



EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions

**C2 - Management of scientific committees; scientific co-operation and networks
Scientific Committee on Toxicity, Ecotoxicity and the Environment**

CSTEE/GEN2/Minutes 01.04.2003 Final

**SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT
(CSTEE)
37TH PLENARY MEETING**

*Held on 1st April 2003
in Brussels*

DRAFT MINUTES

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

Prof. Bridges welcomed the participants to the meeting. Prof. Cantelli Forti, Prof. Skåre, Prof. Terracini and Prof. Vighi sent their apologies.

Declaration of interest:

No declarations of interests were 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 36TH PLENARY MEETING

The draft minutes of the 36th CSTEE plenary meeting were adopted with minor corrections and are available at:

http://europa.eu.int/comm/food/fs/sc/sct/out181_en.pdf

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

Aniline and 3,4 Dichloroaniline

A draft opinion on the human health part of the RAR was distributed at the last plenary meeting for comment. The rapporteur proposed additional corrections with

regards to possible respiratory sensitization and uncertainties on the genotoxic and carcinogenic effects of aniline (CSTEE/2003/9/ADD.1). The draft opinion was adopted with all these corrections and concluded that occupational exposure limits should be reconsidered. High risk scenarios were identified for workers from inhalation or dermal exposure during production or further processing of aniline (concern regarding acute and chronic toxicity, carcinogenic effects and genotoxic properties of the substance). It is available at:
http://europa.eu.int/comm/food/fs/sc/sct/out183_en.pdf

The draft opinions on the environmental risk assessment of aniline and the human health risk assessment of 3,4-dichloroaniline should be circulated among the committee for discussion at the next plenary meeting.

The need to ensure a consistent approach for all amines risk assessments was repeated.

Chromium Trioxide, Sodium Chromate, Sodium Dichromate, Ammonium Dichromate, Potassium Dichromate

A draft opinion on the results of the environmental risk assessment of the chromates above-mentioned was presented at the meeting. Three points were considered as a cause of concern: (a) the effects of the reduced form of Cr(VI) were not assessed, (b) the possible toxic effects of natural background concentrations were ignored, (c) environmental factors e.g. pH, bioavailability were not taken into account in the risk assessment. Consequently the committee agreed to convene a working group to discuss a consistent general approach for the risk assessment of metals. Focus will not only be on criticism but also on proposals for an appropriate way forward. Meanwhile all committee members were invited to send comments on the draft opinion, which was distributed.

Sodium Perborate

The rapporteur presented the draft opinion on the results of the environmental risk assessment of sodium perborate (CSTEE/2003/1/ADD.2). The RAR does not include information on all degradation products of sodium perborate, such as boric acid, whose toxic and long-term effects are of high concern. A risk assessment of boric acid is planned but not available yet. The committee members underlined that the potential risks of metabolites should be considered to allow a complete and meaningful risk assessment of any chemical. Furthermore the members expressed their concern that the RAR were given to them for peer-review, whereas they were sometimes not complete due to the current legislative framework. Ms. Munn (DG JRC) confirmed that the Commission was aware of these issues. The Member States rapporteurs could be encouraged to take these considerations into account at the early stage of the process. The draft opinion was adopted with minor comments and is available at:
http://europa.eu.int/comm/food/fs/sc/sct/out184_en.pdf

5. REQUESTS FOR OPINION FROM THE CSTEE BY COMMISSION SERVICES

Safety and quality of drinking water

Mr. Daskaleros (DG SANCO) clarified the purpose of the two studies that were commissioned and will prepare a short explanatory paragraph to be included in the

opinion. Although the use of the study results are limited due to the methodological approach (e.g. lack of worst case scenario for bottled water, sample representativity and variability, failure to use standard sample methods for tap water), they can provide an insight for further work to be undertaken in this area. The latest draft opinion prepared by the working group was discussed in details (CSTEE/2003/10/ADD.1) and changes will be made accordingly. Furthermore, as the draft opinion is rather long, the rapporteur will prepare a summary, which will refer to the longer report for further details. In the meantime the members of the committee are invited to think of any population subgroups at risks (question 2b) and any additional studies needed to assess the safety of tap/bottled water (question 3a).

