



**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 10.09.2003 Final

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

*Held on 10 September 2003  
in Brussels*

**DRAFT MINUTES**

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

Prof. Bridges welcomed the participants to the meeting. Prof. Soares sent his apologies.

Declaration of interest:

Prof. Greim and Prof. Calow mentioned that they were consulted as scientific advisers for the preparation of the Risk Assessment Reports on the Musk compounds.

As Prof. Jansson was involved in the drafting of the reports relating to the safety of toys, he will not participate to the related discussion.

**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 38th CSTEE plenary meeting were adopted and are available at:

[http://europa.eu.int/comm/food/fs/sc/sct/out189\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/sct/out189_en.pdf)

#### 4. NEW REQUESTS FROM COMMISSION SERVICES

Rapporteurs were appointed to comment on the final draft Risk Assessment Reports on Musk ketone and Musk xylene (HH and ENV), 2-ethylhexyl acrylate (HH and ENV) and Benzene (HH).

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

##### *Edetic acid and Tetrasodium ethylenediaminetetraacetate (HH and ENV)*

After a presentation by the rapporteurs of the opinions on the RARs on EDTA and Na<sub>4</sub>EDTA, both opinions on the environmental and human health parts were adopted and are available at:

[http://europa.eu.int/comm/food/fs/sc/sct/out191\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/sct/out191_en.pdf)

[http://europa.eu.int/comm/food/fs/sc/sct/out194\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/sct/out194_en.pdf)

[http://europa.eu.int/comm/food/fs/sc/sct/out195\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/sct/out195_en.pdf)

##### *Monochloroacetic acid (HH and ENV)*

With a few corrections agreed upon, the opinions on the environmental and human health parts of the RAR on MCAA were adopted and are available at:

[http://europa.eu.int/comm/food/fs/sc/sct/out190\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/sct/out190_en.pdf)

[http://europa.eu.int/comm/food/fs/sc/sct/out196\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/sct/out196_en.pdf)

Additional information on the presence of MCAA in the environment related to emissions of other chemicals and/or possible natural formation was requested in the Environmental Report. The potential consequences for humans indirectly exposed through the environment should be considered.

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

The rapporteur presented the draft opinion on the results of the human health risk assessment of 3,4 dichloroaniline. It was acknowledged that the database on the substance was limited especially with regards to the risk to workers. The draft opinion will be revised taking into account comments on the need for more data on worker exposure, conclusion ii) not acceptable regarding genotoxicity and clarification on dioxin-like contamination.

##### *But-2-yne-1,4-diol (HH and ENV)*

The rapporteurs presented the draft opinions on the results of the RARs on But-2-yne-1,4-diol on human health and environment, which were adopted and are available at:

[http://europa.eu.int/comm/food/fs/sc/sct/out192\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/sct/out192_en.pdf)

[http://europa.eu.int/comm/food/fs/sc/sct/out193\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/sct/out193_en.pdf)

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

A first draft opinion on the human health part was distributed but will be presented at the next plenary meeting when finalised. Main concern regards irritant properties and skin and respiratory sensitization of the substance. Reproductive toxicity does not seem to be well covered.

A preliminary draft opinion was also circulated on the environmental aspects of the RAR. Literature coverage and some specific issues need to be further checked. A revised opinion will be discussed again at the next plenary meeting.

#### ***Cadmium (HH and ENV)***

The chairman of the working group reported back on the discussion of the first working group meeting. The report is very detailed and extensive. An action plan was set up. A draft opinion will be presented at the next plenary meeting.

#### ***Zinc compounds (HH)***

The draft opinion on the results of the RAR (human health) on a few zinc compounds was discussed. Following a few comments made at the meeting, it was decided that a revised draft opinion would be proposed for adoption by written procedure after the meeting. The opinion was adopted and is available at:

[http://europa.eu.int/comm/food/fs/sc/sct/out197\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/sct/out197_en.pdf)

#### ***Chromium compounds (ENV)***

A few corrections were included after the draft opinion was presented at the last plenary meeting. The draft opinion presented again was adopted with minor changes and is available at:

[http://europa.eu.int/comm/food/fs/sc/sct/out198\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/sct/out198_en.pdf)

### **6. REQUESTS FOR OPINION FROM THE CSTEE BY COMMISSION SERVICES**

#### ***Risks posed by the use of SCCPs***

The conclusions of the draft opinion on the recently updated RAR on SCCPs were presented by the working group chairman. There are uncertainties associated with the classification of SCCPs as PBTs according to strict TGD criteria, although the group believes that the PBT classification is appropriate. New information on use patterns and levels raises concerns (backcoating in textiles, rubber processing, waste remaining in the environment), although the working group expressed reservations on the approach used. Among others the working group pointed out the uncertainties in PNECs and PECs. In addition the working group estimated that SCCPs as constituents and impurities of MCCPs in metal working may be cause of concern.

