

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) 2ND Plenary Meeting

Held on 14 December 2004 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

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

Apologies: Prof. Autrup and Prof. Nuti

2. ADOPTION OF THE DRAFT AGENDA

The draft **agenda** was adopted

3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

Prof. Mangeldorf declared a conflict of interest in relation to phenol and 1-propan-ol items 6.2 and 7.3 in the agenda.

Prof Janssen declared a conflict of interest in relation to PFOS, item 9.3 in the agenda.

The Committee agreed that they could participate in the discussion, but can not be nominated for Chairman or Rapporteur of the related Working Groups.

No other interests were declared.

4. APPROVAL OF THE DRAFT MINUTES OF THE 1ST SCHER PLENARY MEETING

The draft minutes of the 1st SCHER plenary meeting were adopted and are available at: <u>http://europa.eu.int/comm/health/ph_risk/committees/04_scher/04_scher_minutes_en.htm</u>

5. CHAIR'S REPORT

5.1. Update on the Coordination meeting of 13 October 2004 on matters of interest to the SCHER

The chair summarized the objectives of the coordination group and highlighted the importance of this group in harmonizing and assisting the scientific work of the three committees.

During the meeting the Chairs of the three Committees share information on activities undertaken by their own Committees. They agreed to circulate new questions to the group and inform the Secretariat of any potential overlaps that they noticed.

The common templates for opinions, agenda and minutes were also discussed.

5.2. Info meeting of 18 November on Regulation 793/93

A meeting concerning risk assessment on existing substances was held with the aim of informing the new members of the SCHER on the work related to the opinions on the risk assessment reports. A representative of DG JRC attended the meeting and presented a short overview of Regulations 793/93 and 1488/94.

The structure and the format of both opinions related to Regulation 793/93 and "ad hoc" opinions were also discussed. It was agreed that, whenever possible, a preliminary draft opinion or points to discuss should be prepared and presented to the first meeting of the appropriate working group for discussion.

5.3. EFSA working group GENTOX: approach for the risk assessment of compounds with both genotoxic and carcinogenic properties.

The scientific committee of the European Food Safety Authority is preparing an opinion on a harmonized approach of the risk assessment of compounds with both genotoxic and carcinogenic properties.

Dr Knaap, Chair of EFSA working group "GENTOX" informally presented to the Coordination Group the current state and views of the EFSA working group on this issue. The exchange of points of view with members of the SANCO Scientific Committees was appreciated and two members were invited to participate, as external experts, in the EFSA working group meeting foreseen for 21 and 22 October 2004.

It was agreed that the SCHER would be the lead Committee to express an opinion on this topic. Members from SCCP and SCENIHR will also be invited to participate in the working group.

5.4. Representatives in SCENIHR nanotechnology working group: SCHER contribution

The SCENIHR asked for a member of the other two Committees to contribute to the working group on nanotechnology.

Two SCHER members with human health expertise and one environmental expert volunteered for this group.

6. New requests on Regulation 793/93 Existing Substances (ESR): (Human Health and/or Environment)

Rapporteurs were appointed to comment on the final draft Risk Assessment Reports on 2-Methoxy-2-methylbuthane (ENV), Deca BDE (ENV), Phenol (HH), 2 – Furaldehyde (HH).

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

7.1. Benzyl butyl phthalate (HH)

A draft opinion on the human health part was presented. The main comment centred on reproductive toxicity and in particular on the report proposal for category 3. The rapporteur will check this part of the report and will propose a revised opinion at the next plenary meeting.

7.2. Tert-butyl hydro peroxide (ENV)

After a presentation by the rapporteur of the draft opinion on the risk assessment report, the opinion on the environmental part was adopted. It is available at: <u>http://europa.eu.int/comm/health/ph_risk/committees/04_scher/docs/scher_o_004.pdf</u>

7.3. Propan-1-ol (ENV)

The rapporteur presented a draft opinion on the results of the environmental risk assessment of Propan-1-ol. The draft will be revised taking comments from the Committee into account and will be presented at the next plenary meeting.