Risks to health and the environment related to the use of lead in products

The rapporteur presented the final draft opinion on the specific questions addressed to the CSTEE on the conclusions of a report on the risks to health and the environment posed by the use of lead in products (CSTEE/2003/11/ADD.1). The text included a few clarifications as required at the last meeting and points out the uncertainties resulting from many assumptions regarding exposure scenarios made in the report. The text was adopted and is available at the following web address: http://europa.eu.int/comm/food/fs/sc/sct/out182_en.pdf

Mr. Hehn (DG ENTR) thanked the committee for this opinion, which will be given to the author of the report. It will also be taken into account together with other reports on economical aspects.

Mr. Daskaleros informed the CSTEE that the opinion recently adopted on the risks posed by lead containing candle-wicks was sent to the Member States in the context of the Consumer Protection Directive.

Phosphate based household detergents and eutrophication

The CSTEE recently adopted an opinion on a study commissioned by both DG ENTR and DG ENV dealing with the impact of phosphate-loaded detergent discharges on eutrophication. Some of the conclusions in the report were evaluated as not adequately substantiated. Thus the CSTEE is invited to elaborate further on this issue based on a more complete analysis of the literature. Specific questions focus on the contribution of phosphate-based detergent to eutrophication and its significance, the impact on eutrophication that would result from a reduced phosphate content of 1% in detergent, and the consequences of substituting STPP by Zeolite A on the environment and in sludge accumulation (CSTEE/2003/4/ADD.1). An opinion on these questions would be appreciated in the month of September. The same working group will convene with an external *ad hoc* expert to be identified.

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

The rapporteur presented the first draft opinion on the risks posed by organostannic compounds to human health and the environment that was issued at a working group meeting the day before this meeting. Questions relate to the quality of the report provided, the risks to consumers from non-food consumer products or from environmental sources, the risks to the environment and industry plans to measure emissions at specific plants. A few issues were identified in the exposure section:

emission factors used for specific substances are based on emission scenarios for other substances, the volatility of the substances is underestimated, some miscalculations have been found, indoor air exposure seems neglected. An attempt by the working group to calculate DBT in indoor air shows exposure levels of concern especially in children. The human health effects section does not discuss an additivity mechanism of such chemicals, whereas it may be suspected. The environmental section focuses on the risks on the freshwater environment, there is no mention of studies on imposex. The working group will refine the text and include the results awaited from the SCF working group mid-May on the possible risks to humans from food sources or food contact material in order to assess the total exposure and risks to organostannic material.

Heavy metals and organic compounds from wastes used as organic fertilisers

The first meeting of the working group on heavy metals and organic compounds from wastes used as organic fertilisers will take place at the end of this week.

Risks posed by the use of copper containing anti-foulings on pleasure crafts

Mr. Ingel (DG MARKT) introduced a new request to the committee following a complaint concerning possible barriers to trade in copper-based anti-foulings in the Netherlands (CSTEE/2003/6/ADD.1). There is indeed a systematic prohibition by the Dutch Pesticides Approval Board to put copper-based anti-foulings on pleasure craft. The CSTEE is invited to comment on the evidence submitted by the Dutch authorities in support of the Dutch Pesticides Approval Board Decisions, as well as on some additional documentation provided by the complainant. In particular, the CSTEE should comment on the methodology and assumptions made in the context of the environmental risk assessment of copper-based anti-fouling products. In addition, if there is sound scientific evidence that the use of copper-based anti-fouling products presents environmental risks, the CSTEE is invited to quantify these risks, if possible. A working group was set up. An *ad hoc* expert will be invited.

Report on the risk assessment of organic chemicals in toys

Ms. Gustafsson (DG ENTR) presented a new request to the CSTEE on a peer-review of the CEN risk assessment report on organic chemicals in toys and the resulting draft standards. The report provides an evaluation of the toxicity data that has been assessed for each substance considered and also a rationale for the requirements proposed for each of the substance categories considered (substance to be prohibited, migration limit to be set, insignificant risk or insufficient toxicity data available). A working group was set up.

