



EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C – Public Health and Risk Assessment

C7 – Risk Assessment

Scientific Committee on Toxicity, Ecotoxicity and the Environment

CSTEE/GEN2/Minutes 08.01.2004 Final

**SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT
(CSTEE)
41ST PLENARY MEETING**

*Held on 8 January 2004
in Brussels*

MINUTES

1. WELCOMING ADDRESS, APOLOGIES FOR ABSENCE, DECLARATIONS OF INTEREST

Prof. Bridges welcomed the participants to the meeting. Apologies were sent as indicated in Annex II.

No declaration of interest was made.

2. ADOPTION OF THE DRAFT AGENDA

The draft agenda was adopted as written in Annex I.

3. APPROVAL OF THE DRAFT MINUTES OF THE 40TH PLENARY MEETING

The draft minutes of the 40th CSTEE plenary meeting were adopted with a few corrections and are available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out212_en.pdf

4. UPDATE ON THE RENEWAL OF THE DG SANCO SCIENTIFIC COMMITTEES

Ms. Marini informed the members of the committee that the internal discussion on the draft proposal regarding the renewal of the DG Sanco Scientific Committees was about to be concluded. Indeed, comments resulting from the Interservice Consultation were currently being collected and analysed. The next step requires the approval of the final proposal by the College of Commissioners. Once the proposal is approved, the call for expression of interest in membership of the Scientific Committees will be launched and advertised (website, scientific journals etc.). Members of the Scientific Committees will be informed when the call is published.

5. NEW REQUESTS FROM COMMISSION SERVICES

A member of the committee was appointed to review the final draft Risk Assessment Report on perboric acid, sodium salt (Regulation 793/93).

Mr. Daskaleros informed the committee that DG SANCO/B was currently preparing a new request on the potential skin sensitisation risks associated with the release of MBT (2-mercaprobenzothiazole) from natural in rubber soothers, teats and consumer products. A member of the committee was appointed to take the lead together with an identified potential external expert.

6. REGULATION 793/93 ON EXISTING SUBSTANCES (ESR): STATUS REPORTS/ OPINIONS (HUMAN HEALTH AND/OR ENVIRONMENT)

Musk ketone and musk xylene (HH and ENV)

Following comments at the previous plenary meeting, changes in the draft opinions on the results of the RARs on musk xylene and ketone were presented and discussed. The final adopted opinions are available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out219_en.pdf

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out218_en.pdf

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out216_en.pdf

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out215_en.pdf

Methylenediphenyl diisocyanate (HH and ENV)

The draft opinion on the human health part of the RAR on MDI was adopted with a few corrections:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out213_en.pdf

The draft opinion on the environmental part of the RAR on MDI will be revised (issue of solubility, lack of data on exposure assessment, inadequacy of toxicity data, PNEC value) and will be presented at the next plenary meeting.

DEHP

Two specific questions on the margin of safety for newborn exposed through breastmilk and the exposure estimated derived from biomonitoring data based on urinary metabolites were addressed to the CSTEE on the revised RAR on DEHP. The CSTEE recommended further information/testing to gain more confidence in the exposure estimates. The safety of margin with respect to testicular toxicity in infants exposed to DEHP from breast milk may be adequate. The adopted opinion is available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out214_en.pdf

(T)RAR Cadmium oxide and metal (HH and ENV)

The chairman of the working group highlighted the changes made on the human health part of the RAR on cadmium oxide/metal following the last plenary meeting. The draft opinion was adopted with minor changes and is available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out220_en.pdf

The draft opinion on the environmental part of the RAR was presented and confirmed the large number of exposure and effects data available and the good data analysis and variability characterisation performed. However, the risk of cadmium to

the environment does not seem to be characterised in the proper way. The draft opinion will be revised and circulated among the committee for approval by written procedure.

The draft opinion on the TRAR on cadmium (oxide) as used in batteries will be discussed in detail at the next plenary meeting, when the opinion on the environmental part of the RAR is adopted (the TRAR being derived from it).

7 ONGOING REQUESTS FOR OPINION FROM COMMISSION SERVICES

Examination of the BUAV report on alternatives to animal testing

The draft opinion was adopted with a few editorial changes. It concluded that in regard with the overall scientific quality of the report, the conclusions and recommendations tended to be based on unsubstantiated assertions rather than scientific evidence. The CSTEE was of the opinion that, if adopted, the proposal by BUAV-ECEAE would lead to a significant reduction in the current levels of human health and environmental protection. The opinion is available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out217_en.pdf

Study on heavy metals and organic compounds from wastes used as organic fertilisers

The CSTEE considered that the study analysed did not rely on sufficiently sound science to represent an acceptable basis in order to set appropriate threshold levels for pollutants in compost produced from biowaste. The opinion was adopted without modification and is available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out221_en.pdf

Risks of ATBC plasticizer in children's toys

The risk assessment report provided was assessed as a report of good quality (exposure data gaps fulfilled, establishment of an adequate NOAEL), which provides sufficient sound scientific evidence to show that toys plasticized with ATBC can be safely used by children. The opinion was adopted and is available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out222_en.pdf

Risks to health and the environment posed by the use of organostannic compounds

A working group meeting will take place the day after the plenary meeting to review new data submitted by industry, as well as the revised RPA consultant report and a report by the Danish Toxicology Centre on consumer products exposure. The CSTEE was asked to consider whether or not they should revise the conclusions of the initial opinion in the light of the new information submitted.

In addition, the CSTEE will take into account the current work on organotins of the EFSA Panel on Contaminants in the Food Chain to assess the overall risks posed by organostannic compounds to human health and the environment.

