



**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 12-13.11.2003 Final

**SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT  
(CSTEE)  
40<sup>H</sup> PLENARY MEETING**

*Held on 12-13 November 2003  
in Brussels*

**DRAFT 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 38<sup>TH</sup> PLENARY MEETING**

The draft minutes of the 39th CSTEE plenary meeting were adopted with a correction and are available at:

[http://europa.eu.int/comm/health/ph\\_risk/committees/sct/documents/out201\\_en.pdf](http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out201_en.pdf)

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

Mr. Wagstaffe first thanked the members of the committee for the impressive amount of opinions prepared by the committee. Mr. Wagstaffe then informed the participants that a draft proposal on the renewal of the Scientific Committees was being discussed internally. The official procedure requires an Interservice Consultation and then the approval of the proposal by the College of Commissioners. Once the proposal is approved, the call for expressions of interest in membership of the Scientific Committees will be launched. The areas of expertise covered by the new Committees are expected to be broader than the current ones.

Mr. Martin, newly arrived in SANCO/C7, was introduced.

## 5. REQUESTS FROM COMMISSION SERVICES

### *ATBC as plasticiser in children's toys*

The CSTEЕ had reviewed a study on the possible use of alternative plasticisers to phthalates conducted in 2000 upon request of the Commission. At that time the CSTEЕ had identified significant gaps in the amount of scientific information available to assess the safety profiles of the substitutes proposed. A new report, which intended to fulfil these gaps regarding ATBC, was submitted to the committee for peer-review.

A new working group was established.

### *Assessment of the CEN report on method development for organic chemicals in toys*

DG ENTR introduced a new mandate to the committee on the development of validated methods suitable for the preparation, extraction, identification and quantification of specific chemical substances in toys (CEN report on method development). These methods will be converted into the draft standards pr EN 71-11 "safety of toys-part 11-method of analysis".

A working group was set up. External expertise will be required. The same working group will work on another mandate already introduced to the CSTEЕ on the revision of the migration limits of certain elements in toys.

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

Following the numerous data gaps identified by the CSTEЕ in their recent opinion on the RPA report assessing the risks to health and environment posed by the use of organostannic compounds, new relevant data are being collected by the Commission, mainly from industry. In addition the Danish Toxicology Centre is preparing a report on consumer products exposure scenarios. The CSTEЕ will be 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 CSTEЕ 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.

### *Regulation 793/93: DEHP (HH)*

Rapporteurs were identified to review the recently updated Risk Assessment Report on DEHP. Specific questions will be addressed shortly to the committee. This request should be dealt with as a priority in the context of the development of a Risk Management Strategy.

Because of the approaching end of the mandate of the current CSTEЕ, the members of the committee agreed that, from now on, only urgent requests could be accepted to ensure the proper finalisation of the work in due time.

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

***3,4-dichloroaniline (HH)***

Comments made at the last plenary meeting were taken into account. The draft opinion was adopted with an additional sentence on the expected induction of spleen tumours and is available at:

[http://europa.eu.int/comm/health/ph\\_risk/committees/sct/documents/out205\\_en.pdf](http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out205_en.pdf)

***Musk ketone and musk xylene (HH and ENV)***

The draft opinions on the results of the RARs on musk xylene and ketone were discussed and will be presented with additional comments at the next plenary meeting for adoption. The opinion of the SCCNFP on the exposure to these substances was checked.

***2-ethylhexyl acrylate (HH and ENV)***

Both draft opinions were discussed and adopted with minor changes. They are available at:

[http://europa.eu.int/comm/health/ph\\_risk/committees/sct/documents/out209\\_en.pdf](http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out209_en.pdf)

[http://europa.eu.int/comm/health/ph\\_risk/committees/sct/documents/out204\\_en.pdf](http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out204_en.pdf)

***Benzene (HH)***

The rapporteur presented the draft opinion on the results of the RAR on benzene, which was adopted with minor additional points. It is available at:

[http://europa.eu.int/comm/health/ph\\_risk/committees/sct/documents/out207\\_en.pdf](http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out207_en.pdf)

***Methylenediphenyl diisocyanate (HH and ENV)***

The substances were not discussed but both revised draft opinions will be presented at the next plenary meeting.

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

The chairman of the working group reported back on the issues identified in the human health part of the RAR. The report is very extensive and detailed but raises important concerns (calculation LOAEL, use of MOS values, rate of absorption, exposure assessment, etc.). The current draft opinion will be refined and presented for adoption at the next plenary meeting.

The environmental part was evaluated as a high scientific quality exposure and effects assessment. However, the large amount of information produced or available on exposure and bioavailability was not taken into account to perform the risk characterisation. The members of the working group will need to meet again to further discuss the scientific approach (deterministic versus probabilistic).