7.4. Trisodium nitrilo triacetate (ENV)

With a few corrections agreed upon, the opinion on the environmental part of the RAR on Na₃ NTA was adopted and is available at: http://europa.eu.int/comm/health/ph risk/committees/04 scher/docs/scher o 001.pdf

8. NEW REQUESTS FOR OPINIONS BY COMMISSION SERVICES ON:

8.1. Compatibility of the ISO standard 10708 (biodegradability test method) with the ultimate biodegradability requirements imposed through Annex III of Regulation 648/2004 of Parliament and of the Council

DG ENTR has sent a new request regarding the compatibility of the biodegradability test method, ISO standard 10708. The SCHER is asked to give an opinion whether the methodology and the pass criterion of this standard are comparable to those of the other OECD methods included in Annex III of the Regulation 648/2004.

A working group was set up and an external *ad hoc* expert on surfactants' biodegradation will be invited to join the working group.

8.2. Launching of a study carried out by the Phosphate industry related to the quantitative cause-effect relationship of sodium tri-polyphosphate-based detergent on the eutrophication process

In a previous CSTEE opinion on phosphate-related eutrophication¹, the Committee concluded that a quantitative assessment should be performed of the extent of eutrophication within the enlarged EU in relation to sodium tri-polyphosphate-based detergents load from different sources.

In relation to a proposed request from DG ENTR regarding an opinion on the methodology to be used in a proposed study which aims at responding to the above mentioned CSTEE opinion, the SCHER decided not to be formally involved at this stage of the project. It was agreed with DG ENTR that the committee will give its opinion on the final report resulting from that study.

8.3. New evidence of air pollution effects on human health and the environment

DG ENV is considering the possibility of revising the Community air quality legislation. The proposal should build on the new evidence of air pollution effects on health and the environment available from several sources (WHO, UN ECE Convention on Long-range Air Pollution, expert groups of the Commission and research projects).

Before making its proposal, DG ENV would like to receive the scientific opinion of the SCHER on key questions related to airborne particulate matter and ozone. A deadline of 18 March, the date of the 4th SCHER plenary meeting, was fixed for the adoption of the opinion.

A working group was set up and external experts on particulate matter and ozone will be invited to join the working group.

8.4. Risk assessment of substances in construction products in contact with drinking water

The request is not yet finalized but may be presented to the Committee at the next plenary.

9. ONGOING REQUESTS FOR OPINIONS BY COMMISSION SERVICES ON:

9.1. Effectiveness of vapour retardants in reducing risk to human health from paint strippers containing dichloromethane

An ETVAREAD study was launched by the Commission to evaluate the existing scientific information in the literature on the effectiveness of vapour retardants in

¹ <u>http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out202_en.pdf</u>

reducing risk to human health from paint strippers containing dichloromethane (DCM). The study includes additional laboratory tests that deliver useful data for the evaluation.

Based on the outcome of the investigation, the Commission would consider launching a proposal restricting the marketing and use of specific paint stripper products which pose unacceptable risks.

The SCHER was requested to assess the overall scientific quality of the ETVAREAD report.

In its preliminary draft the Committee concluded that the study describes a proper experimental setup to determine the DCM emissions from the use of paint strippers. However, since the composition of tested products is not given and the uncertainty in the measurements is not properly determined, it is difficult to judge the influence of vapour retardants. Moreover, the working group agreed that some important points which have been disregarded in the report should be addressed.

The combined working group will convene again in January 2005. A draft opinion will be possibly proposed for adoption at the next plenary.

9.2. Environmental risk assessment of non biodegradable detergent surfactants under anaerobic condition

The working group cannot convene before the plenary meeting. They will meet in January and report back at the next plenary.

