

#### **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) 9<sup>TH</sup> PLENARY MEETING

Held on 27 January 2006 in Brussels

#### **MINUTES**

#### 1. WELCOME AND APOLOGIES

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

Apologies: Prof Sokal, Prof Vighi, and Prof. Vos.

#### 2. ADOPTION OF THE DRAFT AGENDA

The draft <u>agenda</u> was updated and adopted with four more requests for opinions on the results of RARs on Nickel (HH), benzyl butyl phthalate (ENV), 3-Chloro-2-hydroxypropyl-trimethylammonium chloride (HH) and 2, 3-epoxypropyltrimethylammonium chloride (HH).

#### 3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

Prof. Greim and Prof. Dekant declared an interest in relation to item 7.4 of the agenda due to their indirect involvement in the evaluation of the RAR on musk ketone. In relation to musk ketone, Prof. Greim and Prof. Calow declared their participation in the REXPAN of the Research Institute for Fragrance Material. Prof. Calow and Prof. Janssen declared an interest in relation to item 6.7, 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 part of the human health part of the RAR on nickel. Prof. Dekant declared an additional interest in relation to item 7.2, due to his research in the area of TAME, sponsored by the US EPA.

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 8<sup>TH</sup> SCHER PLENARY MEETING

The minutes of the 8<sup>th</sup> SCHER plenary meeting were adopted with a few editorial corrections.

## 5. CHAIR'S REPORT: UPDATE ON THE INTER COMMITTEE COORDINATION GROUP (ICCG) MEETING OF 23 NOVEMBER 2005 ON MATTERS OF INTEREST TO THE SCHER

#### **5.1. REACH:**

Representatives from DG ENTR and DG ENV attended the ICCG meeting to update the SCs' chairs on the state of the REACH, explaining in particular the recent development in Parliament and Council. Some indicative dates were given on the next steps of the process and main changes introduced from the original proposal of the Commission related to the Registration, Evaluation and Authorisation procedures were highlighted. The role of the agency (evaluation of the dossier) was also clarified.

It was agreed by the Committee that the secretariat would circulate the Power point presentation to the members.

## 5.2. Alternatives to animal tests: Scientific Committee Policy Statement

The ICCG was invited to consider the adoption of a policy 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 would be circulated to the three Scientific Committees.

## 5.3. Scientific Committees - work plan

The Chairman reported on possible future requests concerning the SCHER.

## 5.4. USA Federal Standards for Analysing Health and Environmental Risks

SANCO C7 informed the ICCG on new technical guidance on risk assessments proposed by the US. The proposed Risk Assessment Bulletin was released for peer review and public comments on the White House Web site. Comments would be welcomed until 15 June 2006. The secretariat would circulate the link to the bulletin to the members.

### 5.5. Meeting of Chairs of SCs in the Community risk assessment bodies

The representative of the SCHER at the meeting of the Chairs reported back to the Committee on the main points of the discussion. These have been diverging opinions, environmental and health risks, area for mutual cooperation, emerging issues and the quality of data used in risk assessment.

# 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 ten substances.

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

## 7.1. 2-ethoxyethyl acetate (ENV)

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

http://europa.eu.int/comm/health/ph\_risk/committees/04\_scher/docs/scher\_o\_024.pdf

## 7.2. 2-methoxy-2-methylbutane (TAME; HH)

One member of the Committee asked for interpretation of the SCHER statement reported in the opinion "...that the carcinogenicity endpoint was not assessed because of inadequate data..." It was clarified that by this SCHER intends to point out that more data is needed to evaluate the carcinogenicity endpoint. It was decided that this comment should be included in the minutes of the meeting to avoid misinterpretation of the statement.

With minor corrections agreed upon, the opinion on the human health part of the RAR on TAME was adopted and is available at:

http://europa.eu.int/comm/health/ph\_risk/committees/04\_scher/docs/scher\_o\_025.pdf

### 7.3. Antracene (HH)

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

http://europa.eu.int/comm/health/ph\_risk/committees/04\_scher/docs/scher\_o\_023.pdf

#### 7.4. Vinyl acetate (ENV)

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

### 7.5. Ethylbenzene (ENV)

The draft opinion on the environmental part of the RAR on ethylbenzene would be presented at the next plenary meeting.

#### 7.6. CMR classification of musk ketone

With a few corrections agreed upon, the opinion on the CMR classification of musk ketone was adopted and is available at:

http://europa.eu.int/comm/health/ph\_risk/committees/04\_scher/docs/scher\_o\_022.pdf

#### 8. NEW REQUESTS FOR OPINIONS BY COMMISSION SERVICES:

# 8.1. Risk assessment to the environment and health resulting from the use of phosphate fertilizers containing cadmium

The Czech Republic has notified the Commission that it wishes to maintain its pre-accession upper limit of cadmium in phosphate fertilisers. In support of their request for derogation, the Czech authorities submitted a report entitled "Study to assess risks to the environment and health, resulting from the use of phosphate fertilisers containing cadmium".

DG ENTR asked the SCHER to assess the overall scientific quality of the Czech report, the methodology used and to comment on appropriateness of the scenarios studied and the reliability and validity of the conclusions concerning the accumulation of cadmium in the soil. They also asked the Committee for comments on the conclusions concerning the current risk to human health and the environment and on the corresponding risks after 100 years.

Since the Commission must reply to the Czech notification within six months with a decision on whether or not to grant derogation, DG ENTR asked for the adoption of the opinion by the end of March. Considering this date too tight, the SCHER asked for a further 3 months delay for the adoption. DG ENTR agreed.

A SCHER working group was set up and an external *ad hoc* expert would be invited to join the group.

### 8.2. Indoor air quality

#### **8.2.1.** Air fresheners

The draft opinion was revised taking into account comments of the previous plenary, and proposed to the SCHER for adoption. During the meeting other amendments/corrections were introduced, in particular on the paragraph related to the evaluation of potential health risk for consumers and on answers to questions A and C.

The opinion has been adopted and is available at: http://europa.eu.int/comm/health/ph\_risk/committees/04\_scher/docs/scher\_o\_026.pdf

### **8.2.2.** *Main opinion*

The rapporteur informed the Committee that this part of the opinion was ongoing but the priority was given to the air fresheners' part.

## 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 first meeting of the group was held on 16 December 2005. The representative of SCHER attending the meeting reported back on the main points 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 the DEHP meeting reported back on the preliminary discussion.

#### 10. EMERGING ISSUES

No emerging issues were raised.

### 11. NEXT PLENARY MEETING

The next SCHER plenary meeting was confirmed as 17 March 2006.

#### 12. ANY OTHER BUSINESS

The Committee was informed that the procedure for the nomination of a new SCHER member had started.

### **Annex 1: List of participants**

# SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER) $9^{\text{TH}}$ Plenary Meeting

Held on 27 January 2006 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. VILUKSELA.

### **EUROPEAN COMMISSION:**

SCHER Secretariat (DG SANCO):

Ms. G. FONTANESI, Ms. C. DEKINDT, Ms. K. BROMEN.

## Other Commission staff:

Mr S. PICKERING (DG ENTR), Mr. DASKALEROS (SANCO), Mr. J. VOGELGESANG (SANCO).