



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

6TH PLENARY MEETING

*Held on 8 January 2010
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, Dr. J.-M. Pagès, and Prof. D. Stahl.

2. ADOPTION OF THE DRAFT AGENDA

The draft agenda was adopted as written, with a few changes in the order of points under discussion. Additional items were discussed under item 11 of the agenda.

3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

The Chair of the SCENIHR WG on Reprocessing of Single-Use Medical Devices informed the Committee that several of the external experts identified for this Working Group (WG) had declared an interest in view of their affiliations. Taking into account these declarations, the Committee decided that due to their activities involving potential financial benefits related to the topic they could not become full members of the WG. However, due to their specific knowledge on the subject matter they should be invited to one WG-meeting on an ad-hoc basis to provide information on specific issues and to provide comments on the draft opinion.

In the same WG, one expert had explained in more detail one activity in the last WG meeting. Taking into account the nature of this declaration, the Committee decided that it did not constitute a conflict of interest and that the external expert could participate in the discussions on this matter.

Triggered by the discussions on independence in relation to this WG, members discussed a proposal aimed at defining independence, categorization of interests and experts' involvement in WGs under item 11 of the agenda.

4. APPROVAL OF THE MINUTES OF THE PREVIOUS PLENARY MEETING

The draft minutes of the 5th plenary meeting were adopted with one minor modification. The minutes are available at:

http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_mi_033.pdf

5. CHAIR'S/MEMBERS' REPORT

None.

6. ONGOING WORK

6.1. Tobacco Additives (for discussion)

The Chairperson of the WG informed the Committee about the ongoing work. A call for information had been launched on 30 November 2009 (deadline 11 January 2010) and the result and input would be discussed at the next WG-meeting. Depending on the progress of the work it was agreed to discuss a draft of the opinion at the next plenary meeting.

6.2. Reprocessing of Single-use Medical Devices (for discussion)

The Chairperson of the WG informed the Committee about the ongoing work. The call for information had resulted in approximately 80 documents, received from 22 contributors that are being examined by members of the WG. Additional expertise to complement the task of the WG had been identified. However, based on the declarations of interests received, additional experts would be invited to contribute to the work of the WG without becoming full members (see item 3 and 11 on the agenda). Details on scope and form of their contribution would be discussed at the next WG-meeting.

6.3. Antimicrobial Resistance effects of Biocides – Research Strategy (for discussion)

The Secretariat informed the Committee about the ongoing work. An additional member of SCENIHR would join the WG starting from the next meeting. Additional expertise in relation to environmental microbiology was still needed to complement the work.

6.4. Methodology / Weight of Evidence Approach (for discussion)

The Chairperson of the WG informed the Committee about the ongoing work and the discussions at the WG-meeting where tasks had been assigned to individual experts. The members of SCENIHR discussed the level of detail to be presented in the paper. It was agreed that WG-members would send their contribution to the Chairperson who would establish a joint version before seeking input from other SCENIHR-members.

6.5. Artificial Light (for discussion)

The Chairperson of the WG and the Secretariat informed the Committee about the ongoing work and the discussions at the first WG-meeting. The public consultation on the working mandate closed on 4 January 2010. The Secretariat has received 16 contributions, which would be assessed by Commission services in order to finalise the mandate. Additional experts had been identified to support the WG and would be invited to the next meeting.

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

7.1. 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. It was foreseen that the public consultation on the document would start in Mid-January once all comments from the WG and the BIOHAZ panel were adequately reflected in the document. SCENIHR emphasized the need for rules and procedures on collaboration between different EU-bodies involved in risk assessment.

7.2. Improvements in risk assessment approaches (SCHER, SCCS, SCENIHR)

A member participating in the cross-committee WG informed the Committee about the ongoing work and the first WG-meeting in which practical arrangements were made. In particular, members discussed how to address this broad mandate that has a rather long time-frame (Deadline: June 2011).

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

http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_q_090.pdf

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. Additional data in relation to the dossiers delivered by industry had been requested from the providers and an exchange of views had taken place with a representative from industry.

Triclosan

The Secretariat informed the Committee about the ongoing work carried out by the SCCS. It is expected that the opinion would soon be completed.

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

A member and the Secretariat informed the Committee that the opinion, revised after the public consultation and the subsequent hearing, is being finalized based on input from the non-food Scientific Committees. Upon completion it would be circulated to the Committees for adoption.

Depleted uranium

A member participating in the WG organized by the Scientific Committee on Health and Environmental Risks (SCHER) informed the Committee about the ongoing work. The draft opinion would be discussed in the upcoming plenary meeting of the SCHER.

Mercury in light bulbs

A member participating in the WG organized by the SCHER informed the Committee about the ongoing work and the first meeting of the WG in which the Terms of Reference were discussed and practical arrangements made.

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

None

9. NEW REQUESTS

None

10. EMERGING ISSUES

Members discussed the list on emerging issues and the related summary file. Members were asked to please add relevant issues to the collection of topics, to further develop proposals made if needed, to identify six topics as priorities among the subjects listed, and to comment on the style of the presentation. The Chairman and Secretariat would combine the input received and the two files into one working document.

11. ANY OTHER BUSINESS

Definition of independence, categorization of interests, and experts' involvement in WGs

Members discussed a draft document describing different potential mechanisms for involving external experts in WGs and the meaning of independent advice. This would be further revised before discussion at the next meeting of the Inter-Committee Coordination Group (ICCG).

The future of risk assessment – meeting new challenges

Members briefly discussed a proposal on new challenges for risk assessment that may eventually become a new mandate for the non-food Scientific Committees. Members were invited to provide feedback before the next meeting.

Terminology Project - Working Group on Evidence, Uncertainty, and Expression of Risk

The Secretariat informed about ongoing discussions and activities in relation to this international collaborative project. Following the identification of specific case-studies and appropriate terms of reference, a workshop on expression of uncertainty and risk would take place in early June in Ottawa, Canada. SCENIHR members interested in this topic are welcome to contribute to the discussions.

Mandate on Definitions of Nanotechnologies

In light of discussions at EU-level, a new request on nanotechnologies was currently discussed and prepared. This should be an update of the earlier SCENIHR opinion on definitions taking account of recent developments (e.g. development of definitions in certain areas of application) and discussions. It should include consideration of a) qualitative and quantitative criteria; b) rationale for a threshold based on size (present discussion focussing on 100 nm) or other dimensions (e.g. volume specific surface area). The request would be distributed to the SCENIHR upon finalization.

Synthetic Biology Workshop, Brussels, 18-19 March

The Secretariat provided an outline and update on the preparation of a restricted workshop on synthetic biology, in which the SCENIHR would also be represented. While it would focus on scientific developments, research, and applications in synthetic biology, it would also address questions related to ethics, safety, and governance. Members were invited to provide feedback to the Secretariat.

Annex I: List of Participants.

Annex I

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

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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, Prof. A. PROYKOVA, Prof. E. RODRÍGUEZ-FARRÉ, Prof. K. SCHULZE-OSTHOFF, Dr. J. SCHÜZ, 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. J. HOUINS-ROULET (SANCO), Ms. S. OSAER (DG SANCO), Ms. T. PEETSO (DG SANCO), Mr. A. TOTH (DG TREN)