

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) 17^{TH} Plenary Meeting

Held on 29 May 2007 in Brussels MINUTES

1. WELCOME AND APOLOGIES

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

Apologies: Prof. Steenhout, Prof Sokal

2. ADOPTION OF THE DRAFT AGENDA

The draft <u>agenda</u> was adopted with an additional request for opinions on four Risk Assessment Reports (RARs) under regulation 973/93 – existing substances.

3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

Prof C. Janssen declared a conflict of interest in relation to item 7.1 since he was heavily involved in consultation on the report from both competent authorities and industry. Taking into account the nature of the declarations, the committee decided that he could not participate in the working group.

Prof P. Calow declared a possible conflict of interest in relation to the same item since he was chairman of the NiPERA (Nickel Producers Environmental Research Association) risk assessment report peer review group and in the same group the zinc industry was present as observer.

Prof. J Linders declared a possible conflict of interest in relation to the same item being The Nederland the Member State rapporteur for the RAR on zinc. Taking into account the nature of the declarations, the Committee decided that he could not be nominated as possible Rapporteur of the opinion on zinc.

Prof. J Tarazona declared a conflict of interest in relation to item 8.2 being the scientific supervisor of the report.

Prof M Vighi declared a conflict of interest in relation to the same item since he was directly involved in the working group. The committee decided that they could not participate in the preparation of the related opinion.

Prof. W Dekant declared a possible conflict of interest in relation to item 8.4 since he was consulted for an environmental remediation company regarding needs to clean up some Hg-contaminated sites in former East Germany and fish consumption from these sites.

4. APPROVAL OF THE DRAFT MINUTES OF THE 16TH SCHER PLENARY MEETING

The <u>minutes</u> of the 16th SCHER plenary meeting were adopted with minor corrections.

5. CHAIR'S REPORT

5.1 Presentation from ECVAM

The Chair reported back on the presentation of Dr T. Hartung on the activities and progress on the development of the alternative methods, especially in view of the objectives of the 7th amendment of the Cosmetics directive and REACH. The Chairs highlighted the need for appropriate data to assess all relevant toxicological aspects especially in regard to cosmetics. They also pointed out that there are domains of toxicology, such as neurotoxicity, endocrine disruption, metabolism etc. that cannot be studied with simple alternative tests. Dr. Hartung highlighted that the aim of in vitro test is to reduce use of animal testing, not necessarily to replace them completely.

5.2 Declaration of interest

Both EMEA and EFSA have categorised the levels of potential conflict and recognise in the evaluation both financial and intellectual interests (of last 5 years). The practices in WHO and IARCH resemble the above mentioned ones. The Chairs considered important to ensure the consistence between SCs.

5.3 Renewal of the Committees

DG Sanco will send a letter to members of the Committees on the prolongation of their mandate. After that, it will be necessary to assess the need for additional expertise.

5.4 US/EU risk assessment approaches

A 1st conference on the risk assessment approach used in US and Europe will be held in June 2008. The programme of that conference will be out in December 2007.

5.5 Setac meeting Porto 2007

One of the platforms of the meeting was dedicated to the "Contributions of Scientific Committees and Panels to decision making" and was held in honour of Prof. Jeff Vos. The Head of Unit of DG Sanco C7 and members of the SCHER were invited to contribute with presentations.

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 RARson 2-4-nitrotoluene (CAS 121-14-2; HH), 2,2-bis(chloromethyl) trimethylene bis(bis(2-chloroethyl) phosphate) (V6 - CAS 38051-10-4; ENV), tris(2-chloro-1-methylethyl) phosphate (TCPP; CAS 13674-84-5; ENV), tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP; CAS 13674-87-8; ENV).

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

7.1 Zinc (ENV)

An updated draft opinion was presented and discussed in the meeting.

The day after the plenary, the working group would meet the rapporteur of the risk assessment report (RAR) answering some questions posed by SCHER on the report. The meeting would be necessary to clarify some approaches and results reported in the RAR.

