

#### **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) 8<sup>th</sup> Plenary Meeting

Held on 25 November 2005 in Brussels

#### **MINUTES**

### 1. WELCOME AND APOLOGIES

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

Apologies: Prof. Calow, Dr Mangelsdorf, Prof Sokal, and 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. Janssen declared a conflict of interest in relation to item 9.1. Prof. Greim and Prof. Dekant declared also the same in relation to item 7.4 of the agenda due to their indirect involvement in the evaluation of the RAR on musk ketone. Prof. Greim also declared his participation on the REXPAN of the Reasearch Institute for fragrance material in relation to musk ketone. Prof. Dekant declared a possible conflict of interest in relation to item 7.3. Prof. Viluksela stated that he had possible conflict of interest in relation to item 8.1 of the agenda due to a submitted project on organostannic compounds (evaluation still pending). Taking into account the nature of the declarations, in each case the committee decided that they could participate in the discussion.

## 4. APPROVAL OF THE DRAFT MINUTES OF THE 7<sup>TH</sup> SCHER PLENARY MEETING

The minutes of the 7<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:**

The ICCG expressed concern on how important endpoints were addressed in the REACH. The group asked to be updated on the state of the discussion. It was decided that REACH would be a

fixed point of the agenda of the next ICCG meetings. DG ENV and ENTR would be invited to meet the ICCG to update the group on the current state of the discussion on REACH.

### 5.2. Workshop on chemical and physical mixture

DG JRC would organize a workshop on chemical and physical mixture at the beginning of 2006. The DG JRC representative attending the ICCG meeting invited members to express their interest in participating in the workshop.

### 5.3. Scientific Committees - work plan

The ICCG was informed of possible future requests for the three scientific committees. The Chairman reported on those concerning the SCHER and on some requests of possible common interest.

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

The SCHER was invited to send possible comments or information on topics which would be addressed in the Chairs meeting. The Chair who would attend the meeting and the SCHER secretariat would collect comments.

# 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 Vinyl acetate (ENV) and Ethylbenzene (ENV).

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

### 7.1. Antracene (HH)

A draft opinion on the human health part was presented. The Committee decided that reproductive toxicity information needed to be checked for conclusion i) or ii). The rapporteur would check this point and propose a revised draft opinion at the next plenary meeting.

#### 7.2. 2-ethoxyethyl acetate (ENV)

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

### 7.3. 2-methoxy-2-methylbutane (TAME; HH)

The draft opinion on the human health part of the RAR on Tame would be presented at the next plenary meeting.

### 7.4. CMR classification of musk ketone

The rapporteur needed to check more thoroughly other endpoints for classification of musk ketone. The draft opinion would be revised, completed and presented at the next plenary meeting.

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

# 8.1. Revised assessment of the risks to health and the environment associated with the use of the four organostannic compounds TBT, DBT, DOT and TPT

DG ENTR asked the SCHER to revise the updated RPA report "Risk assessment studies on targeted consumer applications of certain organostannic compounds". The mandate included nine terms of reference; among others, the SCHER was requested to assess the total integrated (food and non-food) risks for humans from organostannic compounds, in collaboration with EFSA.

A SCHER working group was set up. The secretariat would contact the coordinators of the EFSA Contaminant and the AFC panels to ask for the participation of some of their members in the joint working group. Subject to the EFSA reply, the SCHER would consider the involvement of external experts to be able to answer questions possibly not completely covered by SCHER and EFSA members.

The secretariat would also contact DG SANCO D5, interface Unit with EFSA.

## 8.2. Revised chapter for Human Health Risk Characterisation of the Technical Guidance Document (TGD)

DG ENV requested a SCHER opinion on the revised chapter for Human Health Risk Characterisation of the Technical Guidance Document on Risk Assessment. This chapter was developed over the last couple of years by a sub-group of the TC NES with participants from Member States, Industry and the Commission, for application to new and existing substances.

This chapter includes the recommendations of default assessment factors for assessing threshold effects and, where appropriate, approaches to quantitative assessment of non-threshold effects.

The SCHER was asked to consider the merits of this approach and possibly to give suggestions on possible alternative.

### 9. ONGOING REQUESTS FOR OPINIONS BY COMMISSION SERVICES ON:

## 9.1. Environmental risk assessment of non biodegradable detergent surfactants under anaerobic conditions

The text of the draft was revised and some parts reworded. The opinion was adopted and is available at:

http://europa.eu.int/comm/health/ph\_risk/committees/04\_scher/docs/scher\_o\_021.pdf

### 9.2. Non animal testing for endocrine disrupting chemicals

The opinion was adopted and is available at:

http://europa.eu.int/comm/health/ph\_risk/committees/04\_scher/docs/scher\_o\_015.pdf

## 9.3. Indoor air quality

### **9.3.1.** Air fresheners

Each part of the draft was thoroughly reviewed and discussed. The Committee decided that the document was not ready for adoption and the deadline requested by the mandate cannot be respected.

The main conclusions discussed were:

- <u>1.</u> The insufficient information provided by the BEUC report to allow an appropriate risk characterization; such as:
  - The insufficient information provided on exposure peak levels.
  - The lack of information on continuous exposure concentrations and background levels from indoor and outdoor sources.
  - The questionable use of "limit values" for risk characterisation, those values being designed for long term (lifetime) exposure and
  - The lack of information on the contribution of compounds released from air fresheners' use to other sources like food, cosmetics etc...
- 2. It was decided to primarily comment on the quality of the BEUC report rather than to provide a SCHER risk assessment on air fresheners' exposure.

## **9.3.2.** Main opinion

This part of the opinion was ongoing but the priority was given to the air fresheners' part.

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

- **10.1.** EFSA: Working group on BMD. The first meeting of the group was confirmed for mid December. A representative of SCHER was invited to attend the meeting.
- **10.2.** EMEA: Conference on environmental risk assessment for human and veterinary medicinal products, 27-28 October 2005, in London. The representative of SCHER attended the meeting and reported back main points of the workshop discussion.
- **10.3.** SCENIHR: The Committee would set up a joint working group on DEHP (di-2-ethylexylphthalate) in medical devices and asked the SCHER for possible volunteers to participate in the group. Three members of the Committee volunteered.

### 11. EMERGING ISSUES

No emerging issues were pointed out.

### 12. NEXT PLENARY MEETINGS

Dates for the 2006 SCHER plenary meetings were confirmed as follow: 27 January, 17 March, 4 May, 4 July, 19 September, and 30 November.

### 13. ANY OTHER BUSINESS

The Committee was informed of the EFSA call for members.

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

## SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER) $8^{\text{TH}}$ Plenary Meeting

Held on 25 November 2005 in Brussels

### LIST OF PARTICIPANTS

#### **MEMBERS OF THE SCHER:**

Prof. H. AUTRUP, 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, 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

### Other Commission staff:

Mr. S. BRION (DG ENTR), Mr S. PICKERING (DG ENTR), Mr S. BINTEIN (DG ENV), Ms A. HUICI MONTAGUD (DG EMPL), Ms. B. SCHWARZ-SCHULZ (DG JRC)