



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Risk assessment

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

5TH PLENARY MEETING

*Held on 25 November 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. A. Auvinen, Prof. K. Dawson, 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

Dr. T. Jung declared that he and his institution would become involved in a 1-year research project funded by the Swiss Nanoscience Institute (a public subsidiary of the University of Basel, see <http://www.nanoscience.ch/nccr/>) on organic dyes in solar cell prototypes. The grant would be paid to the institution and the organic dyes should be provided by a Swiss research facility of the Dutch company DSM (see <http://www.dsm.com/>). The collaboration may eventually result in joint papers. The nature of the activity is not related to any current activity of the SCENIHR.

The Chair of the SCENIHR Working Group (WG) on Antimicrobial Resistance effects of Biocides – Research Strategy informed the Committee that several of the invited external experts had declared an interest in view of their affiliations.

The Chair of the SCENIHR WG on Reprocessing of Single-Use Medical Devices 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. For another expert, clarification on the nature and extent of a particular activity would be sought by the Secretariat before taking a final decision.

With the exception of this case and taking into account the nature of the other declarations, the Committee decided that they did not constitute a conflict of interest and that Dr. Jung and 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 4th plenary meeting were adopted with one minor modification. The minutes are available at:

http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/docs/scenihhr_mi_032.pdf

5. CHAIR'S/MEMBERS' REPORT

5.1. Inter-Committee Coordination Group (ICCG), 12 October 2009

The Chairman and Secretariat provided feedback on the revision of the rules of procedure, plans and efforts to assess the functioning of the Scientific Committees, the implementation of the revised rules on indemnities for participation in meetings and for the rapporteur, and the plan to organize more meetings via teleconference or in form of virtual meetings. Furthermore, the work programme of the Scientific Committees for 2010 was discussed and members were invited to identify relevant topics. Members mentioned the need to have joint rules of procedure when collaborating with other EU-bodies.

5.2. 5th Meeting of Chairs/Secretariats of EU Risk Assessment Bodies, Brussels, 18-19 November 2009

The Chairman informed members about the presentations on Nanotechnologies and Synthetic Biology, the dinner discussion with members of the European Parliament, and the Breakout groups on Emerging Issues, Exposure assessment, and Terminology including related follow-up activities. In the afternoon of Day 2 of the meeting, a special session was held on Alternative methods for animal testing that would be a topic for further work for the three non-food Scientific Committees.

5.3. Risk Assessment Day, Brussels, 20 November 2009

Members discussed the joint plenary meeting of the three non-food Scientific Committees, the presentations of relevant research projects funded under the Framework Programme, and the discussions with stakeholders. The final version of the Rules of Procedures, agreed at the meeting, would be sent to all members for final approval.

5.4. Other

Prof. A. Proykova informed members about a recent workshop on Nanometrology (Braunschweig, Germany, 17-20 November) dealing with modelling and simulation as well as new achievements (<http://www.co-nanomet.eu/page1044/Nanometrology-Workshop-Nov-09/Workshop-Overview>).

6. ONGOING WORK

6.1. Tobacco Additives (for discussion)

The Chairperson of the WG informed the Committee about the ongoing work. Following the last WG-meeting and screening of the information available to the experts, WG-members had suggested to launch a call for information and provided a draft for this purpose. Based on the discussion in the SCENIHR it was decided to publish the call as soon as possible. Further information would be available at the following webpage:

http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/scenihhr_call_info_08_en.htm

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

The Chairperson of the WG informed the Committee about the first two meetings of the WG. Upon suggestion by WG-members, the Terms of Reference had been slightly modified to enhance clarity of the mandate. DG Enterprise and Industry (ENTR) agreed with the proposal. The WG had developed a structure of the opinion and had prepared a first draft. A call for information had been launched and was available at the following webpage:

A representative from DG Health and Consumers (SANCO) briefly described the role of DG SANCO in monitoring patient safety and quality assurance of medical devices.

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

The Chairperson of the WG informed the Committee about the first meeting of the WG. The WG had developed a provisional structure of the opinion and made a preliminary distribution of tasks to current members. Furthermore, the WG had proposed a Rapporteur, who was confirmed by the SCENIHR. Additional experts would be contacted to contribute to this work.

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

Members discussed the draft position paper prepared. It was decided to develop the paper further within a dedicated meeting. Therefore, the SCENIHR set up a Working Group and appointed a Chairperson. Sections were provisionally assigned to members for input.

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. Both, the deadline of the mandate and the public consultation on the document have been postponed and an additional WG meeting was scheduled for early December. SCENIHR emphasized the importance of having its view adequately reflected in the final version of the document.

7.2. 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 would be requested from the providers.

Triclosan

A member participating in the WG organized by the Scientific Committee on Consumer Safety (SCCS) informed the Committee about the ongoing work. Relevant new findings were published recently that would be considered in the opinion.

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

A member provided feedback on the hearing that took place on 24 September 2009 and two WG-meetings. The hearing provided an opportunity for stakeholders to explain and discuss their contributions which were submitted during the public consultation on this opinion. It was considered useful for revising the opinion. Upon finalization it would be circulated to the three Scientific 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 and an upcoming WG-meeting.

