

#### **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) $\mathbf{20}^{\text{TH}} \quad \text{Plenary Meeting}$

Held on 29 November 2007 in Brussels

#### **MINUTES**

### 1. WELCOME AND APOLOGIES

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

Apologies: Prof. H. Autrup

### 2. ADOPTION OF THE DRAFT AGENDA

The draft agenda was adopted as written

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

Prof. J. Tarazona declared a possible conflict of interest in relation to item 7.11 and 7.12 since even if he was not directly involved on the human part of the two RARs on nitrotoluenes, a laboratory of his department was involved

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 9.1 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 9.2 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.

In relation to item 8.1, Prof. W. Dekant declared his involvement in the preparation of the EFSA opinion on poultry treatment with antimicrobials adopted on December 2005.

E. Testai declared a conflict of interest in relation to item 6.3 of the agenda, since she was involved in the drafting of the HH-part

# 4. APPROVAL OF THE DRAFT MINUTES OF THE 19<sup>th</sup> SCHER PLENARY MEETING

The minutes of the 19<sup>th</sup> SCHER plenary meeting were adopted.

### 5. CHAIR'S REPORT ON THE INTER COMMITTEE COORDINATION GROUP (ICCG)

## 5.1 Third meeting of Chairs - Stockholm, 6-7th November 2007

Two working groups discussed on how to move towards a common risk assessment framework. Both groups should discuss the following topics:

- -Mandate, goal, objectives, of these meetings, role, future developments, harmonisation of procedures
- Emerging risks/Rapid risk assessment: Definitions, terminology, methodology
- Follow up and monitoring the impact of the Risk Assessments
- Coordination of risk assessment, data needs within RTD framework process

### 5.1.2 Rapid Advice Procedure

When assessments are performed during crisis, it is necessary to nominate them differently from the ones delivered in time of peace (i.e. preliminary advice, statement...).

There is a need to coordinate agencies when involved during a crisis meaning that would be necessary to create an "operational crisis group".

### 5.1.3 Planned meetings for 2008

Some meetings have been planned in 2008:

- antimicrobial resistance in January
- emerging risks foreseen for February and March, which would also involve the Joint Research Centre (JRC)
- international seminar on nanotechnologies to be organized in Brussels in October
- international risk assessment conference in November
- terminologies in May

### **5.2 Inter Committee Coordination Group (ICCG)**

### 5.2.1 Presentation on RA Training and Terminology on non-food RA

Prof. T. Hardy and Dr. A. Hart of the Central Science Laboratory, York, UK, presented the results on two tenders:

 An inventory of risk assessment training relevant to the non-food scientific committees The objective of this exercise was to compile a list of formal and practical risk assessment (RA) training schemes and to identify sources of training available within Europe.

The final report would be circulated for information and published on the website. It was proposed to provide a possibility for feedback on additional courses offered to ensure a regular update of the list.

# A comparative review of risk terminology used by the non-food scientific committees

The aim of the activity was to undertake a comparative review of the terms and expressions used by different former and present non-food scientific committees in order to identify best practices in the expression of complex ideas used in RA. The final report would be published.

This issue would be further discussed in a specific workshop and at a meeting on terminology to be organized by the European Environmental Agency (EEA) in May 2008. The follow-up would be discussed at the next meeting of the ICCG.

Commission would plan meetings on RA training with MS representatives and universities to identify activities and discuss possible ways for improvement.

### 5.2.2 Possible new requests for SCHER:

### MDI respiratory allergy:

A study protocol financed by industry and designed by experts from FP6 research programme on respiratory allergy might be submitted to SCHER after finalisation.

### Phthalates in school supplies

The Danish Environmental Protection Agency (EPA) has recently analysed phthalates in school supplies such as school bags, play bags, pencil cases and erasers. From the concentrations found for DEHP and DINP in erasers, the Danish EPA considers that sucking and ingesting small amounts of such erasers over an extended period could be harmful to a child. SCENIHR work on such substances in medical devices might also be used to support work.

# 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 RARs on Diphenylamine (CAS 122-39-4; HH), Bis(hydroxylammonium) sulphate (BHAS; CAS 10039-54-0; HH), Sodium hypochlorite (CAS 7681-52-9; ENV + HH), Pitch, coal tar, high-temp. (CTPHT; CAS 65996-93-2; HH), Hexabromocyclododecane (HBCDD; CAS 25637-99-4; ENV + HH) and Styrene (CAS 100-42-5; HH)

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

### **7.1 Zinc (ENV)**

The opinion was adopted with minor typos corrections. It was discussed if this opinion, considered quite important and of relevance to general RA of heavy metals, should be distributed widely (i.e. published). Concerns were raised that SCHER should be careful not to duplicate other possible recent publications which might cover the same subject.