**7. ONGOING REQUEST FOR OPINION FROM THE CSTE E BY COMMISSION SERVICES ON:**

***Phosphate based household detergents/alternatives and eutrophication***

The chairman of the working group presented the complete draft opinion. The conclusions had been agreed upon at the last plenary meeting. The contribution of phosphorus from STPP in detergents to the total phosphorus load in surface water

can be very variable. A combined approach including a significant to complete reduction of STPP in household detergents is a necessary measure, even if in some cases not sufficient, to cure the problem of eutrophication in Europe. Furthermore there are no toxicological or ecotoxicological problems related to the use of Zeolites in detergents, and Zeolites will not increase the sludge volume. The detailed opinion is available at:

[http://europa.eu.int/comm/health/ph\\_risk/committees/sct/documents/out202\\_en.pdf](http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out202_en.pdf)

### ***Risks posed by mercury in products***

The draft opinion showed disagreement with the conclusions of the report that mercury is unlikely to present significant risks to health and the environment due to the assumptions made and the approach taken. A major issue is the use of the EUSES model which is not suitable to assess the distribution of metals in the environment. No scientifically justified conclusions on potential risks are possible based on the report submitted. The opinion was adopted and is available at:

[http://europa.eu.int/comm/health/ph\\_risk/committees/sct/documents/out210\\_en.pdf](http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out210_en.pdf)

### ***Alternative methods to animal testing***

The draft opinion was reviewed in detail. Few corrections were suggested for clarifications. An additional editorial process will take place. The revised draft will then be circulated again to the committee for approval by written procedure and also to the working group for any further comments.

### ***CEN Report on the risk assessment of organic chemical in toys***

The committee adopted the draft opinion on the CEN report. The CSTEE concluded that the report was not useful for the initial purpose and did not provide a suitable basis for setting standards. It showed indeed many deficiencies and errors and rather focused on hazard identification but not risk assessment. The opinion is available at:

[http://europa.eu.int/comm/health/ph\\_risk/committees/sct/documents/out203\\_en.pdf](http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out203_en.pdf)

### ***Risks to health and the environment from PAHs in extender oils and tyres***

The chairman of the working group presented the draft opinion on the risks to health and the environment from PAHs in extender oils and tyres. PAHs are considered as likely carcinogens for humans. The CSTEE agreed that PAHs are emitted into the environment as a consequence of the abrasion of the tyre tread, however, a reduction of the concentration of PAHs in tyres would insignificantly reduce the overall concentration of PAHs found in the environment. The draft opinion was adopted with a few corrections and is available at:

[http://europa.eu.int/comm/health/ph\\_risk/committees/sct/documents/out206\\_en.pdf](http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out206_en.pdf)

### ***Studies on scientific evaluation of substances showing evidence or potential for endocrine disruption***

The CSTEE adopted its opinion on the two studies commissioned by DG ENV on (a) 12 substances with evidence or potential effect but not currently restricted or addressed under existing Community legislation and (b) 435 substances for which there is insufficient data. It agreed with the overall scientific approach and overall conclusions of the reports but disagreed with specific conclusions on the assessment of a few specific compounds. The CSTEE pointed out that the prioritisation of such substances should be an iterative process, especially as the database of most compounds on endocrine disruption is limited, in particular in the field of ecotoxicity.

The draft opinion was adopted and is available at:

[http://europa.eu.int/comm/health/ph\\_risk/committees/sct/documents/out208\\_en.pdf](http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out208_en.pdf)

***Risk of sensitisation of humans to nickel by piercing post-assemblies***

The draft opinion was presented to the members of the committee. It concluded that the use of a nickel migration limit of 0.2 µg/cm<sup>2</sup>/week instead of maximum nickel content by mass would enable to reduce the risks of sensitization of the general population. The migration limit proposed in the report is nevertheless not adequately justified in the report. The draft opinion was adopted provided a sentence would be added on the use of an adjustment factor counting for the difficulties in the measurement of nickel migration rate. It is available at:

[http://europa.eu.int/comm/health/ph\\_risk/committees/sct/documents/out211\\_en.pdf](http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out211_en.pdf)

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

The draft opinion was presented to the committee and expressed a few concerns. A working meeting will be organized to clarify the issues. An additional external expert will be invited.

***Reports on the risk assessment of organic chemicals and heavy metals in toys***

Appropriate external experts need to be identified before undertaking the task.

**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. No applicants have responded so far.

**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.

A member of the CSTEE working group on organostannic compounds ensures exchange of information with the Organotin Working Group of the EFSA Panel on Contaminants in the Food Chain.

**10. ARRANGEMENTS FOR THE NEXT (41<sup>TH</sup>) PLENARY MEETING OF THE CSTEE**

The next plenary meeting was confirmed on 8 January 2004. Dates will be circulated for a plenary meeting in March.

**11. ANY OTHER BUSINESS**

P. Calow mentioned that ENDS Daily Newsletter had referred to the recent opinions of the CSTEE on the copper-containing antifoulings and SCCPs. It was questioned

whether references to the Scientific Committees' activities in the press were systematically collected. The Secretariat will further enquire with DG Press.

