



**SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER)
13TH PLENARY MEETING**

*Held on 19 September 2006
in Brussels*
MINUTES

1. WELCOME AND APOLOGIES

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

Mr Delogu, new Head of Units of Sanco C7, introduced himself to the Committee.

Apologies: Prof. Autrup, Prof. Calow, Prof. Ladefoged, Dr. Mansgeldorf, Prof. Sokal,
Prof. Tarazona.

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

Prof. Linders declared an interest in relation to item 8.2 since he was involved in the EFSA opinion on harmonized scientific approach in Europe to assess the environmental risks posed by substances used in animal feed.

Taking into account the nature of the declarations, the committee decided that he could only participate in the discussion for possible clarifications.

All members of the Committee decided to declare a possible interest related to point 8.2 and 9.6 since some part of the discussion might touch aspects of their work, as they were all involved in research.

4. APPROVAL OF THE DRAFT MINUTES OF THE 12TH SCHER PLENARY MEETING

The [minutes](#) of the 12th SCHER plenary meeting were adopted without corrections.

5. CHAIR'S REPORT

5.1. Visibility of the Scientific Committees

The chair informed the Committee that some editors of relevant scientific journals were contacted and that some were interested in the publication of opinions or summaries concerning specific topics.

Since most of these journals are related to human health it was proposed to contact also journals which include more specific environmental aspects.

Two members of the Committee volunteered to find a relevant editor to be contacted.

5.2. Chairs meeting

The Chair informed the Committee of the next Chair meeting which will be held on 24-25 October 2006.

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

6.1. Two Rapporteurs were appointed to comment on the Target Risk Assessment Reports (TRAR) on Sodium hydroxide (CAS No: 1310-73-2; ENV and HH).

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

7.1. 2-nitrotoluene (ENV)

The opinion on the environmental part of the RAR on 2 nitrotoluene was adopted with minor changes. The opinion is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_042.pdf

7.2. 2,4-dinitrotoluene (ENV))

The opinion on the environmental part of the RAR on 2, 4 dinitrotoluene was adopted with minor changes. The opinion is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_041.pdf

8. NEW REQUESTS FOR OPINIONS BY COMMISSION SERVICES ON:

8.1. EFSA Public consultation: Harmonized scientific approach in Europe to assess the environmental risks posed by substances used in animal feed – DG SANCO

The EFSA panel on additives and products or substances used in animal feed (FEEDAP) has drafted a working document which gives an overview of the current situation concerning the environmental risk impact of feed additives, with regard to farming and aquaculture practices in Europe.

Before the final adoption, the draft opinion has been put on the EFSA website for public consultation.

Following Commission Decision 2004/210/EC establishing the non-food Scientific Committees and Regulation 178/2002 establishing the EFSA, which include provisions to avoid divergences of scientific opinions, DG SANCO asked the SCHER to contribute to the public consultation of the EFSA document.

Some members of the SCHER volunteered to prepare a draft to be circulated to the Committee members and to be adopted by written procedure within the deadline of 31 October 2006 set by the EFSA.

8.2. Research priorities for the 7th Framework Program - Human Health and Environment – DG Research

DG Research submitted a request for an opinion on possible research needs to be included in calls for the 7th Framework Program (7th FP) which should be launched by the end of 2006 and which will include a theme called 'Environment and Health'.

This theme will fund research projects under three areas: (i) Health effects of exposure to environmental stressors; (ii) Integrated approaches for environment and health risk assessment; (iii) Delivery of methods and decision support tools for risk analysis and policy development.

Due to the urgency of the issue the proposal for the request was already discussed in the previous SCHER plenary meeting with the responsible Commission services and a working group was set up. DG Research also requested that the opinion be adopted by 31 October 2006 for research priorities linked to the first call of the 7th FP.

Due to this deadline, the working group already met at end of August and prepared a draft opinion to be discussed in the present plenary meeting (see item 9.6 below).

9. ONGOING REQUESTS FOR OPINIONS BY COMMISSION SERVICES ON:

9.1. Cadmium in fertilizers

The Czech Republic has notified the Commission that it wishes to maintain its pre-accession upper limit of cadmium in phosphate fertilisers.

DG ENTR asked the SCHER to assess the overall scientific quality of the report “Study to assess risks to the environment and health, resulting from the use of phosphate fertilisers” prepared by the Czech Republic in support of their request for derogation.

