

EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER) 24th PLENARY MEETING

Held on 15 July 2008 in Brussels

Minutes

1. WELCOME AND APOLOGIES

Prof. Greim, Chair of the Committee, opened the meeting and welcomed the participants.

Apologies: Prof H Autrup, Prof J Tarazona

2. ADOPTION OF THE DRAFT AGENDA

The draft <u>agenda</u> was adopted with an additional point concerning new requests for opinions on substances under Regulation 793/93.

3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

Prof. C Janssen declared a possible conflict of interest in relation to item 6.1 being involved in the environment steering committee performing the voluntary RA on lead and its compounds. He also declared a possible conflict related to item 6.3

Prof. P Calow declared a possible conflict of interest in relation to item 6.3 since he was involved in the environment steering committee of NiPERA (Nickel Producers Environmental Research Association).

Dr I Mangelsdorf declared a possible conflict of interest in relation to item 7.1 being involved in the preparation of the biocides dossier on propan-1-ol.

Prof. Ladefoged declared a possible conflict of interest in relation to item 7.2 since he was involved in the preparation of the indirect human exposure part of the RAR on nickel.

Dr E Testai declared a possible conflict of interest in relation to item 7.6 since she was involved in the preparation of the voluntary RAR on copper and copper compounds.

4. Approval of the draft minutes of the 23RD SCHER plenary meeting

The minutes of the 23rd SCHER plenary meeting were adopted.

5. CHAIR'S REPORT

5.1 Transatlantic Risk Dialogue

The meeting was convened in Washington and it was attended by over 60 participants from the US, EU and Canada. Representatives of EU Scientific Committees and Panels also participated in the meeting.

The overall goal of the meeting was to launch the transatlantic risk assessment dialogue by a first discussion between representatives of relevant departments and bodies and scientific experts on the role and organisation of risk analysis in the US, EU and CA.

The meeting was also intended to prepare for the First International Risk Assessment Conference planned for 13-14 November 2008 in Brussels.

Several subjects were discussed on the basis of invited presentations.

5.2 ICCG group

5.2.1 Revision of the scientific committees

The Chair updated on the progress of the revision of the scientific committees (e.g. modified field of competences, and the proposed modifications such as creation of a pool of experts, joint opinions and needs for rapid advice). He also informed the Committee on the nature of the rapid-advice needs and structure as discussed at the ICCG meeting.

5.2.2 STOA meeting

Following up to the presentation of STOA at the Inter-Committee Coordination Group (ICCG) meeting of 7 February and further contacts, representatives of SCCP, SCHER and SCENIHR were invited to the STOA meeting of 19 June 2008, for presenting the committees' work, in particular on Nanotech, EMF, alternative test methods, and a discussion on possible collaboration with them.

6. New requests on Regulation 793/93 Existing Substances (ESR): (Human Health and/or Environment) – DG ENV/DG JRC

Rapporteurs were appointed to comment on the RARs on nitrobenzene (CAS 98-95-3; HH part) and vinyl acetate (CAS 108-05-4; HH part). Working groups were set up on the voluntary RAR on lead and lead compounds (ENV part), the voluntary RAR on copper and copper compounds (ENV part) and the RAR on nickel and its compounds (ENV part).

The representative of DG ENV informed that these were the last requests for opinions on existing substances submitted to SCHER.

7. ONGOING REQUESTS ON REGULATION 793/93 EXISTING SUBSTANCES (ESR): (HUMAN HEALTH AND/OR ENVIRONMENT) – DG ENV/DG JRC

7.1 Propan-1-ol (CAS 71-23-8; HH part)

The Committee decided that the effect assessment part of the draft need to be better reworded. The draft would be proposed for adoption at the next plenary.

7.2 Nickel and compounds (indirect human exposure)

The opinion on the indirect human exposure part of the RAR was adopted and is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_099.pdf

7.3 Aluminium fluoride (CAS No: 7784-18-1; ENV part)

The Rapporetur reported back on the main points of the RAR on aluminium fluoride. A draft opinion will be available at the next plenary.

