



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 25.June.2004

**SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT
(CSTEE)
43RD PLENARY MEETING**

*Held on 28 May 2004
in Brussels*

MINUTES

Adopted by the CSTEE by written procedure on 25 June 2004

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

Prof. Bridges welcomed the participants to the meeting. The Chairman noted that this was the very last meeting of the CSTEE which began in 1997.

Participants are indicated in Annex II.

Declaration of interest

Prof. Tarazona mentioned that he was involved in the assessment of three of the chemicals under the Water Framework Directive so he will not take part in that discussion.

Prof. Janssen said that he was involved in the external peer review board of ongoing risk assessment exercises of nickel and lead.

2. ADOPTION OF THE DRAFT AGENDA

The draft agenda was adopted as written in Annex I.

3. APPROVAL OF THE DRAFT MINUTES OF THE 42ND PLENARY MEETING

The draft minutes of the 42nd 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 application and evaluation part have been completed and the list of suitable applicant has been compiled. The proposal list has been made on the basis of 1 Expertise, 2 Country representatives, 3 Gender balance, 4 Continuity with the previous committees.

A reserve list of 65 experts will be also published. Those experts will act as possible associate members of SCHENIR (Scientific Committee on Emerging and Newly Identified Risks), substitutes in case of leave of one of the members, experts involved in particular issues in which their expertise is required.

The formal nomination following by Decision adoption and publication of the two lists is expected by the end of June. It is foreseen that the first meeting of the three new committees will not take place before September.

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

Methylenediphenyl diisocyanate (ENV)

Minor editorial changes suggested during the previous plenary have been made. The adopted opinion is available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out227_en.pdf

RAR Cadmium oxide and metal (ENV)

Changes have been made as agreed in the last plenary meeting. Major concerns identified by the CSTEE have been listed in the conclusion section as requested in the previous discussion. The opinion has been adopted with minor editorial corrections and is available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out228_en.pdf

TRAR Cadmium oxide as used in batteries

The rapporteur presented a revised version of the draft opinion on the TRAR which now includes recommendations on how to deal with exposure assessment as requested in the last plenary. The opinion has been adopted with minor editorial corrections and is available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out229_en.pdf

Mrs Schwarz-Schultz (DG JRC) said that JRC is still trying to organize a meeting between the CSTEE members involved in the working group on cadmium, the rapporteur of cadmium and some technical meeting experts to discuss the CSTEE opinion on the report.

The chairman clarified that the three members will attend the meeting all together and as former members of the Cadmium Environmental working group of the CSTEE.

Sodium perborate (HH)

Comments made at the last plenary meeting were taken into account. Few typing corrections have been made. The adopted opinion is available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out225_en.pdf

Piperazine (ENV)

Amendments and minor changes as requested in the previous plenary have been made. The adopted opinion is available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out226_en.pdf

Piperazine (HH)

The rapporteur presented a final draft opinion on the results of the human health part of the RAR on piperazine. CSTEE supports most of the conclusions of the report, but it would prefer conclusion i) for neurotoxicity effects. Moreover, since the nitrosamine formation from piperazine seems to be linked to potential cancer risk the CSTE recommends conclusion i).

The adopted opinion is available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out233_en.pdf

6. ONGOING REQUEST FOR OPINION FROM THE CSTE BY COMMISSION SERVICES ON:

Setting of Environmental Quality Standards for the priority substances included in the Annex X of the Water Framework Directive (2000/60/EC).

The CSTE was invited to comment on the general methodology that was used for setting the quality standards (QS) as well as the identification of specific problems on additional information received for specific substances. A manual on methodology was also presented that summarized the method employed for the derivation of the Qs as well as datasheets that were presented for each substance. During the process other additional documents on several chemicals have been provided by the Commission.

The chairman of the working group reported back on the draft opinion.

The opinion is divided in one more general part which includes methodology and QS for drinking water and a second part related to the proposed QS for each substance.

The CSTE found the manual to be not enough precise, in addition, several significant issues were not considered. The CSTE was particularly concerned that this manual should be used later on by the basins and rivers authorities for the development of QSs values which are not covered at EU level. The CSTE found several proposals not acceptable as they stand and gave suggestions on how to implement some parts of the manual.

The committee found that the human health related data were written in a too condensed way and for some chemicals readily available dataset on toxic responses observed after overall exposure have not been used.

The draft opinion was reviewed in detail and several corrections/suggestions have been added during the meeting. The opinion has been adopted and is available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out230_en.pdf

The Commission appreciated that, even if the request came very late the CSTEE accepted the mandate and it thanks the committee for the huge amount of work.

Mr Murphy (DG ENV) explained that the Commission did not ask the committee for a detailed review of the EQs in relation to each substance but if the committee would give its opinion on those chemicals it would be grateful. Accordingly, the Commission presented the data to the CSTEE in a condensed way.