Members of the Committee were requested to send any comments on the back up detailed text within the following week.

The opinion was adopted by written procedure and is available at the following web address:

[http://europa.eu.int/comm/food/fs/sc/sct/out200\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/sct/out200_en.pdf)

Mr. Hehn (DG ENTR) thanked the committee for this opinion, which has been delivered in a very short notice.

#### ***Phosphate based household detergents and eutrophication***

The working group met the day before the plenary meeting. Preliminary concluding statements were presented and discussed. The contribution of phosphorus load in surface water can be very variable. In many countries detergent phosphorus is no

more a substantial contributor. A combined approach of significant reduction of STTP in household detergents and the implementation of the Urban Waste Treatment Directive seems necessary to cure the problem of eutrophication. The substitution of STTP by Zeolite A in detergents did not appear to pose toxicological or ecotoxicological problems and do not increase sludge volume. A complete draft opinion will be circulated before the next plenary meeting.

#### ***Risks posed by the use of copper containing anti-fouling on pleasure crafts***

The chairman of the working group presented the summary of the draft opinion relating to the Dutch notification for a reduction of the use of copper in antifouling on pleasure crafts. The CSTEE was asked to comment on the methodology and assumptions made in the context of the environmental risk assessment of copper-based anti-fouling products. The working group evaluated the approach used as not sound scientifically justified (e.g. lack of transparency on data selection, bioavailability of copper not taken into account, incorrect application of methodology). Members of the Committee should provide any comments on the detailed text within a week.

The opinion was adopted by written procedure and is available at:  
[http://europa.eu.int/comm/food/fs/sc/sct/out199\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/sct/out199_en.pdf)

#### ***Heavy metals and organic compounds from wastes used as organic fertilisers***

The working group chairman reminded the tasks of the working group. Another working group meeting will be organised to complete the work.

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

The Commission is considering a proposal for a Directive relating to restrictions on the marketing and use of certain PAHs in extender oils and tyres and asked the CSTEE to assess the potential risks to humans and to the environment posed by the PAHs emissions following tyre tread abrasion. The chairman of the working group reported that the major problem was the calculation of the acute contribution of these emissions to PAHs already present in the environment (including release from soil, bioavailability in water etc.). Preliminary information does not seem to support that the impact is major. An additional working group meeting may be needed. A draft opinion will be presented at the next plenary meeting.

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

The chairman of the working group reported back on the progress made. The CSTEE was asked to assess the overall scientific quality of the BUAV-ECEAE report on 'Action to end animal toxicity testing' proposing action plans and high priority programmes for research funding in order to replace or reduce animal toxicity testing. The CSTEE should particularly comment on the adequacy of the proposed non-animal alternative for each endpoint considered in the report in the context of classification, labelling and risk assessment of chemicals. A draft opinion was already discussed in the first working group meeting and will be further elaborated. Preliminary conclusions showed many points of disagreement. The working group comprises members of the CSTEE, SCCNFP, SCMPMD; involvement of EFSA Scientific Committee representatives is proposed. It is intended to present a final draft opinion for adoption at the next plenary meeting.

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

The CSTEE was asked to peer-review 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. The second working group meeting will take place next week. The report (b) has been improved a lot since the CSTEE reviewed it in 2000. The report (a) seems to be also of good quality. Main remaining task is to analyse a few specific chemicals in details. A draft opinion will be circulated before the next plenary meeting.

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

The CSTEE was asked to review a report proposing to replace the existing requirement of a maximum nickel content of 0.05% by mass in post assemblies by a migration limit of 0.2µg/cm<sup>2</sup>/week to prevent nickel sensitisation. The discussion in the first working group meeting showed that the working group agreed with the approach but had some reservations mainly on the justifications used to establish the limit value of 0.2µg/cm<sup>2</sup>/week. There is no need for an additional meeting and a draft opinion will be distributed before the next plenary meeting.