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

Mercury Sphygmomanometers

The Secretariat informed members that based on the scientific opinion, DG Enterprise and Industry (ENTR) would send a report to the European Chemical Agency (ECHA). It is foreseen that ENTR would instruct ECHA to prepare an Annex XV dossier under the provisions of the REACH Regulation to restrict the marketing of mercury sphygmomanometers. Further information on follow-up activities would be reported in due course.

9. NEW REQUESTS

9.1. Possible improvements in risk assessment approaches in view of risk management needs and effective risk communication

The Chairman and Secretariat informed members about a new mandate to the three non-food Scientific Committees developed as a result of a reflection process within SCHER.

The aim of this mandate is to review current risk assessment practices in view of better adaptation to the needs of risk managers as well as more effective management and communication of risk-related issues. Therefore, the Working Group should identify approaches that can provide results which are informative, consistent, transparent, and easy to interpret and communicate. It is foreseen to involve risk managers, policymakers, experts from other EU and international risk assessment bodies, and other relevant stakeholders in the discussion, e.g. via a public consultation and a thematic workshop.

A cross-committee group, also involving experts covering socio-economic disciplines, was set up to develop an opinion and to organise a thematic workshop that would produce a report with a review of the relevant issues and related recommendations.

Several members of SCENIHR expressed an interest in this topic and in participating in the WG. They would be invited to the upcoming first WG-meeting.

9.2. Health effects of artificial light

Representatives from DG Transport and Energy (TREN), ENTR and SANCO introduced the request and provided information on its background. The request is made within the context of promoting the wide-spread use of energy saving lamps and phasing-out incandescent lamps. It follows the SCENIHR opinion on **Light sensitivity**¹ of 23 September 2008. Since the publication of the opinion and the adoption of Commission Regulation 244/2009 setting ecodesign requirements for non-directional lamps (in practice phasing out incandescent lamps by 2012), further claims and information relating to light sensitivity and potential health effects of artificial light have been brought to the attention of the Commission. Therefore, the SCENIHR is asked inter alia to update its earlier opinion and to carry out an analysis of a wider range of lighting technologies and associated potential health risks.

¹ http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_019.pdf

Members discussed the working mandate and provided feedback to Commission services. The SCENIHR set up a Working Group and appointed a Chairperson. Members also identified additional expertise that would be needed for the task.

A consultation on the working mandate would be carried out according to the provisions of the Rules of Procedure of the Scientific Committees. Furthermore, a call for information and a public consultation in relation to a hearing on the pre-consultation opinion are foreseen. The deadline for the opinion would be confirmed after the finalisation of the mandate.

The working mandate is available at the following webpage:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_023.pdf

10. EMERGING ISSUES

The Chairman had revised the working paper on emerging issues based on input from members. However, the Chairman and the Secretariat would further revise the working document to improve consistency and clarity.

11. ANY OTHER BUSINESS

Members discussed different potential mechanisms for involving external experts in WGs. This would be further discussed at the next meeting of the Inter-Committee Coordination Group (ICCG).

The Secretariat informed about a recent meeting on **Risk Assessment and Terminology**, organized by the International Commission on Non-Ionizing Radiation Protection (ICNIRP), co-sponsored by the World Health Organization. Both the SCENIHR-approach to Weight of Evidence and other EU-activities on Terminology were presented.

The Secretariat and members discussed the **3rd Annual Nanotechnology "Safety for Success" Dialogue: Building Trust in Nanotechnologies**, Brussels 3-4 November. The meeting involved more than 230 participants (scientists, risk assessors, public authorities, industry, consumer and environmental NGOs). Based on four case studies, the discussion focussed on how to ensure the safety of products of nanotechnologies and how to build public trust. In a concluding session, practical recommendations for the next European Action Plan for nanoscience and nanotechnologies were developed.

More information about the conference is available at the following webpage:

http://ec.europa.eu/health/ph_risk/ev_20091103_en.htm

The Secretariat informed members about a current mandate of the SCHER on **Mercury in certain Energy-saving Light Bulbs**. To ensure consistency between the two committees in relation to the work on light bulbs, a member of SCENIHR would join the SCHER WG.

The working mandate is available at the following webpage:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_q_087.pdf

The Secretariat informed members that the joint report on **Antimicrobial resistance - zoonotic infections** that the SCENIHR had written jointly with EMEA, EFSA and ECDC, had been adopted by the four bodies involved. The opinion was published at the following webpage:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_026.pdf

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. J. BRIDGES (Chair), Dr. W. DE JONG (Vice chair), Prof. P. HARTEMANN (Vice chair), Prof. P. HOET, Dr. T. JUNG, 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, Ms. A. KANELLOPOULOU, Mr. P. MARTIN

Other Commission staff:

Ms. A. EGELAND (DG SANCO), Ms. J. HOUINS-ROULET (SANCO), Mr. N. MICHAILIDIS (DG ENTR), Ms. T. PEETSO (DG SANCO), Mr. A. TOTH (DG TREN), Mr. J. VOGELGESANG (DG SANCO)