7.2 2,3-epoxypropyltrimethylammonium chloride (EPTAC – ENV)

The main points of opinion on the environmental part of the RAR on EPTAC were presented. A draft opinion would be proposed at the next plenary.

7.3 3-chloro-2-hydroxypropyl)trimethylammonium chloride (CHPTAC – ENV)

The discussion was postponed at the next meeting.

7.4 2 – nitrotoluene

The discussion was postponed at the next meeting.

8. ONGOING REQUESTS FOR OPINIONS BY COMMISSION SERVICES ON:

8.1 Non surfactant Organic Ingredients and Zeolite-based Detergents

The Rapporteur presented the updated version of the draft. The opinion was adopted but the committee decided that human exposure to EDTA, NTA and the phosphonates needed to be assessed and inserted in the opinion. Due to the urgency of the issue, it was decided to add the chapter and to adopt it by written procedure.

The opinion is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_057.pdf

8.2 Model implementation and quantification of the eutrophication risk associated to the use of phosphates in detergents

Several comments were made during the discussion on the draft opinion. Since several clarifications were still necessary before presenting a final draft, it was decided that, in spite of the deadline asked by DG ENTR, the adoption of the opinion should be postponed. It was also decided that another external expert would be necessary to finalize the document before the next

plenary. The secretariat would circulate some dates for another WG meeting to be held on beginning of July.

8.3 CEN report – organic chemicals in toys

The opinion was adopted and is available at: <u>http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_056.pdf</u>

8.4 Use of Hg in dental amalgam

A call for information on mercury from dental amalgam was ongoing on the website of SCHER. Contributions received would be evaluated by the WG and discussed in a meeting to be held on June. An updated draft opinion would be presented for discussion at the next plenary.

8.5 Indoor air risk assessment

The SCHER adopted a preliminary report on indoor air risk assessment during its plenary held on 30 January 2007. The preliminary report was then published on the web for public consultation until 3 April 2007. 19 contributions were received, most of them in agreement with the results and conclusions of the SCHER report.

The working group met again on mid May to discuss contributions and eventually to update the opinion. An updated version of the draft taking into account contributions received was proposed and discussed at the plenary. The Committee decided that since the contributions received did not change the conclusions of the preliminary report, the opinion can be adopted. It is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_055.pdf

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

9.1 SCENIHR:

DEHP (di-2-ethylhexyl phthalate) in medical devices joint working group: the draft was quite finalized and the last joint wg would be held in June.

TGD on nanomaterials working group: the representative of SCHER reported back on the discussion of the last wg meeting.

9.2 EFSA

BMD the work was still ongoing and the next wg meeting would be held on June.

10. NEXT PLENARY MEETING

The next SCHER plenary meeting was confirmed as 19 July 2007.

11. ANY OTHER BUSINESS

12.1 Publications

The secretariat informed that an official note to the Editor-in-Chief of Ecotoxicology and Environmental Safety was on the pipeline for the signature of the hierarchy.

12.2 Cost-benefit analysis

A member of the Committee prepared and presented a paper on the possible involvement of the committee in socio-economic assessment and cost-benefit analysis. The document would be also proposed for discussion at the next ICCG meeting of June.

Annex 1: List of participants

Annex I

SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER) 17th Plenary Meeting

Held on 29 May 2007 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. B. JANSSON (vice Chair), Prof. H. KOMULAINEN, Prof. O. LADEFOGED, Prof. J. LINDERS, Dr. I. MANSGELDORF, Prof. M. NUTI, Prof. J. TARAZONA (vice Chair), Dr. E. TESTAI, Prof. M. VIGHI, Prof. M. VILUKSELA.

EUROPEAN COMMISSION:

SCHER Secretariat (DG SANCO):

Mrs. G. FONTANESI, Mrs. C. DEKINDT.

Other Commission staff:

Mr. S. KIOKIAS (DG ENTR); Mr. B. LUND (DG JRC); Mrs. A. NAM (DG ENV); Mr. S. PICKERING (DG ENTR); Mrs. A. VAN HAELST (DG ENV).