EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C7 - Risk assessment

SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS
19TH PLENARY MEETING

Held on 21-22 June 2007
in Brussels

1. WELCOME AND APOLOGIES

The Chairman, Prof. J. Bridges, opened the meeting and welcomed the participants. Apologies were received from Prof. J. Hajslová and Prof. M.-O. Mattsson.

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 Dental Amalgam informed the Committee that one of the external experts had declared a new interest in view of his affiliation.

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

4. APPROVAL OF THE MINUTES OF THE PREVIOUS PLENARY MEETING

The draft minutes of the 18th plenary meeting were adopted with minor modifications. The minutes are available at:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_mi_018.pdf

5. CHAIR'S/MEMBERS' REPORT

5.1. Inter Committee Coordination Group (ICCG) on 20 June 2007

The Chairman informed members about the prolongation of the terms of office of members until 2008, about the revision of mandates and restructuring of the Scientific Committees after 2008. The chairman furthermore reported about the progress on a position paper covering socioeconomic aspects which was prepared

by SCHER and which could be used in light of future discussions on the role of the SCs after 2008.

Members discussed follow-up activities from the 2nd Meeting of Chairs of EU Risk Assessment bodies and the upcoming 3rd Meeting to be held in Stockholm (6-7 November 2007). The Secretariat informed that emerging issues have been proposed for discussion. A meeting of the discussion group on emerging issues was foreseen in September. A SCENIHR-member was selected for participation in the debate.

The Chairman furthermore informed about a meeting on EMF with Member States representatives and follow-up activities to the Risk Assessment Days. For the latter, meetings with the European Parliament are foreseen in the second half of 2007.

The Chairman and Secretariat reported on discussions of dealing with confidential data within Commission services and within the ICCG based on the draft paper proposed by SCENIHR, which was welcomed. In the ICCG-meeting it was agreed to have a horizontal approach across the SCs. The issue was further discussed under point 9 (Any other business).

5.2. Other

The Secretariat informed about a Meeting of the WHO International Advisory Committee on EMF where, among other issues, research priorities and ongoing research were discussed.

The chairman and the Secretariat informed members about the initiative of the Commission to prepare a document in lay-language on the first SCENIHR opinion on Nanotechnologies ("The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies").

6. ONGOING REQUESTS

6.1. Smokeless Tobacco Products (for approval for public consultation)

Members discussed the draft opinion which the working group had proposed to SCENIHR for approval for public consultation. The preliminary report was revised and approved subject to final editing. The public consultation would start once the editing was concluded. Further information would be available at the following link:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/scenihr_cons_06_en.htm

6.2. DEHP (for approval for public consultation)

Members discussed the updated draft opinion on di(2-ethylhexyl)phthalate (DEHP) proposed for approval for public consultation. The SCENIHR revised and approved the preliminary report for public consultation subject to final editing. Before the consultation, approval from companies to publish a summary on alternative compounds based, inter alia, on their confidential data in the annex of the opinion would be sought by the Secretariat. This summary had been prepared by the SCENIHR. Further information on the consultation would be available at the following link:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/scenihr_cons_05_en.htm

6.3. Nanotechnologies – TGDs (for adoption)

Members discussed the opinion on "The appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials" which had been revised by the WG following the public consultation. During the consultation 34 contributions were received, 27 from organisations, of which 7 came from manufacturers of nanomaterials. The majority of respondents mostly agreed with the opinion. Further modifications of the SCENIHR opinion were made in particular for the clarification of the text on mutagenity/genotoxicity and *in vitro* testing. Following final editing the opinion would be available at the following website:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_010.pdf

6.4. Nanotechnologies – Definitions (for adoption)

The Chair of the WG informed the Committee about the ongoing work and members discussed the draft opinion. It was decided that the draft was not yet ready for adoption. An additional WG-meeting was scheduled and it was foreseen to discuss the report in the next plenary meeting.

6.5. Dental Amalgam (for discussion)

The Chair of the WG informed the Committee about the ongoing work. During the call for information (deadline: 4 June 2007) 25 contributions and 139 documents had been received which would be assessed by the WG.

6.6. Biocides (for discussion)

The mandate was still under discussion in Commission services. Therefore, further discussion on this issue was postponed again to the next meeting. However, a first potential date for a WG-meeting was scheduled.

6.7. Noise (for discussion)

The chair informed members about the arrangements and selection of external experts in view of the upcoming first WG-meeting.

7. NEW REQUESTS

The Secretariat informed about potential new mandates in relation to Biocides and Nanotechnologies. However, the requests were still under discussion at Commission services.

8. EMERGING ISSUES

Members discussed briefly the latest version of the document and suggested that an updated version should be brought into the discussion at the 3rd Meeting of Chairs of EU Risk Assessment bodies. The chairman and members would revise and update the list which would be circulated by the Secretariat.

9. ANY OTHER BUSINESS

1) Presentation by DG SANCO on future challenges: A representative from DG SANCO gave a presentation on SANCO future challenges. Members provided feedback.

2) International Commission on Non-Ionizing Radiation Protection (ICNIRP) - Proposal for revision of Guidelines on Static Fields: The chairman and a member will assess the document and possibly provide input.

3) Confidential data: The SCENIHR discussed and revised their draft working paper on this topic, taking into account the discussion at Commission services. It was suggested that in future calls for information interested parties would be informed that confidential data will only be considered in the following situation:

- Confidential data submitted is clearly specified as such.
- The data is accompanied by appropriate documentation to justify the confidentiality requirement.
- A statement is provided confirming/permitting that
    - the data may be considered in the risk assessment carried out by the Scientific Committee and
    - at least a summary including the data provided may be presented in the opinion. This summary will be written by the Scientific Committee.

If any of these conditions is not met, the data will not be considered.

Interested parties would also be informed that the Commission services will retain the confidential files, where these have been used to generate an opinion. Otherwise the files will be returned/destroyed.

The SCENIHR proposed to use this approach in all SCs and to take the general document as a SCENIHR working paper.

4) The Secretariat informed the Committee about the **Workshop on Nanotechnology**, (25/26 October, Brussels) with the title "Nanotechnologies for Food, Consumer Products and Medical Applications: Safety for Success"

Annex I

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LIST OF PARTICIPANTS

MEMBERS OF THE SCENIHR:

Prof. A. AHLBOM (Day 1), Prof. J. BRIDGES (Chair), Dr. W. DE JONG (Vice chair), Prof. P. HARTEMANN (Vice chair), Dr. T. JUNG, Dr. J.-M. PAGÈS, Prof. K. RYDZYNSKI, Prof. D. STAHL (Day 1), Dr. M. THOMSEN, Prof. D. WILLIAMS

EUROPEAN COMMISSION:

SCENIHR Secretariat (DG SANCO):

Ms. K. BROMEN, Ms. N. FOUVEZ, Ms. M. PUOLAMAA

Other Commission staff:

Ms. C. BILLAUX (DG SANCO), Ms. I. DEMADE (DG ENTR), Ms. T. PEETSO (DG SANCO), Ms. B. VAN TONGELEN (DG ENV)