9.3. RPA's report "Perfluorooctane Sulphonate - Risk reduction strategy and analysis of advantages and drawbacks"

The SCHER was requested to assess the overall scientific quality, methodology and conclusions of the RPA report on PFOS. The Committee was also asked to evaluate the contribution of the ongoing uses to the overall risks for the environment and to human health.

The rapporteur presented a preliminary draft opinion which circulated among the working group members. In this preliminary document the working group concluded that reported findings were generally adequately substantiated and the recommendations justified, although uncertainty remains with regard to the actual usage of PFOS and PFOS related substances in consumer products. The Committee also agreed that a risk assessment of all substitutes should be conducted where not yet available.

They also concluded that it is difficult to judge the contribution of the confirmed ongoing industrial/professional uses to the overall risks for the environment and to human health, because of the limited data available on actual PFOS usage in preparations and products.

The combined working group will convene two days following the plenary meeting. They will report back at the January plenary.

10. Issues for which the SCHER is the leading committee:

10.1. Call for tender – Endocrine disruption (Human Health)

The call for tender to support a meta-analysis on temporal changes of sperm quality and associated risk factors launched several months ago by DG SANCO/B was completed. The contract was signed with the University of Mainz. The final report will be prepared in ten months and submitted to the SCHER for an opinion.

10.2. Indoor air quality

A discussion with DG SANCO/C4 on a draft request concerning indoor air quality is ongoing. The official request will possibly be presented to the Committee at the next plenary meeting

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

One of the members of the SCHER working group on PFOS volunteered for the EFSA working group on PFOS to ensure exchange of information.

Three members volunteered for a SCENIHR working group on nanotechnology.

Two members participate as external experts in the EFSA GENTOX working group.

12. NEXT (3^{RD}) PLENARY MEETING

The date of the next meeting of the Committee was confirmed as 28 January 2004.

13. ANY OTHER BUSINESS

13.1. EFSA meeting on PFOS

An EFSA working group under the Scientific Panel on Contaminants in the Food chain is preparing an opinion on the relative contribution of food to the total human exposure to perfluorooctane sulfonate (PFOS) and its salts. It is planed to adopt the opinion before end 2005.

During a brainstorming meeting organized by EFSA, an exchange of draft opinions on PFOS between the SCHER and the EFSA working groups was proposed. The possibility of the involvement of one SCHER member in the EFSA group was also suggested.

13.2. Reserve list: proposals for a possible new SCHER environmental member.

The Committee stressed the need for environmental experts for the SCHER. In particular, it recommended looking for extra expertise in the domain of environmental exposure when filling the current vacancy in the Committee.

13.3. Budget 2005 and working group meetings

For administrative and organisational reasons the Committee was requested to plan, before the end of 2004, as many working group meetings as possible for the next two months.

13.4. SINAPSE e-network

The Committee was informed of a new open network, SINAPSE. This is a multi-purpose communications tool that will build up an extensive database of professional activities and expertise. Individuals and organisations with scientific expertise or interest are invited to register. The web address of SINAPSE was given to the SCHER members for more information.

Annex 1: List of participants

Annex I

SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER) 2ND 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. Bo JANSSON (Vice Chair), Prof. H. KOMULAINEN, Prof. O. LADEFOGED, Prof. I.A. MANGELSDORF, Prof. J. SOKAL, Prof. A. STEENHOUT, Prof. J. TARAZONA (Vice Chair), Dr E. TESTAI, Prof. M. VIGHI, Prof. M. VILUKSELA and Prof. J. VOS.

EUROPEAN COMMISSION:

SCHER Secretariat (DG SANCO):

Ms. G. FONTANESI, Ms. M. PHILIPPÉ

Other Commission staff: Ms. E. GUSTAFSSON (DG ENTR), Mr D. HADRICH (DG ENTR), Mr. T. KARJALAINEN (DG RTD), Mr. S. PICKERING, Ms. B. SCHWARZ-SCHULZ (DG JRC), Mr. A. ZUBER (DG ENV)