

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) 10^{TH} Plenary Meeting

Held on 17 March 2006 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

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

Apologies: Prof Sokal and Prof. Vos.

2. ADOPTION OF THE DRAFT AGENDA

The draft <u>agenda</u> was updated and adopted with three more requests for opinions on the results of RARs on Nickel (HH), 3-Chloro-2-hydroxypropyl-trimethyl-ammonium chloride (HH) and 2, 3-epoxypropyltrimethylammonium chloride (HH).

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.

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 9TH SCHER PLENARY MEETING

The <u>minutes</u> of the 9th SCHER plenary meeting were adopted with a few editorial corrections.

5. CHAIR'S REPORT

5.1. Alternatives to animal tests: Scientific Committee Position Statement

The ICCG was invited to consider the adoption of a position statement setting out their views on the use of alternative methods for the safety assessment of chemicals. A draft of the statement was prepared and circulated to the three Scientific Committees. The SCHER accepted the draft.

5.2. Letter from BUAV

A letter from BUAV, addressed to the Chairman, was distributed for comment to the SCHER. In this letter, strong criticisms were addressed to the Committee opinion, adopted in the 8th SCHER plenary, on the BUAV report "Endocrine Disrupting Chemicals: a Non-animal Testing Approach",.

The Committee concluded that the responses to points raised in the letter were well described in the opinion itself and that the Chair would prepare a general draft reply on behalf of the SCHER to be circulated at the following Inter Committee Coordination Group meeting.

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

6.1. Risk Assessment Reports

Rapporteurs were appointed to comment on the Risk Assessment Reports (RAR) on 4-methyl-m-phenylenediamine (2,4TDA, HH), tris(nonylphenyl)phosphite (TNPP, HH), and tris (2-chloroethyl) phosphate (TCEP, ENV).

7. Ongoing requests on Regulation 793/93 Existing Substances (ESR): (Human Health and/or Environment)

7.1. Vinyl acetate (ENV)

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

http://europa.eu.int/comm/health/ph_risk/committees/04_scher/docs/scher_o_030.pdf

7.2. Ethylbenzene (ENV)

The rapporteur presented a draft opinion on the results of the environmental part of the RAR on ethylbenzene. The draft would be revised taking into account comments from the Committee and would be presented at the next plenary meeting.

7.3. 2,4,4,- Trimethylpentene

A preliminary draft opinion on the results of the human health part of the RAR on 2,4,4,-Trimethylpentene was presented by the rapporteur. It will be completed and presented at the next plenary meeting.

7.4. Hexachlorocyclopentadiene (HCCP; ENV)

The draft on the results of the environmental part of the RAR on HCCP would be revised taking into account comments from the Committee and would be presented at the next plenary meeting.

7.5. 1-methoxypropan 2-ol (ENV)

The opinion on the environmental part of the RAR on 1-methoxypropan 2-ol was adopted and is available at:

http://europa.eu.int/comm/health/ph_risk/committees/04_scher/docs/scher_o_029.pdf

7.6. 2-methoxy-1-methylethyl acetate (ENV)

The discussion on the draft opinion on the environmental part of the RAR on 2-methoxy-1-methylethyl acetate would be postponed to the next plenary meeting.

7.7. 2-buthoxyethanol (ENV)

The opinion on the environmental part of the RAR on 2-buthoxyethanol was adopted with a few corrections and is available at:

http://europa.eu.int/comm/health/ph risk/committees/04 scher/docs/scher o 028.pdf

7.8. 2-buthoxyethyl acetate (ENV)

The opinion on the environmental part of the RAR on 2-buthoxyethanol acetate was adopted with a few corrections and is available at:

http://europa.eu.int/comm/health/ph risk/committees/04 scher/docs/scher o 027.pdf

7.9. Nickel (HH)

The rapporteur presented a draft opinion on the results of the human health part of the RAR on nickel and its salts. The draft would be completed and presented at the next plenary meeting.

7.10. 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. The draft would be revised taking into account comments from the Committee and would be presented at the next plenary meeting.

8. ONGOING REQUESTS FOR OPINIONS BY COMMISSION SERVICES ON:

8.1. Indoor air quality

The rapporteur reported back on the last working group meeting and presented the draft opinion. Some input from the Committee on Question 1 and Question 2 will be taken into consideration in the following updated draft.

The Committee was also informed that a new external expert on sensory irritation and allergic airway diseases would be invited to be part of the group.

8.2. Organotins

The rapporteur informed the Committee on the first working group meeting and the organization of the work inside the group which includes member from EFSA, SCHER and external members.

The group was collecting material for the work and would start to prepare contributions for a first draft which would be discussed at the second working group meeting.

8.3. TGD - risk characterisation

The Chairman of the working group reported back on the first meeting and presented the second draft opinion. Main point to be addressed would be the interpretation of the application of default factors. The Committee was also informed on comments received from DG ENV and DG JRC whose representatives attended the first working group meeting.

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

9.1. EFSA

- Working group on BMD: The second meeting of the group was held on 2 March 2006. The representative of SCHER attending the meeting reported back on the main parts of the discussion.

9.2. 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 was organising a Working Group which would give an opinion on the appropriateness of the TGD risk assessment methodology for assessing the risk of nanomaterials. Two representatives of SCHER were invited to be part of the working group.

10. EMERGING ISSUES

No emerging issues were raised.

11. NEXT PLENARY MEETING

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

12. ANY OTHER BUSINESS

A member of the SCHER informed the Committee about the public consultation published on the EMEA web site with the title "Guideline on environmental impact assessment for veterinary medicinal products in support of the VICH guidelines".

It was decided that the Committee would contribute with comments, possibly prepared in collaboration with the EFSA FEEDAP and PPR panels.

Annex 1: List of participants

SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER) 10^{TH} Plenary Meeting

Held on 17 March2006 in Brussels

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. C. JANSSEN, Prof. Bo JANSSON (Vice Chair), Prof. H. KOMULAINEN, Prof. O. LADEFOGED, Dr. I. MANGELSDORF, Prof. M. NUTI, Prof. A. STEENHOUT, Prof. J. TARAZONA (Vice Chair), Dr. E. TESTAI, Prof. M. VIGHI, Prof. M. VILUKSELA.

EUROPEAN COMMISSION:

SCHER Secretariat (DG SANCO):

Ms. G. FONTANESI, Ms. C. DEKINDT, Ms. T. PEETSO.

Other Commission staff:

Mr S. PICKERING (DG ENTR), Mrs. K. GRODZSKI (DG ENTR), Mrs. S. MUNN (DG JRC).