ENV declared that due to the critical opinion, they will follow-up closely on the subject. SCHER offered further discussion if needed, as done for cadmium.

The opinion is available at:

http://ec.europa.eu/health/ph\_risk/committees/04\_scher/docs/scher\_o\_069.pdf

# $7.2\ 2,2$ -bis(chloromethyl) trimethylene bis(bis(2-chloroethyl) phosphate) (V6; ENV)

A few comments on effects section were made. The opinion on the environmental part of the RAR on V6 was adopted and is available at:

http://ec.europa.eu/health/ph\_risk/committees/04\_scher/docs/scher\_o\_067.pdf

### 7.3 Tris [2-chloro-1-(chloromethyl) ethyl] phosphate (TDCP; ENV)

The opinion on the environmental part of the RAR on TDCP was adopted and is available at:

http://ec.europa.eu/health/ph risk/committees/04 scher/docs/scher o 068.pdf

# 7.4 2-furaldehyde (ENV)

Many open questions and discussion about fish test. The original study was received unofficially from MS. This was seen critically by members so ECB will contact Rapporteur officially for authorisation of use of the original study. It was proposed to also include algae data.

Information and updated draft would be expected for the next meeting

# 7.5 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (tetrabromobisphenol-A; ENV)

The draft would be discussed at the next meeting

### 7.6 Alkanes, C14-17, chloro (MCCP; HH)

The read-across approach in carcinogenicity from SCCP to MCCP seems to be a problematic point. Some specific points were discussed and modifications will be made by the rapporteur. An updated version will be proposed at the next plenary.

### 7.7 N-Cyclohexylbenzothiazol-2-sulphenamide (CBS; HH)

Reproductive toxicity seems to be a problematic point. ECB explained that the proposed classification was already been discussed, and it would not be classified for reprotoxicity. SCHER should look at the report of the classification group to check argumentation; ECB will check the access to the report.

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

# 8.1 Environmental impact and effect on antimicrobial resistance of four substances used for the removal of microbial surface contamination of poultry carcasses

The first draft was presented; the final report would be foreseen for adoption at the March plenary. SANCO E2 gave some background information about the use of these substances. This was considered quite important and E2 would be invited to explain more

about this use at the next WG meeting. E2 stressed the importance of the March deadline with regard to the planned regulatory actions. More background documents would also be provided by E2.

# 8.2 Risk assessment methodologies and approaches for mutagenic and carcinogenic substances

The Rapporteur shortly reported back on the first meeting of the WG.

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

A final version was circulated to the committee before the plenary. Since no further comments were received from external WG members nor from the Committee, the opinion was adopted and is available at:

http://ec.europa.eu/health/ph\_risk/committees/04\_scher/docs/scher\_o\_066.pdf

# 8.4 Use of Hg in dental amalgam

Two new sentences explaining a calculation that were proposed by the WG were agreed and included. It was decided to make a reference to the SCENIHR opinion in the chapter on alternatives to amalgams. With minor changes for clarification on the part related to the screening RA, the document was approved as preliminary report for public consultation.

Information on the public consultation is available at:

http://ec.europa.eu/health/ph\_risk/committees/04\_scher/docs/scher\_o\_070.pdf

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

#### **9.1 EFSA**

BMD: the work was still ongoing.

### 10. EMERGING ISSUES

A proposal for a topic that should be evaluated was put forward. Some concerns were stated about the availability of data and suitability of the substances for assessment. SCHER agreed that an updated proposal would be mailed to the secretariat for discussion by the Commission.

ECB stated that there was a recent update on the HH and ENV part of the decaBDE, which might be interesting in this respect.

#### 11. NEXT PLENARY MEETING

The next SCHER plenary meeting was confirmed as 15 January 2008.

### 12. ANY OTHER BUSINESS

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

### Annex I

# SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER) $20^{\text{TH}}$ Plenary Meeting

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### LIST OF PARTICIPANTS

#### MEMBERS OF THE SCHER:

Prof. P. CALOW, Prof. W. DEKANT, Prof. Dr. H. GREIM (Chair), Prof. W. HANKE, Prof. C. JANSSEN, Prof. B. JANSSON, Prof. H. KOMULAINEN, Prof. O. LADEFOGED, Prof. J. LINDERS, Dr. I. MANGELSDORF, Prof. M. NUTI, Prof. STEENHOUT, Prof. J. TARAZONA (vice Chair), Dr. E. TESTAI, Prof. M. VIGHI, Prof. M. VILUKSELA.

### **EUROPEAN COMMISSION:**

SCHER Secretariat (DG SANCO):

Mrs. K.KILIAN, Mrs. I. COPPOLA.

### Other Commission staff:

Mr. B. LUND (DG JRC); Mrs. G. LUVARA' (DG ENTR); Mr. S. PICKERING (DG ENTR)