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

The CSTEE was asked to comment on a report assessing potential emissions and health risks from the use of mercury in a variety of products. The EUSES model was used to measure the distribution of mercury in the environment and subsequent risks to humans. The working group met and included an external expert to assess the validity of the distribution model programme. The author of the report had to be contacted again to provide further details. A draft opinion will be presented for adoption at the next plenary meeting.

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

The working group will soon held a meeting and develop a draft opinion for presentation at the next plenary meeting.

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

The working group is awaiting the EFSA opinion on the risks posed by organotins from dietary source to express an opinion on the overall risk posed by organotin compounds.

## **7. EMERGING ISSUES IDENTIFIED BY THE SSC AND FOR WHICH THE CSTEE IS THE LEADING COMMITTEE**

### ***Endocrine disruption (Human Health)***

The status progress of the launch of a call for tender to support a systematic review of epidemiological evidence of temporal changes of sperm quality and associated risk factors will be checked with the responsible official at DG SANCO/B.

## **8. HEALTH AND ENVIRONMENT STRATEGY**

On the occasion of a preliminary meeting of the Consultative Forum on the same day, L. BONTOUX (DG JRC) updated the CSTEE on the activities related to the Health and Environment Strategy. It is intended that a baseline report (Community Strategy) and an Action Plan should be proposed in June 2004 (Budapest Interministerial Conference) as a result of these activities. Technical Working Groups are being created and three regional Conferences will be organised in fall covering the following topics: indicators and priority diseases, integrated monitoring, and research needs. The task of the Technical Working Groups consists in reviewing the state-of-knowledge, identifying information gaps, and proposing actions in the area selected. Members of the Technical Working Group will be selected by the Commission. Members of the CSTEE are free to apply as individuals. The work produced by the CSTEE will be taken into account whenever appropriate along the process.

Further information is available at the following website address:

[http://europa.eu.int/comm/environment/health/index\\_en.htm](http://europa.eu.int/comm/environment/health/index_en.htm)

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

The collaborative work between of a few members of the CSTEE and the new EFSA Panel on Feed Additives on the environmental effects of some substances present in animal feed is ongoing.

A member of the CSTEE working group on organostannic compounds ensures exchange of information with the Organnotin Working Group of the new EFSA Panel on Contaminants.

No interactive issues have been recently identified within the EFSA Scientific Committee or the EFSA Panel on Contaminants.

## **10. ARRANGEMENTS FOR THE NEXT (40<sup>TH</sup>) PLENARY MEETING OF THE CSTEE**

The next meeting of the Committee was confirmed on 12-13 November 2003.

## **11. ANY OTHER BUSINESS**

Following a letter received by DG ENTR from the Canadian Asbestos Institute, Prof. Bridges presented a response with comments on a few key points raised and which were within the remit of the CSTEE as well as specific comments on the report on the biopersistence of Canadian chrysotyle asbestos by Bernstein, Rogers and Smith (2003).

The new organigramme of DG SANCO was presented. The new unit C7 on Risk assessment belongs to the restructured direction C on Public Health and Risk Assessment. The scope of this unit will be to manage the existing 'non-food' Scientific Committees, ensure overall coordination of SANCO's relationship with DG RDT and DG JRC and to facilitate co-operation on risk assessment of subjects of mutual interest with national, Community and international bodies as appropriate.

Mrs. M. Marini further indicated that a draft proposal for the renewal of the ‘non-food’ Scientific Committees was being prepared. The official procedure consists then in internal consultation steps and eventually approval by the College of Commissioners.

In addition Mrs. M. Marini informed the CSTEE that a brainstorming meeting would be organised by the unit with external experts to discuss the issue of exposure to mixture of chemicals. Members of the CSTEE were welcome to suggest any names of experts to be involved.

It was clarified that, for practical reasons, the feed back from the Commission was no longer addressed under a specific point of the agenda but covered when the specific issues are addressed during the meeting.

Prof. Bridges closed the meeting with thanking the audience and the members of the committee for their participation.

