



**SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER)**  
**12<sup>TH</sup> PLENARY MEETING**

*Held on 4 July 2006*  
*in Brussels*  
**MINUTES**

**1. WELCOME AND APOLOGIES**

Prof. Greim, Chair of the Committee, opened the meeting and welcomed the participants. The Chair introduced Prof Linders who attended the meeting as SCHER external expert on environmental issues.

Apologies: Prof Hanke, Prof Sokal.

**2. ADOPTION OF THE DRAFT AGENDA**

The draft [agenda](#) was adopted as written, with a few changes in the order of points under discussion.

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

Dr. Tarazona declared an interest in relation to items 6.1 and 6.2 being supervisor of the two reports on nitrotoluene prepared by Spain. Dr. Mangelsdorf declared an interest in relation to item 9.2 using the TGD to prepare dossiers for industry.

Taking into account the nature of the declarations, the committee decided that they could participate in the discussions on those matters but Prof. Tarazona could not be nominated as possible Rapporteur of the opinions on nitrotoluene.

**4. APPROVAL OF THE DRAFT MINUTES OF THE 11<sup>TH</sup> SCHER PLENARY MEETING**

The [minutes](#) of the 11<sup>th</sup> SCHER plenary meeting were adopted with a few minor corrections.

## **5. CHAIR'S REPORT UPDATE ON THE COORDINATION MEETING OF 3 JULY 2006 ON MATTERS OF INTEREST TO THE SCHER**

### **5.1. Alternatives to animal tests: Scientific Committee Position Statement**

The statement on in vivo/in vitro test was accepted by the three scientific committees. It was decided that the document should be published.

### **5.2. Mid term review of the Scientific Committees activities**

An external consultant was contracted to undertake the intermediate evaluation of the functioning of the SANCO non-food Scientific Committees. For the evaluation they contacted Chairs and vice-Chairs, secretariat and responsible of different EC services who were interviewed for about one hour. The evaluation was also based on case studies (published opinions).

### **5.3. Renewal of the scientific Committees**

For the next call it was highlighted the importance of a great publicity to maintain the interest of high level experts on the work of the scientific committees and consequently receive their application for membership. It was suggested to inform external experts, experts in different areas, universities, etc... in view of the future call.

In the ICCG meeting it was also proposed to contact scientific journals to explore the possibility for publication of some of the opinions of the committees. This would make the work of the Scientific Committees more visible to the public. New requests on Regulation 793/93 Existing Substances (ESR): (Human Health and/or Environment)

A Rapporteur was appointed to comment on the Risk Assessment Reports (RAR) on 2-nitrotoluene (CAS No: 88-72-2, ENV) and 2, 4-dinitrotoluene (CAS No: 121-14-2, ENV).

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

### **6.1. Benzyl butyl phthalate (BBP; ENV)**

The opinion on the environmental part of the RAR on BBP was amended on the basis of the previous discussion and adopted. The opinion is available at:

[http://ec.europa.eu/health/ph\\_risk/committees/04\\_scher/docs/scher\\_o\\_037.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_037.pdf)

### **6.2. Tris (nonylphenyl) phosphite (TNPP; HH)**

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

[http://ec.europa.eu/health/ph\\_risk/committees/04\\_scher/docs/scher\\_o\\_039.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_039.pdf)

### **6.3. Tris (2-chloroethyl) phosphate (TCEP; ENV)**

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

[http://ec.europa.eu/health/ph\\_risk/committees/04\\_scher/docs/scher\\_o\\_038.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_038.pdf)

## **7. NEW REQUESTS FOR OPINIONS BY COMMISSION SERVICES ON:**

### **7.1. Questions arising in the context of Dutch Notification 2003/0201/NL concerning the risks arising from the use of copper-based antifouling paints used in leisure boating**

Based on the CSTEE [opinion](#) of 19 September 2003, the Commission delivered a detailed opinion pursuant to article 9.2 of Directive 98/34/EC against the Dutch draft on 27.11.2003 in which The Nederland notified the Commission a draft text by which the Pesticides Licensing Board (PLB) intends to extend application of the standards and criteria laid down in the Decree on environmental licensing requirements for pesticides.

Several exchanges of information and communication have been followed between EC and the Dutch authorities including two additional documents on approaches to address bioavailability in the case of copper in risk assessments provided by the Dutch Government to the Commission.

In its communication of 3 February 2006 the Commission indicated to the Dutch authorities that it needed to analyse the above mentioned RIVM Reports before taking a position. Having examined the reports and having heard the opinion of the interested economic operators, the Commission services decided to submit additional questions to the Scientific Committee on Health and Environmental Risks (SCHER)

The SCHER is asked to give an opinion on the scientific sound of the analysis of the four methods to determine bioavailability described in the RIVM report and if the Committee agrees with conclusions of the report on uncertainties associated with the individual methods. The SCHER is also asked whether they consider those methods suitable to determine the bioavailability of copper in the context of environmental risk assessments for regulatory purposes.

A SCHER working group was set up and will meet in September.

