EC (adopted on 5 September 2007, amending Directive 93/42/EEC) defines a 'single-use' medical device as 'a device intended to be used once only for a single patient'

[6] http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_021.pdf

is requested to further develop the research recommendations presented in its earlier opinion and to propose a research strategy.

Members discussed the mandate and provided feedback to Commission services. The SCENIHR set up a Working Group and appointed a Chairperson. Members identified additional expertise that would be needed for the task. This would be further discussed at the first WG-meeting. Given the deadline of the request, it was agreed that no Public Consultation would be carried out.

The final version of the mandate is available at the following webpage:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_022.pdf

## 10. EMERGING ISSUES

The Chairman had revised the working paper on emerging issues and has started to prioritize the topics based on input from members. The topic would be further discussed at the next meeting. Members were invited to include additional proposals and to provide feedback to the Secretariat and the Chairman who would further revise the document.

The Secretariat and Chairman informed about an upcoming meeting with other EU-bodies involved in risk assessment to collaborate on emerging issues.

## 11. ANY OTHER BUSINESS

A draft paper on Methodology / Weight of Evidence had been prepared but would be further revised for discussion at the next meeting. In this context, the Secretariat informed about a meeting organized by the World Health Organization and International Commission for Non-Ionizing Radiation Protection (Salzburg, 23-24 November) on Terminology for Risk Assessment and Weight of evidence.

The following dates were scheduled for SCENIHR Plenary meetings in 2010: **8 January, 15 March, 10 May, 28 June, 20 September, 24 November**.

**Annex I:** List of Participants.

**Annex I**

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

**4TH PLENARY MEETING**

*Held on 23 September 2009*
*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. P. HOET, Dr. T. JUNG, Prof. M.-O. MATTSSON, Dr. H. NORPPA, Dr. J.-M. PAGÈS, Prof. A. PROYKOVA, Prof. E. RODRÍGUEZ-FARRÉ, Prof. K. SCHULZE-OSTHOFF, Dr. J. SCHÜZ, Prof. D. STAHL, Dr. M. THOMSEN, Dr. T. VERMEIRE

**EUROPEAN COMMISSION:**

### SCENIHR Secretariat (DG SANCO):

Mr. L. BONTOUX, Ms. K. BROMEN, Ms. N. FOUVEZ, Mr. V. GARKOV, Ms. A. KANELLOPOULOU, Mr. P. MARTIN

### Other Commission staff:

Ms. C. BOURGUIGNON (DG ENTR), Mr. S. KIOKIAS (DG ENTR), Ms. S. LECRENIER (DG ENTR), Ms. G. LUVARA' (DG ENTR), Ms. T. PEETSO (DG SANCO), Mr. A. PEREZ (DG ENTR), Mr. S. PICKERING (DG ENTR), Ms. B. VAN TONGELEN (DG ENV)