**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**  
**Scientific Committee on Toxicity, Ecotoxicity and the Environment**

CSTEE/00/Plen.age.10.09.2003 Final

<p style="text-align: center;"><b>SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT</b> <b>(CSTEE)</b> <b>39<sup>TH</sup> PLENARY MEETING</b></p>
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*10 September 2003, 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 38<sup>th</sup> CSTEE plenary meeting
- (4) New requests from Commission Services
  - (a) Regulation 793/93 : *Musk ketone* (CAS No. 81-14-1) and *Musk xylene* (CAS No. 81-15-2) - HH and ENV
  - (b) Regulation 793/93 : *2-ethylhexyl acrylate* (CAS No. 103-11-7) - HH and ENV
  - (c) Regulation 793/93 : *Benzene* (CAS No. 71-43-2) - HH
- (5) Regulation 793/93 on Existing substances (ESR): Status reports/opinions
  - (a) *Edetic acid* (CAS No. 60-00-4) and *Tetrasodium ethylenediaminetetraacetate* (CAS No. 64-02-8) (HH-ENV)
  - (b) *Monochloroacetic acid (MCAA)* (CAS No. 79-11-8) (HH-ENV)
  - (c) *3,4 Dichloroaniline* (HH)
  - (d) *But-2-yne-1,4-diol* (CAS No. 110-65-6) (HH-ENV)
  - (e) *Methylenediphenyl diisocyanate (MDI)* (CAS No. 26447-40-5) –(HH-ENV)
  - (f) *2-ethylhexyl acrylate* (CAS No. 103-11-7) (HH)
  - (g) *Cadmium metal* (CAS No. 26447-40-5 ) and *Cadmium oxide* (CAS No. 26447-40-5) (HH-ENV)
  - (h) *Zinc metal* (CAS No. 7440-66-6), *Zinc oxide* (CAS No. 1314-13-2), *Zinc distearate* (CAS No. 557-05-1), *Zinc chloride* (CAS No. 7646-85-7), *Zinc sulphate* (CAS No. 7733-02-0), *Zinc phosphate* (CAS No. 7779-90-0) (HH)
  - (i) *Chromium trioxide* (CAS No. 1333-82-0), *Sodium chromate* (CAS No. 7775-11-3), *Sodium dichromate* (CAS No. 10588-01-9), *Ammonium dichromate* (CAS No. 7789-09-5) and *Potassium dichromate* (CAS No. 7778-50-9) (ENV)

- (6) Ongoing requests for opinion from the CSTEE by Commission services on:
- (a) Risks posed by the use of *SCCPs*
  - (b) *Phosphate based detergents and eutrophication*
  - (c) Risks to the environment posed by the use of *copper containing anti-foulings on pleasure craft*
  - (d) Study on *Heavy metals and organic compounds from wastes used as organic fertilisers*
  - (e) Risks to health and the environment from *PAHs in extender oils and tyres*
  - (f) Examination of a report on *alternative non-animal methods for chemical testing*
  - (g) Two studies on substances showing evidence of or potential of *endocrine disruption*
  - (h) Risk of sensitisation of humans to *nickel by piercing post assemblies*
  - (i) Risks posed by *Mercury in products*
  - (j) Reports on the risk assessment of *organic chemicals in toys* and on the assessment of the *bioavailability* of certain elements *in toys*
  - (k) Risks to health and environment posed by the use of *Organostannic compounds*
- (7) Emerging issues identified and for which the CSTEE is the leading committee: *Endocrine disruption -Metaanalysis (Human Health)*
- (8) Participation of the CSTEE in activities/working groups of other scientific Committees of the Commission or EFSA
- (9) Next plenary meeting of the CSTEE
- (10) Any other business

## Annex II

<p style="text-align: center;"><b>SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE) 39<sup>TH</sup> PLENARY MEETING</b></p>
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*Held on 10 September 2003  
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. José TARAZONA, Prof. Benedetto TERRACINI, Prof. Katarina VICTORIN, Prof. Marco VIGHI and Prof. Joseph VOS.

*Apologies:* Prof. Amadeu SOARES

#### EUROPEAN COMMISSION:

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

Mrs. G. FONTANESI, Ms. V. ROLLAND

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

Ms. M. MARINI

##### *DG Enterprise:*

Mr. S. BRION, Mr. D. HADRICH, W. HEHN, Mr. G. INDIRLI, Mrs. C. KOENIGUER,  
Mr. S. PICKERING

##### *DG Environment:*

Mrs. C. RANCANCIO PENA

##### *DG Research:*

Mr. T. KARJALAINEN

##### *DG JRC:*

Mr. L. BONTOUX