Assessment of the CEN report on method development for organic chemicals in toys and Release of certain elements in toys

External expertise is required. The identification of appropriate experts is ongoing. A single working group will be set up to tackle both issues.

8 EMERGING ISSUES IDENTIFIED BY THE SSC AND FOR WHICH THE CSTEE IS THE LEADING COMMITTEE

The call for tender to support a meta-analysis on temporal changes of sperm quality and associated risk factors has been launched by DG SANCO/B. Applications received are evaluated.

9 PARTICIPATION OF THE CSTEE IN ACTIVITIES/WORKING GROUPS OF OTHER SCIENTIFIC COMMITTEES OF THE COMMISSION

A few CSTEE members are involved in Technical Working Groups within the Health and Environment Strategy framework.

Some members of the CSTEE are involved in the evaluation of substances used as additives in animal feed (environmental effects) in the EFSA FEEDAP Panel or in a new working group on animal by-product waste disposal of the EFSA Panel on biological hazards.

The EFSA Scientific Committee has started activities that may be of interest to the CSTEE on exposure assessment, the identification and evaluation of emerging risks, the risk assessment of genotoxic and carcinogenic substances, and the evaluation of non-nutritional compounds.

10 ARRANGEMENTS FOR THE NEXT (42ND) PLENARY MEETING OF THE CSTEE

The next plenary meeting was confirmed on 4 March 2004. It will very likely be the last plenary meeting of the existing committee.

11 ANY OTHER BUSINESS

It was proposed to draft a list of relevant topics/issues that could be suggested to the future scientific committees (e.g. integrated risk assessment, definitions of biomarkers and indicators, ecotoxicological evaluation of metals). Ideas from the members of the committee will be collected by the Secretariat.

Prof. Bridges closed the meeting with thanking the members of the committee for their active and high quality contribution.

Annex I: Agenda.

Annex II: List of Participants.

Annex I



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate C – Public Health and Risk Assessment
C7 – Risk Assessment

CSTEE/00/Plen.age.08.01.2003 Final

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| <p>SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE) 41ST PLENARY MEETING</p> |
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*8 January 2004, starting at 10h00
CCAB, Rue Froissart, 36
B – 1040 Brussels*

AGENDA

- (1) Welcoming address, apologies for absence, declarations of interest
- (2) Adoption of the draft agenda
- (3) Approval of the draft minutes of the 40th CSTEE plenary meeting
- (4) Update on the renewal of the DG SANCO Scientific Committees
- (5) New request from Commission Services
 - Regulation 793/93 : *perboric acid, sodium salt* (CAS No. 11138-47-9) – HH
- (6) Regulation 793/93 on Existing substances (ESR): Status reports/opinions (Human Health and/or Environment)
 - (a) *Musk ketone and musk xylene* - HH – for adoption
 - (b) *Musk ketone and musk xylene* - ENV – for adoption
 - (c) *MDI* - HH – for adoption
 - (d) *MDI* - ENV – for adoption
 - (e) *DEHP* – HH – for discussion
 - (f) *Cadmium* HH – for adoption
 - (g) *Cadmium* ENV – for discussion
 - (h) TRAR on *Cadmium* in batteries – for discussion
- (7) Ongoing requests for opinion from the CSTEE by Commission services on:
 - (a) Examination of the BUAV report on *alternatives to animal testing* – for adoption
 - (b) Study on *Heavy metals and organic compounds from wastes used as organic fertilisers* – for adoption

- (c) *Risks of ATBC plasticiser in children's toys – for discussion*
 - (d) *Review of complementary new data on organostannic compounds*
 - (e) *Assessment of the overall risk posed by organostannic compounds*
 - (f) *CEN Report on method development for organic chemicals in toys*
 - (g) *Release of heavy metals and other elements in toys - Current limit values and test methods*
- (8) Emerging issues identified and for which the CSTEE is the leading committee:
Call for tender – Meta-analysis on temporal changes of sperm quality
- (9) Participation of the CSTEE in activities/working groups of other Scientific Committees of the Commission or EFSA
- (10) Next plenary meeting (42nd) of the CSTEE.
- (11) Any other business

Annex II

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| <p style="text-align: center;">SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE) 41ST PLENARY MEETING</p> |
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*Held on 8 January 2004
in Brussels*

LIST OF PARTICIPANTS

MEMBERS OF THE CSTEE:

Prof. Jim BRIDGES, Prof. Peter CALOW, Prof. Giorgio CANTELLI FORTI, Prof. Dr. Wolfgang DEKANT, Prof. Erik DYBING, Prof. Dr. Helmut GREIM, Prof. Colin JANSSEN, Prof. Bo JANSSON, Prof. Soterios KYRTOPOULOS, Prof. Claude LAMBRE, Prof. Amadeu SOARES, Prof. José TARAZONA, Prof. Benedetto TERRACINI, Prof. Katarina VICTORIN, Prof. Marco VIGHI and Prof. Joseph VOS.

Apologies: Prof. Janneche SKÅRE

EUROPEAN COMMISSION:

CSTEE Secretariat (DG Health & Consumer Protection):

Mrs. G. FONTANESI, Ms. V. ROLLAND

DG Health & Consumer Protection:

Mr. T. DASKALEROS, Ms. M. MARINI

DG Enterprise:

Mr. W. HEHN, Mr. M. SCHMAHL

DG Environment:

Mr. M. BLAINEY, Ms. I. DEMADE, Ms. C. BANET, Ms. J. HOLMQVIST

DG Joint Research Centre:

Ms. S. MUNN