7.4 Calcium fluoride (CAS No: 7789-75-5; ENV part)

The Rapporetur reported back on the main points of the RAR calcium fluoride. A draft opinion will be available at the next plenary.

7.5 4-tert-butylphenol (CAS 98-54-4; HH part)

Clarifications were needed on the part of the risk characterization, in particular on the use of MOS. The Rapporteur would clarify it at the next plenary.

7.6 Voluntary RAR on lead and lead compounds (HH part)

The Rapporetur reported back on the main points of the VRAR on lead and its compounds. A draft opinion will be available at the next plenary.

7.6 Voluntary RAR on copper and copper compounds (HH part)

The opinion on the RAR was adopted with minor amendments and is available at: http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_100.pdf

9. ONGOING REQUESTS FOR OPINIONS BY COMMISSION SERVICES ON:

9.1 Use of non-human primates in biochemical research, production and testing products and devices

A public consultation on the working mandate and a call for information were published on the SCHER web side and ran in parallel from 15 May to 6 June 2008. Around 700 scientific articles and 140 comments were received.

The working group was looking at the contributions and comments received. Moreover, it decided that more external experts would be needed to cover some points of the request.

The Rapporteur also informed the committee on the outcome of the first working group meeting.

9.2 Anaerobic biodegradation of surfactants and Biodegradation of non surfactant organic ingredients

The Rapporteur updated the Committee on the outcome of the last working group meeting that was held the day before the plenary. The draft opinion would be updated on the basis of the WG meeting and plenary discussion and presented at the next meeting.

9.3 Phthalates in school supplies

The final draft opinion was presented to the committee and discussed. SCHER agreed on the contents but decided that some rewording and clarifications were needed. The Committee decided to postpone the adoption at the next plenary. Commission services agreed.

9.4 Risk assessment methodologies and approaches for mutagenic and carcinogenic substances

The rapporteur reported back on the last working group meeting. An updated draft opinion would be presented at the next plenary.

10. Participation of the SCHER in activities/working groups of other Scientific Committees of the Commission or EFSA

10.1 SCCP

The SCHER member involved in the working group on the use of the Threshold of Toxicological Concern (TTC) approach for the safety assessment of chemicals informed on the developments of the ongoing work. It was proposed to exchange the next drafts on TTC and GenTox with SCCP for information and discussion at the next plenary meetings of the Committees.

11. EMERGING ISSUES

No emerging issues

12. NEXT PLENARY MEETING

The next SCHER plenary meeting was confirmed as 9 September 2008.

13. Any Other Business

Future mandate of SCHER

The Committee discussed a letter on the future mandate of SCHER. The letter highlighted the need for a comprehensive, combined and simultaneous risk assessment of HH <u>and</u> the ENV.

The letter was unanimously supported by SCHER members and sent to DG SANCO for possible consideration.

Annex 1: List of participants

Annex 1

SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER) 24TH PLENARY MEETING

Held on 15 July 2008 in Brussels

LIST OF PARTICIPANTS

MEMBERS OF THE SCHER:

Prof. P. CALOW, Prof. W. DEKANT, Prof. H. GREIM (Chair), Prof. W. HANKE, Prof. C. JANSSEN, Prof B. JANSSON (vice Chair), Prof. H. KOMULAINEN, Prof. O. LADEFOGED, Prof. J. LINDERS, Dr I. MANGELSDORF, Prof. M. NUTI, Prof. A. STEENHOUT, Dr. E. TESTAI, Prof. M. VIGHI, Prof. M. VILUKSELA.

EUROPEAN COMMISSION:

SCHER Secretariat (DG SANCO):

Mrs. G. FONTANESI, Mrs. N. FOUVEZ

Other Commission staff:

Mrs. K. ASCHBERGER (DG JRC); Mrs. A. VAN HAELST (DG ENV); Mr M. SCHMAHL (DG ENTR)