CEN Report on *method development for organic chemicals in toys*

The CSTEE has been asked to give an opinion on the CEN report on methods of analysis to detect organic chemicals in toys. The CSTEE decided to look at the whole analytical process commenting also on three draft documents coming from CEN: substances and background, the report on extraction and handling techniques and the report on the analytical determination.

The CSTEE is generally happy with the report on methods development. Some comments have been made regarding the overall process; main comments are on total exposure which is not taken into account, the application of solvent extraction, the presence of different chemicals in complex toys, the selection of the saliva stimulant and of extraction solvents.

The opinion has been adopted and is available at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out232_en.pdf

Release of heavy metals and other elements in toys - Current limit values and test methods

The rapporteur of the working group reported back on some main points identified by the CSTEE such as the choice of the eight chemicals, the definition of bioavailability, and the introduction of the correction factor in setting the standard.

The current draft opinion will be subjected to an additional revision process to permit the external experts to make other possible comments. The revised draft will then be circulated again 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

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

The CSTEE was asked to review additional information provided following the numerous data gaps identified by the CSTEE in its recent opinion on the 2002 RPA report assessing the risks to health and environment posed by the use of organostannic compounds.

The CSTEE disagrees with several of the new data used for the exposure assessment. The risk for human health especially for children remains not only due to the exposure to organotin compound groups but also due to the wider exposure which was considered in the original version of the report. The CSTEE also underline that the total exposure for the assessment of the risk must include all uses.

In the new version of the report it is still difficult to understand the origin of data used for different environmental and human exposures. Endocrine effects are still

not considered. A paragraph on application of group TDI and more literature on this issue have been included in the opinion.

The CSTEE concludes that there is no scientific reason to change the conclusions it gave in its previous opinion in June 2003.

The opinion has been adopted and is available at:

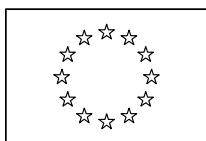
http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out231_en.pdf

Prof. Bridges closed the meeting with thanking the audience and the members of the committee for their outstanding contributions over the past 7 years. He also thanked Gigliola Fontanesi and Valerie Rolland for their excellent support to the Committee.

Annex I: Agenda.

Annex II: List of Participants.

Annex I



EUROPEAN COMMISSION
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Directorate C – Public Health and Risk Assessment
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CSTEE/43/Plen.age. 28.05.2004 Draft1

**SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT
(CSTEE)
43RD PLENARY MEETING**

*28 May 2004, starting at 10h00
CCAB, Rue Froissart, 36
B – 1040 Brussels*

DRAFT AGENDA

- (1) Welcoming address, apologies for absence, declarations of interest
- (2) Adoption of the draft agenda
- (3) Approval of the draft minutes of the 42nd CSTEE plenary meeting
- (4) Update on the renewal of the DG SANCO Scientific Committees
- (5) Regulation 793/93 on Existing substances (ESR; 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 adoption
 - (d) *Perboric acid, sodium salt* (HH) – for adoption
 - (e) *Piperazine* (HH) – for adoption
 - (f) *Piperazine* (ENV) – for adoption
- (6) Ongoing requests for opinion from the CSTEE by Commission services on:
 - (a) Water Framework Directive: *Environmental Quality Standards* for the priority substances – for adoption
 - (b) Revised assessment of the overall risk posed by *organostannic compounds*– for adoption
 - (c) CEN Report on *method development for organic chemicals in toys* – for adoption
 - (d) *Release of heavy metals and other elements in toys* - Current limit values and test methods – for adoption
- (7) Any other business

Annex II

<p style="text-align: center;">SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE) 43RD PLENARY MEETING</p>

*Held on 28 May 2004
in Brussels*

LIST OF PARTICIPANTS

MEMBERS OF THE CSTEE:

Prof. Jim BRIDGES, Prof. Dr. Wolfgang DEKANT, Prof. Dr. Helmut GREIM, Prof. Colin JANSSEN, Prof. Bo JANSSON, Prof. Soterios KYRTOPOULOS, Prof. Claude LAMBRE, Prof. José TARAZONA, Prof. Katarina VICTORIN, Prof. Marco VIGHI and Prof. Joseph VOS.

Apologies: Prof. Peter CALOW, Prof. Giorgio CANTELLI FORTI, Prof. Erik DYBING, Prof. Janneche SKÅRE, Prof. Amadeu SOARES, Prof. Benedetto TERRACINI,

EUROPEAN COMMISSION:

CSTEE Secretariat (DG Health & Consumer Protection):

Mrs. G. FONTANESI

DG Health & Consumer Protection:

Mrs. C. ESTEBAN, Mr. P. WAGSTAFFE

DG Enterprise:

Mrs K. DIMITRIOU, Mrs. I. GUERRA, Mrs. E. GUSTAFFSON

DG Environment:

Mrs BRÄTTEMARK, Mr. P. MURPHY

DG Joint Research Centre:

Mrs. B. SCHWARZ-SCHULZ