



CSTEE/GEN2/Minutes 04.03.2004

**SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT
(CSTEE)
42ND PLENARY MEETING**

*Held on 4 March 2004
in Brussels*

MINUTES

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

Prof. Bridges welcomed the participants to the meeting. Participants are 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 but with the agenda points related to cadmium being postponed for discussion in the afternoon.

3. APPROVAL OF THE DRAFT MINUTES OF THE 41ST PLENARY MEETING

The draft minutes of the 41st CSTEE plenary meeting were adopted with an editorial correction. They are available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/sct_minutes_en.htm

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

Mr. Wagstaffe informed the members of the committee that the Commission Decision on the renewal of the DG SANCO Scientific Committees was approved on 3 March 2004 (2004/210/EC) and published in the Official Journal of the European Union on 4 March 2004. It is available at:

http://europa.eu.int/eurlex/pri/en/oj/dat/2004/l_066/l_06620040304en00450050.pdf

The decision sets up three scientific advisory committees in the field of consumer safety, public health and the environment: the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health risks (SCENIHR). These scientific committees will replace the existing scientific committees established by Decision 97/579/EC (i.e. the CSTEE, SCCNFP and SCMPMD). The call for expressions of interest for membership of a new committee will be published on 11 March on the DG SANCO website, among others, at: http://europa.eu.int/comm/health/ph_risk/documents/call_2004_en.htm.

It is expected that the first meeting of the new committees could take place end of June.

5. NEW REQUESTS FROM COMMISSION SERVICES

Mrs. Brättemark (DG ENV) introduced a new request on the setting of Environmental Quality Standards for the priority substances included in the Annex X of the Water Framework Directive (2000/60/EC). In the light of the preparation of a Commission proposal on these priority substances in September 2004, DG ENV would like to receive the opinion of the CSTEE on general issues (methodology to derive EQS values, establishment of quality standards taking into account drinking water protection, quality standards for sediments and biota, quality standards for transitional waters) as well as specific issues (use of the Added Risk Approach for metals, quality standards for HCH, PAHs and mercury) by May 2004.

Due to the urgency and importance of the question, and despite that the plenary meeting of 4 March should have been the last one of the current committee, the members accepted the mandate of DG ENV. It may nevertheless be that time constraints will not allow to answer all detailed questions.

Three working groups were established to work on the methodology approach, the establishment of specific EQS values and the establishment of quality standards taking into account the drinking water protection. Dates for working group meetings will be circulated.

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

Methylenediphenyl diisocyanate (ENV)

The draft opinion on the environmental part of the RAR on MDI has been revised. The issue of reactivity of MDI has been checked and general comments on the RAR clarified (gaps and uncertainties in data or calculations). The CSTEE concluded that conclusion ii) as proposed in the RAR was not supported by scientific evidence. A final draft opinion incorporating all these changes will be circulated to the CSTEE for approval by written procedure. It will then be published at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/sct_opinions_en.htm

Sodium perborate (HH)

The rapporteur presented the draft opinion on the results of the RAR on sodium perborate and pointed out some inconsistencies in the effect assessment part, as well as missing information on exposure scenarios and additional studies available in the

literature. In addition, the CSTEE indicated that the risks for workers and consumers could not be evaluated without a proper evaluation of the degradation products of sodium perborate, in particular boric acid. Clarifications discussed at the meeting regarding acute toxicity animal studies, skin sensitization in humans and skin absorption by consumers will be incorporated. A final draft opinion will be circulated to the committee for approval by written procedure. It will then be available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/sct_opinions_en.htm

Piperazine (ENV)

The CSTEE agreed with most conclusions of the environmental part of the RAR on piperazine but recommended to revise the conclusions for the aquatic environment (in particular because local PECs proposed could be overestimations) and the terrestrial compartment (further toxicity tests on terrestrial organisms are requested). In addition the committee suggested a more precise exposure assessment including site-specific local conditions. Following some rewording to better distinguish local and regional considerations, the revised opinion will be circulated to the CSTEE for approval by written procedure. The adopted opinion will then be available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/sct_opinions_en.htm

Piperazine (HH)

The rapporteur presented a first draft opinion on the results of the human health part of the RAR on piperazine. There is a lack of information on the metabolic fate of piperazine. Piperazine is confirmed as a skin and respiratory sensitizer and induces neurotoxicity effects. The issue of nitrosamine formation from piperazine was discussed with regard to potential cancer risk. The draft opinion will be revised following the comments raised at the meeting and will be presented for adoption at the next plenary meeting.

RAR Cadmium oxide and metal (ENV)

The draft opinion on the environmental part of the RAR was circulated to the CSTEE prior to the meeting with minor changes as agreed in the last plenary meeting. However, it appeared that more clarity would be welcome in the conclusion section presented, especially in the context of such a sensitive issue. The rapporteur will expand the conclusion section to clarify that the fact that a probabilistic approach was not applied, was only one of a few important concerns identified by the CSTEE (e.g. bioavailability, monitoring data used, regional differences). All major concerns will be listed in the conclusion section. The final draft opinion will be circulated to the committee for approval by written procedure. The adopted opinion will then be available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/sct_opinions_en.htm

The CSTEE also clarified that the role of the committee was to focus on the scientific aspects of the reports submitted, but not in the strict context of existing regulatory considerations or related guidelines. The issues raised while evaluating this RAR confirmed the need to develop appropriate guidelines and methods to evaluate the risks posed by metals. The CSTEE agreed with the proposal by Mr. Hehn (DG ENTR) to give further advice on this matter to the RAR Rapporteur/ECB if needed.