CSTEE members asked for more feedback from the Commission on the impact of their opinions. Officials confirmed the usefulness and importance of the scientific advice given by the CSTEE to the Commission and mentioned that they would try to give better feedback to the committee.

The chairman indicated the publication of a report on the priorities in the European Union for risk assessment in the non-food area. It is available for information and any comments at:

[http://europa.eu.int/comm/health/ph\\_risk/documents/risk\\_key02\\_en.pdf](http://europa.eu.int/comm/health/ph_risk/documents/risk_key02_en.pdf)

Prof. Bridges closed the meeting with thanking the members of the committee for successfully facing the heavy work.

*N.B.: the work of DG SANCO Scientific Committees is now reported in the new risk assessment section of the EC Public Health website under:*

[http://europa.eu.int/comm/health/ph\\_risk/risk\\_en.htm](http://europa.eu.int/comm/health/ph_risk/risk_en.htm)

**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.12-13.11.2003 Final

<p style="text-align: center;"><b>SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE) 40<sup>TH</sup> PLENARY MEETING</b></p>
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*12-13 November 2003, starting at 10h00  
Rue de Genève, 1  
B – 1140 Brussels (Evere)*

### 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 39<sup>th</sup> CSTEE plenary meeting
- (4) Update on the renewal of the DG SANCO Scientific Committees
- (5) New request from Commission Services
  - (a) ATBC as plasticizer in children's toys
  - (b) Assessment of the CEN report on method development for organic chemical compounds in toys
  - (c) Risks to health and environment posed by the use of Organostannic compounds – Additional data
  - (d) Regulation 793/93 :*DEHP* (HH)
- (6) Regulation 793/93 on Existing substances (ESR): Status reports/opinions (Human Health and/or Environment)
  - (a) *3,4 Dichloroaniline* HH – for adoption
  - (b) *Musk ketone and musk xylene* - HH – for adoption
  - (c) *Musk ketone and musk xylene* - ENV – for discussion
  - (d) *2-ethylhexyl acrylate* HH – for adoption
  - (e) *2-ethylhexyl acrylate* ENV – for adoption
  - (f) *Benzene* HH – for adoption
  - (g) *Cadmium* HH – for discussion
  - (h) *Cadmium* ENV – for discussion
  - (i) TRAR on *Cadmium* in batteries – status report
  - (j) *MDI* HH – for next meeting

- (k) *MDI ENV* – for next meeting
- (7) Ongoing requests for opinion from the CSTEE by Commission services on:
  - (a) *Phosphate based detergents/alternatives and eutrophication* – for adoption
  - (b) Risks posed by *Mercury in products* – for adoption
  - (c) Examination of a report on *Alternatives to animal testing* – for adoption
  - (d) CEN Report on the risk assessment of *organic chemicals in toys* – for adoption
  - (e) Release of *heavy metals and other elements in toys*
  - (f) Study on *Heavy metals and organic compounds from wastes used as organic fertilisers* – for discussion
  - (g) Two studies on substances showing evidence of or *potential of endocrine disruption* – for adoption
  - (h) Risk to health and the environment from *PAHs in extender oils and tyres* – for adoption
  - (i) Risk of sensitization of humans to *nickel in piercing post-assemblies* – for adoption
- (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 meetings (41<sup>th</sup> and 42<sup>th</sup>) of the CSTEE.
- (11) Any other business



## Annex II

<p style="text-align: center;"><b>SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE) 40<sup>TH</sup> PLENARY MEETING</b></p>
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*Held on 12-13 November 2003  
in Brussels*

### LIST OF PARTICIPANTS

#### MEMBERS OF THE CSTEE:

Prof. Jim BRIDGES, Prof. Peter CALOW, Prof. Dr. Wolfgang DEKANT, Prof. Dr. Helmut GREIM, Prof. Bo JANSSON (13 November), Prof. Soterios KYRTOPOULOS, Prof. Claude LAMBRE, Prof. Janneche SKÅRE (12 November), Prof. José TARAZONA, Prof. Katarina VICTORIN, Prof. Marco VIGHI (12 November) and Prof. Joseph VOS.

*Apologies:* Prof. Giorgio CANTELLI FORTI, Prof. Erik DYBING, Prof. Colin JANSSEN, Prof. Amadeu SOARES and Prof. Benedetto TERRACINI.

#### EUROPEAN COMMISSION:

##### *CSTEE Secretariat (DG Health & Consumer Protection):*

Mrs. G. FONTANESI, Ms. V. ROLLAND

##### *DG Health & Consumer Protection:*

Mr. P. WAGSTAFFE, Mr. P. MARTIN

##### *DG Enterprise:*

Mr. S. BRION, Ms. K. GRODZKI, Ms. I. GUERRA, Ms. E. GUSTAFFSON, Mr. D. HADRICH, Mr. S. PICKERING

##### *DG Environment:*

Mr. M. BLAINEY, Mrs. C. RANCANCIO PENA