### **7.2. Health and Environmental risks on CEN's response to the opinion of the CSTEE on assessment of CEN report on the risks assessment of organic chemicals in toys**

In March 2003 the CSTEE was requested to give an opinion on the European Committee for Standardisation (CEN) report on the risk assessment of organic chemicals in toys.

In its [opinion](#) of 9 January 2003, the CSTEE concluded that there were numerous inconsistencies and errors in the report, e.g. the report focuses on hazards and not on risk assessment, it does not

make a clear distinction between risk assessment and risk management, it does not follow the European Chemicals Bureau (ECB) approach and there are deficiencies in the outcome of the implementation of the ranking system. Therefore, the approach followed does not provide a suitable basis for setting standards.

On the 19<sup>th</sup> of January 2006, CEN sent the Commission services a request to publish in the Official Journal the reference numbers of the three standards on organic chemicals that have been approved by CEN members, that is EN 71:9 (Organic chemical compounds – Requirements), EN 71:10 (Organic chemical compounds – Sample preparation and extraction) and EN 71:11 (Organic chemical compounds – Methods of Analysis), in order for them to give presumption of conformity to the essential safety requirements of the Directive 88/378/EEC.

On the basis of the above, the Committee is requested to give its opinion on whether the CEN response is sufficient to reassure the Committee about the concerns raised in the opinion of the CSTEE and whether if the evaluation of the Committee is positive, the report as completed by the CEN, can be used for setting standards on organic chemicals.

A SCHER working group was set up. A member of the SCENIHR will be also contacted by the secretariat and invited to be part of the group.

### **7.3. Research needs**

A new mandate for an opinion on possible research needs to be included in calls for the 7 Framework Program will be send by DG RTD. Due to the urgency of the issue, a working group was set up and the possible first meeting proposed for end of August.

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

### **8.1. Indoor air quality**

The rapporteur presented the updated draft opinion. This version of the draft was originally intended to be adopted and put on the SCHER web site for public consultation. However, it was decided that this version of the opinion was not ready for pre-adoption because the reply to question 2 was too vague. The draft opinion would be amended giving justification and prioritisation for research needs.

Moreover, the chapter of the draft related to the vulnerable groups, in particular children would need to be clarified.

### **8.2. Organotins**

The rapporteur reported back on the discussion in the last working group meeting. Contributions were received from some of the working group members and the first draft opinion would be discussed in the working group meeting of September.

### **8.3. TGD - risk characterisation**

A new version of the draft taking into account comments from the previous plenary and Commission services was presented to the plenary. DG JRC notified that they were still not in agreement with some parts of the draft opinion and asked for another meeting with the group to clarify their view. Another meeting was tentatively proposed for the end of August.

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

**SCENIHR:** Joint working group on DEHP (di-2-ethylexylphthalate) in medical devices: a first preliminary draft opinion was discussed in the working group meeting of June. Combined exposure to various plasticizers was considered an important point since it could produce additive effects on human health.

The next working group will be held end of July

## **10. EMERGING ISSUES**

No emerging issues were raised.

## **11. NEXT PLENARY MEETING**

The next SCHER plenary meeting was confirmed for 19 September 2006.

## **12. ANY OTHER BUSINESS**

### **12.1. SETAC 2007**

The next annual meeting of SETAC Europe will be held in Porto in May 2007. It includes a specific topic on Political and Socio Economic Aspects of Environmental Issues. It was suggested that a session on the role of EU Scientific Committees, contributions and future expectations could be attractive. It was also proposed that the session could be chaired by SCHER members and held In Memoriam of Jeff Vos.

### **12.2. Environmental risk assessment of chemicals in soils amendments**

Despite the benefits linked to the use of animal manure and organic matter as fertilizers, the presence of toxic components and their potential risks for human health and the environment, represent a concern that has been addressed several times by former CSTEE and SCHER. It was highlighted in particular, that it was urgent to propose a harmonized European scenario and methodology on these issues and that the Commission should ask an opinion on this issue. SCHER also suggested that a joint group including experts from Scientific committees, external experts and experts from EFSA and EMEA should be set up to work on the opinion.

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

## **Annex I**

<p style="text-align: center;"><b>SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER)</b> <b>12<sup>TH</sup> PLENARY MEETING</b></p>
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### **LIST OF PARTICIPANTS**

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

Prof. H. AUTRUP, Prof. P. CALOW, Prof. W. DEKANT, Prof. Dr. H. GREIM (Chair), Prof. C JANSSEN, Prof. Bo JANSSON (Vice Chair), Dr. 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, Dr. M. VILUKSELA.

#### **EXTERNAL EXPERT:**

Prof. J. LINDERS

#### **EUROPEAN COMMISSION:**

##### ***SCHER Secretariat (DG SANCO):***

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

##### ***Other Commission staff:***

Mr S. PICKERING (DG ENTR), Mrs. K. GRODZSKI (DG ENTR), Mr. S. KIOKIAS (DG ENTR). Mr T. DASKALEROS (DG SANCO), Mrs. S. MUNN (DG JRC)