TRAR Cadmium oxide as used in batteries

The rapporteur presented a revised version of the draft opinion on the TRAR. As the TRAR was based on the results of the RAR, similar concerns as the ones identified in the RAR were raised. A new draft will be prepared, which will include recommendations, especially on how to deal with the exposure assessment. There is a need to clearly present the contribution of cadmium from Ni-Cd batteries in regional areas and to present the risks in a comparative way. The next version will be circulated to the CSTE.

7 ONGOING REQUESTS FOR OPINION FROM COMMISSION SERVICES

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

Some inconsistencies were identified between the CSTE and EFSA current working groups on organotins with regard to the inclusion of DOT in a group TDI. Liaison between the working groups is ensured to solve this.

It was mentioned that it would be useful to collect new data (short-term animal studies) for TBT, DBT, DOT and TPT to further support the group TDI. Mr. Daskaleros confirmed that DG SANCO could explore funding possibilities to support such research project to help solving any divergent opinion.

A next working group meeting date was fixed.

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

Appropriate experts have been identified and agreed to join the working group. A date for a first working group meeting is being set up.

Risk associated with the release of MBT from natural rubber soothers, teats and consumer products

The CSTE was given the mandate to assess the potential skin sensitisation risks to infants and adults from exposure to MBT released from natural rubber products, to comment on the existing CEN standard limit for MBT in rubber soothers and teats, to comment on possible health risks from certain antioxidants (i.e. BHT, A2246, A 245) and volatile compounds, and, last, to identify any relevant additional investigative work on the chemicals detected in these products.

In the light of the amount of work involved, a working group, including an external *ad hoc* expert, was created and a date for a first meeting set up.

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

The applicant selected following the call for tender to support a meta-analysis on temporal changes of sperm quality and associated risk factors did not accept some legal features in the standard contract proposed by the Commission. Thus a new call will be launched.

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

A few CSTEE members are involved in other Community activities: Technical Working Groups within the Health and Environment Strategy framework, working group of the EFSA FEEDAP Panel (coccidiostats), working group of the EFSA BIOHAZ panel (animal by-products), EFSA Scientific Committee and working group of ECVAM (alternatives to animal toxicity testing).

10 ARRANGEMENTS FOR THE NEXT (43RD) PLENARY MEETING OF THE CSTEE

Further to the urgent request submitted by DG ENV, a provisional date for a CSTEE plenary meeting was fixed on 28 May 2004.

11 ANY OTHER BUSINESS

Prof. Lambré presented a draft proposal on the definition of biomarkers and bioindicators which could be taken up by the new committee. As some activities on this matter are already ongoing, committee members will provide available documents and ideas on this matter to the Secretariat.

The Secretariat was asked to check the list of priorities that is currently being established within the SCALE project to investigate if, and how, the CSTEE (or the future committee SCHER) could contribute in the near future.

Prof. Bridges closed the meeting with thanking the members of the committee for their patience and excellent work even sometimes in difficult situations.

Prof. Greim, 1st vice-chair of the CSTEE, thanked Prof Bridges for his excellent chairmanship on behalf of the whole committee.

On behalf of the Commission, and in particular DG SANCO, Mrs. Marini (DG SANCO) thanked the members of the committee for their very useful and important help during the last few years and expressed hope that members will be involved again in the future committees or related activities.

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.04.03.2004 Final

<p style="text-align: center;">SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE) 42ND PLENARY MEETING</p>

*4 March 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 41st CSTEE plenary meeting
- (4) Update on the renewal of the DG SANCO Scientific Committees
- (5) New request on the setting of Environmental Quality Standards for the priority substances within the Water Framework Directive
- (6) Regulation 793/93 on Existing substances (ESR): Status reports/opinions (Human Health and/or Environment)
 - (a) *MDI* (ENV) – for adoption
 - (b) *Cadmium oxide/metal* (ENV) – for adoption
 - (c) TRAR on *Cadmium oxide* in batteries – for discussion
 - (d) *Perboric acid, sodium salt* (HH) – for adoption
 - (e) *Piperazine* (HH) – for discussion
 - (f) *Piperazine* (ENV) – for discussion
- (7) Ongoing requests for opinion from the CSTEE by Commission services on:
 - (a) Review of complementary new data on *organostannic compounds*
 - (b) Assessment of the overall risk posed by *organostannic compounds*
 - (c) CEN Report on *method development for organic chemicals in toys*
 - (d) *Release of heavy metals and other elements in toys* - Current limit values and test methods
 - (e) Risks associated with the release of *MBT* from natural rubber soothers, teats and consumer products

- (8) Emerging issues identified and for which the CSTE is the leading committee:
 - (a) Call for tender – Meta-analysis on *temporal changes of sperm quality*
 - (b) Relevant issues for the future scientific committees
- (9) Participation of the CSTE in activities/working groups of other Scientific Committees of the Commission or EFSA
- (10) Provisional date for a plenary meeting of the CSTE
- (11) Any other business

Annex II

<p style="text-align: center;">SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE) 42ND PLENARY MEETING</p>

*Held on 4 March 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. Janneche SKÅRE, Prof. Amadeu SOARES, Prof. José TARAZONA, Prof. Benedetto TERRACINI, Prof. Katarina VICTORIN, Prof. Marco VIGHI and Prof. Joseph VOS.

EUROPEAN COMMISSION:

CSTEE Secretariat (DG Health & Consumer Protection):

Mrs. G. FONTANESI, Ms. V. ROLLAND

DG Health & Consumer Protection:

Mr. T. DASKALEROS, Ms. M. MARINI, Mr. P. WAGSTAFFE

DG Enterprise:

Mr. W. HEHN, Mr. S. PICKERING

DG Environment:

Ms BRÄTTEMARK, Ms. A. CHEZEAU, Ms. I. DEMADE, Ms. C. OLAZABAL

DG Joint Research Centre:

Mr. J. DE BRUIJN, Ms. B. SCHWARZ-SCHULZ