

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) 11^{TH} Plenary Meeting

Held on 4 May 2006 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

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

Apologies: Prof Janssen, Prof Sokal, Dr. Testai, Prof. Vos.

2. ADOPTION OF THE DRAFT AGENDA

The draft agenda was adopted as written

3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

Prof. Calow and Prof. Janssen declared an interest in relation to item 7.9, being respectively chairman and member of the NiPERA (Nickel Producers Environmental Research Association) risk assessment report peer review group. Prof Ladefoged declared an interest on the same point since he was involved in the preparation of some chapters of the human health part of the RAR on nickel. Dr. Mangelsdorf declared an interest in relation to item 8.3 using the TGD to prepare dossiers for industry.

Taking into account the nature of the declarations, the committee decided that they could participate in the discussions on those matters.

4. APPROVAL OF THE DRAFT MINUTES OF THE 10TH SCHER PLENARY MEETING

The minutes of the 10th SCHER plenary meeting were adopted without corrections.

5. CHAIR'S REPORT UPDATE ON THE COORDINATION MEETING OF 5 APRIL 2006 ON MATTERS OF INTEREST TO THE SCHER

- **5.1.** EFSA has been asked by DG Sanco for an opinion on the recent carcinogenicity study on aspartame. SCHER's chair participates in the WG and reported that the final draft opinion will be available by end of April.
- **5.2.** The coordination meeting agrees with SCHER's position in its Opinion on the TGD, that when default factors are used, their size should be adjusted according to the available data.
- **5.3.** Dr. Michael Gribble and Prof. Geoff Randall (ECETOC) gave a presentation on ECETOC activities in risk assessment, their work procedures and collaboration with stakeholders. Potential exchange of information and knowledge with the scientific committees were discussed.
- **5.4.** The draft position statement setting out the Committees views on the use of alternative methods for the safety assessment of chemicals was adopted by the three Committees previously. It was proposed to ask the SC of EFSA for agreement.
- **5.5.** DG RTD provided a presentation on the Draft Action Programme for the European Partnership for Alternative Methods. Members expressed their interest and wish to be informed about the results of research projects that are relevant for the work of the Scientific Committees.

6. ONGOING REQUESTS ON REGULATION 793/93 EXISTING SUBSTANCES (ESR): (HUMAN HEALTH AND/OR ENVIRONMENT)

6.1. Ethylbenzene (ENV)

The opinion on the environmental part of the RAR on ethylbenzene was amended on the basis of the previous discussion and adopted. The opinion is available at: http://ec.europa.eu/comm/health/ph_risk/committees/04_scher/docs/scher_o_031.pdf

6.2. 2,4,4,- Trimethylpentene (**HH**)

The opinion on the human health part of the RAR on 2,4,4,- Trimethylpentene was revised taking into account comments from the Committee and adopted. It is available at: http://ec.europa.eu/comm/health/ph_risk/committees/04_scher/docs/scher_o_033.pdf

6.3. Hexachlorocyclopentadiene (HCCP; ENV)

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

http://ec.europa.eu/health/ph risk/committees/04 scher/docs/scher o 036.pdf

6.4. 2-methoxy-1-methylethyl acetate (ENV)

The opinion on the environmental part of the RAR on 2-methoxy-1-methylethyl acetate was adopted and is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_035.pdf

6.5. Nickel (HH)

The opinion on the results of the human health part of the RAR on nickel and its salts was adopted and is available at:

http://ec.europa.eu/comm/health/ph_risk/committees/04_scher/docs/scher_o_034.pdf

6.6. 2, 4-methyl-m-phenylenediamine (2,4 – TDA; HH)

The opinion on the results of the human health part of the RAR on 2,4-methyl-m-phenylenediamine was adopted and is available at:

http://ec.europa.eu/comm/health/ph_risk/committees/04_scher/docs/scher_o_032.pdf

6.7. Benzyl butyl phthalate (BBP; ENV)

The rapporteur presented a draft opinion on the results of the environmental part of the RAR on benzyl butyl phthalate. Some comments from the Committee would be added and the draft opinion would be presented at the next plenary meeting.

7. ONGOING REQUESTS FOR OPINIONS BY COMMISSION SERVICES ON:

7.1. Indoor air quality

The rapporteur presented the updated draft opinion. The final draft opinion would be available for the plenary in July. It was decided that the preliminary adopted opinion would be put on the SCHER web site for public consultation.

Points which needed to be better explained or justified:

- Definition of combined effects/combined exposure
- -Vulnerable groups
- Sensory irritation

7.2. Organotins

The rapporteur reported back on the discussion in the last working group meeting. More information was needed on realistic data on human exposure, organotins in recycling and land fill sites, long terms effects due to organotins exposure. Two working group meetings were foreseen before the following plenary where the first draft opinion would be discussed.

7.3. TGD - risk characterisation

The SCHER commented on the suggested TGD use of default factors and agreed that they should be used only case by case. If available, good data should be used first; otherwise, interspecies data or default factors as a last choice, if those data are not available. DG ENV asked for to clarification on:

- Scientific argumentation for the definition of default factors (5 or 2 to be used);
- Use of good data or assessment factors first.

A new version of the draft would circulate to the WG members; whether a new working group meeting would be needed, will be decided accordingly.

8. PARTICIPATION OF THE SCHER IN ACTIVITIES/WORKING GROUPS OF OTHER SCIENTIFIC COMMITTEES OF THE COMMISSION OR EFSA

8.1. EFSA

- Working group on BMD: The second meeting of the group was held on 2 March 2006. The representative of SCHER already reported back in the SCHER plenary of March. Next meeting would be held on June.

8.2. SCENIHR:

- The first joint working group on DEHP (di-2-ethylexylphthalate) in medical devices met two days before the SCHER plenary. The two representatives of the SCHER who attended that meeting reported back on the ongoing discussion.
- The SCENIHR Working Group on TGD on nanomaterials. The working group meeting was held at short notice; representatives of SCHER were not available on that date.

9. EMERGING ISSUES

No emerging issues were raised.

10. NEXT PLENARY MEETING

The next SCHER plenary meeting was confirmed for 4 July 2006.

11. ANY OTHER BUSINESS

No other business.

Annex 1: List of participants

SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER) 11^{TH} Plenary Meeting

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LIST OF PARTICIPANTS

MEMBERS OF THE SCHER:

Prof. H. AUTRUP, Prof. P. CALOW, Prof. W. DEKANT, Prof. Dr. H. GREIM (Chair), Prof. W. HANKE, Prof. Bo JANSSON (Vice Chair), Dr. H. KOMULAINEN, Prof. O. LADEFOGED, Dr. I. MANGELSDORF, Prof. M. NUTI, Prof. A. STEENHOUT, Prof. J. TARAZONA (Vice Chair), Prof. M. VIGHI, Dr. M. VILUKSELA.

EUROPEAN COMMISSION:

SCHER Secretariat (DG SANCO):

Mrs. T. PEETSO, Mrs. C. DEKINDT.

Other Commission staff:

Mr S. PICKERING (DG ENTR), Mrs. K. GRODZSKI (DG ENTR), Mr. S. KEPHALOPOULOS (DG JRC), Mr. P. VAN DER ZANDT (DG ENV).