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.

The SCHER is of the opinion that despite the abundance of available monitoring data presented, they were not used in a manner which would address the question on possible future risks for the environment and human health.

A major SCHER concern is the use of PNEC values for the determination of the environmental risk characterisations ratios (PEC/PNEC). Indeed, the PNEC values used in the report are different than those proposed by the EU draft RAR on Cd oxide and metal. The SCHER is of the opinion that the risk characterisation ratios derived in the Czech report could be influenced by these different PNECs values.

The SCHER is of the opinion that the scenarios assessed in the Czech report for human health are insufficient to allow a reliable evaluation of the long term Cd accumulation. More detailed information on the actual intake of cadmium by the Czech population should be given or the worst case scenarios should be used.

The lack of detail in the exposure assessment scenarios and a rather conservative PEC value does not allow the presence or absence of the risk of Cd to Czech soil resulting from the application of the Cd containing phosphate fertilizers to be described.

The opinion was adopted with minor corrections and is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_043.pdf

9.2. Organotins

The rapporteur reported back briefly on the issue. The next working group meeting will be held mid October.

9.3. TGD - risk characterisation

An updated version of the draft taking into account comments from the previous plenary and Commission services was presented to the plenary.

The SCHER acknowledges the efforts that have been undertaken to revise and update the human health risk characterisation chapter of the TGD which describes all necessary tools and procedures for the risk assessment of chemical substances and, in particular, of those chemicals with limited or insufficient data.

However, the SCHER has major concerns on the preferred and general use of uncertainty assessment factors and their combination. In its conclusion the SCHER recommends that the TGD clearly requires a case-by-case evaluation considering the specific data available for any specific substance before using any default assessment factor. This implies that, before any default assessment factors are applied, an expert evaluation of the available database is done to verify whether the data is sufficient and reliable for a sound risk assessment of the substance.

SCHER also notes that the proposed methodologies are sometime incomplete and not transparent, and that, therefore, a high probability exists for inconsistencies and unrealistic outcomes in the resulting risk characterisation process.

The proposed version of the opinion was adopted and is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_040.pdf

DG JRC notified that they were not happy with the conclusion of the SCHER opinion.

9.4. Indoor air quality

The draft opinion was updated taking into account comments from the last plenary meeting and DG SANCO. The SCHER decided that in particular the reply to Q4 should be better addressed. An updated draft opinion would be presented at the next plenary.

9.5. Copper in antifouling paint

A new draft will be circulated to the WG and proposed at the next plenary meeting for possible adoption.

9.6. Research needs

The preliminary draft opinion includes recommendation for research on specific areas in the field of environmental impact of certain pollutants on reproduction and development, health impacts of indoor air quality, human biomonitoring. Recommendations will follow on a proposal for research in the field of the impact of environmental stressors on the health of ecosystems.

The final draft opinion will be circulated to the SCHER mid October 2006 and proposed for adoption by written procedure before the deadline of 31 October.

10. 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. The member of SCHER involved in the work reported back briefly on the last working group discussion.

SCENIHR: The Working Group on TGD on nanomaterials is looking for possible information concerning criteria for toxicity evaluation, tests and methods already proposed for nanomaterials.

11. EMERGING ISSUES

No emerging issues were raised.

12. NEXT PLENARY MEETING

The next SCHER plenary meeting was confirmed for 30 November 2006.

Four plenary meetings were also agreed for 2007: 30 January, 23 March, 29 May and 19 July. The remaining two plenary meetings will be decided in the next plenary.

13. ANY OTHER BUSINESS

No other business.

Annex 1: List of participants

Annex I

<p style="text-align: center;">SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER) 13TH PLENARY MEETING</p>

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LIST OF PARTICIPANTS

MEMBERS OF THE SCHER:

Prof. W. DEKANT, Prof. H. GREIM (Chair), Prof. HANKE, Prof. C JANSSEN, Prof. Bo JANSSON (Vice Chair), Dr. H. KOMULAINEN, Prof. J. LINDERS, , Prof. M. NUTI, Prof. A. STEENHOUT, Dr. E. TESTAI, Prof. M. VIGHI, Dr. M. VILUKSELA.

EUROPEAN COMMISSION:

SCHER Secretariat (DG SANCO):

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

Other Commission staff:

Mr S. PICKERING (DG ENTR), Mrs. S. SCHWARZ-SCHULZ (DG JRC)