

EUROPEAN COMMISSION

HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER) 23RD PLENARY MEETING

Held on 6 May 2008 in Brussels

Minutes

1. WELCOME AND APOLOGIES

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

Apologies: Prof M.Nuti

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

Dr E Testai declared a possible conflict of interest in relation to item 7.4 since her Institute was involved in the preparation of the RAR on chlorine. She also declared a possible conflict of interest in relation to item 7.10 since she was involved in the preparation of the voluntary RAR on copper and copper compounds.

Prof. C Janssen declared a possible conflict of interest in relation to item 6 being involved in the environment steering committee of NiPERA (Nickel Producers Environmental Research Association).

Prof. Ladefoged declared a possible conflict of interest in relation to item 6 since he was involved in the preparation of the indirect human exposure part of the RAR on nickel.

Prof P Calow declared a possible conflict of interest in relation to items 7.6 and 7.8 (RAR on HHCB) since he was involved in the expert panel of the Research Institute for Fragrance Materials. He also declared a possible conflict of interest in relation to item 6 since he was involved in the environment steering committee of NiPERA (Nickel Producers Environmental Research Association).

4. APPROVAL OF THE DRAFT MINUTES OF THE 22ND SCHER PLENARY MEETING

The <u>minutes</u> of the 22nd SCHER plenary meeting were adopted.

5. CHAIR'S REPORT

No ICCG meeting to be reported following the last SCHER plenary.

- Risk assessment terminologies would be discussed in the workshop of the European Environment Agency on 28-29 May 2008. Representatives of the three Scientific Committees would be invited to participate in the meeting.
- The Chairs and vice-Chairs of the three Scientific Committees were invited to attend the meeting with the EP STOA Panel on 19 June 2008 in Strasbourg.
- The Risk Assessment Days meeting was planned on 24-25 June 2008. The Chairs and vice-chairs of the three Scientific Committees and some EP Committees would meet at the European Parliament on 24 June. The following day the three Scientific Committees would meet with stakeholders.

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 propan-1-ol –HH and nickel and its compounds – indirect human exposure part.

The representative of ECB informed that the last six requests for opinions on existing substances are foreseen in July.

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

7.1 Hexabromocyclododecane (HBCD; ENV)

The opinion on the environmental part of the RAR on HBCD was adopted and is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_093.pdf

7.2 4-tert.-butylbenzoic acid (ENV)

The opinion on the environmental part of the RAR was adopted with minor corrections and is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_098.pdf

7.3 4-methyl-m-phenylenediamine (2,4-TDA; ENV)

The opinion on the environmental part of the RAR on 2,4-TDA was adopted with a few amendments and is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_090.pdf

7.4 Chlorine (ENV)

The opinion on the environmental part of the RAR on chlorine was adopted with a few corrections and is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_092.pdf

7.5 1-(5,6,7,8-tetrahydo-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one (AHNT; ENV)

The opinion on the environmental part of the RAR on AHNT was discussed and amended. It was proposed for adoption by written procedure and is available at: http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_097.pdf

7.6 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno[5,6-c] pyran (HHCB; ENV)

The opinion on the environmental part of the RAR on HHCB was discussed and some amendments were included. It was proposed for adoption by written procedure and is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_096.pdf

7.7 1-(5,6,7,8-tetrahydo-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one (AHNT; indirect human exposure)

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

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_091.pdf

7.8 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno[5,6-c] pyran (HHCB; indirect human exposure)

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

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_094.pdf

7.9 Styrene (HH)

The opinion on the human health part of the RAR on styrene was adopted with minor corrections and is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_095.pdf

7.10 Voluntary RAR copper and copper compounds (HH)

The Rapporteur presented the draft opinion for discussion. An updated version of the draft including comments from the plenary would be proposed for adoption at the next plenary.

8. NEW REQUESTS FOR OPINIONS BY COMMISSION SERVICES ON:

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

DG ENV is currently revising the Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes. The revision addresses several issues including specific problems relating to the use, care and acquisition of non-human primates.

In the scope of the revision, DG ENV requested SCHER to issue a scientific opinion on the possibilities to replace the use of non-human primates. The scientific opinion would need to be available by the end of October 2008 to support the co-decisions procedure and the related discussions at the European Parliament and the Council.

A public consultation on the working mandate and a call for information would be published on the SCHER web side and would run in parallel from 15 May to 6 June 2008.

The working group was set up and included both SCHER members and external experts.

The mandate is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_q_073.pdf

9. ONGOING REQUESTS FOR OPINIONS BY COMMISSION SERVICES ON:

9.1 Environmental risks and indirect health effects of mercury in dental amalgam

The working group on amalgam met after the last plenary to discuss and decide on the comments received from the public consultation on the preliminary report. The updated draft opinion including some amendments done on the bases of those comments was presented to the SCHER. The opinion was adopted with minor editorial corrections and is available at http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_089.pdf

9.2 Phthalates in school supplies

The rapporteur reported back on the last working group meeting and on the ongoing work. A draft opinion would be proposed for adoption at the next plenary of July.

9.3 Risk assessment methodologies and approaches for mutagenic and carcinogenic substances

The rapporteur reported back on the last working group meeting. A draft opinion would be presented for discussion at the next plenary meeting. A preliminary report would be tentatively proposed for adoption and publication for public consultation in October.

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.

11. EMERGING ISSUES

No emerging issues

12. NEXT PLENARY MEETING

The next SCHER plenary meeting was confirmed as 15 July 2008.

13. Any Other Business

NoB

Annex 1: List of participants

Annex 1

SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER) 23RD PLENARY MEETING

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LIST OF PARTICIPANTS

MEMBERS OF THE SCHER:

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

EUROPEAN COMMISSION:

SCHER Secretariat (DG SANCO):

Mrs. G. FONTANESI, Mrs. I. COPPOLA.

Other Commission staff:

Mrs. K. ASCHBERGER (DG JRC); Mrs. G. LUVARA' (DG ENTR); Mr. P. MOURATIDIS (DG ENV); Mr S. PICKERING (DG ENTR)