Risks posed by heavy metals in toys

Ms. Gustafsson (DG ENTR) introduced another request regarding the assessment of the bioavailability of certain metals in toys material. The CSTEE is invited to assess if the current limit values for heavy metals should be revised based on the information provided by the Danish Technological Institute and on the latest scientific developments in this area. The CSTEE is also invited to identify any other metals or substances other than those already considered, that could pose a risk by its use in toys material. In addition the CSTEE is asked for an opinion regarding a

possible revision of the worst case assumption made on a child “toy consumption” value. The same working group as above will deal with this request.

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

Mrs. Rancancio Pena presented in details the whole process and past/future activities following the announcement of the Community Strategy for Endocrine Disruptors COM (1999) 706, whereby it was intended to establish a priority list of substances for further evaluation of their role in endocrine disruption. As a consequence a first list of 553 substances was established and two studies were commissioned 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 CSTE is invited to assess the scientific quality of these two reports and to comment on the conclusions reached, and in particular on the adequacy of the preliminary evaluation of the 435 substances as a basis for a priority list for further evaluation. An expert group was set up. The involvement of two *ad hoc* experts was agreed.

Alternative methods to animal testing

The CSTE Secretariat informed the committee that a new request was in preparation with regards to the use of alternative non-animal methods for chemical testing. Particular attention should be put on the consistency of all opinions issued in this area. It is planned to create a joint working group with members of other scientific committees to ensure a consistent approach whatever the uses of the chemicals (pesticides, additives etc.) and the various existing legislative frameworks (e.g. cosmetics).

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

Endocrine disruption (Human Health)

An official call for tender is being prepared by DG SANCO/B to support a systematic review of epidemiological evidence of temporal changes of sperm quality and associated risk factors.

Indoor air quality

Most experts who had been identified to become members of the two future working groups on the health impact of indoor air quality and future possible strategy have been contacted. Before convening the working groups, two literature research should be undertaken to review the current knowledge on the impact on health of indoor air quality and future trends, and to identify important gaps in knowledge. The official procedure within the Commission requires launching a public call for tender. Any interested candidates will be welcome to apply when the call is launched.

Persistence, bioaccumulation and toxicity criteria

Following the proposal by the CSTE to create a new working group to discuss the definition and use of the PBT criteria as well as possible alternative approaches for persistent substances, DG ENV is preparing an official request to the CSTE.

7. PARTICIPATION OF THE CSTEЕ IN ACTIVITIES/WORKING GROUPS OF OTHER SCIENTIFIC COMMITTEES OF THE COMMISSION

The collaborative work between of a few members of the CSTEЕ and the SCAN on the environmental effects of some substances present in animal feed is either finalised (zinc, copper) or about to be finalised (coccidiostats).

A member of the CSTEЕ working group on organostannic compounds ensures the link with the SCF working group on organotins in food.

The CSTEЕ Secretariat informed the committee that a comparative table between the assessment of the CSTEЕ and the SCF on phthalates was being prepared for the establishment of the list of plastics additives in food contact material. CSTEЕ members interested, especially those who have been involved in the preparation of previous opinions on phthalates in toys, would be welcome to participate to the next SCF meeting planned in June. Two members will join, provided date availability.

8. UPDATE ON THE LATEST MEETINGS OF THE SSC ON MATTERS OF INTEREST TO THE CSTEЕ

Prof. Bridges informed that the last meeting of the task force on Harmonisation of risk assessment would take place on 5 April. The complete report is likely to be published end April-early May. It is a substantive document including a long list of recommendations.

9. ARRANGEMENTS FOR THE NEXT (38TH) PLENARY MEETING OF THE CSTEЕ

The next meeting of the Committee was confirmed on 12 June 2003.

10. ANY OTHER BUSINESS

Following some concern of a few members of the committee, the CSTEЕ secretariat enquired about the CSTEЕ involvement in reviewing Guidance Documents associated with the implementation of the Water Framework Directive. The WFD Team co-ordinator (DG ENV) confirmed the relevance of consulting the CSTEЕ on key scientific elements in the policy preparation (e.g. environmental quality standards). However guidance documents in relation to the implementation policy are not considered as “scientific“ documents to be reviewed by the CSTEЕ. The WFD Team co-ordinator will be invited to the next plenary meeting to directly exchange with the committee members on this matter.

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 - Scientific Opinions
C2 - Management of scientific committees; scientific co-operation and networks
Scientific Committee on Toxicity, Ecotoxicity and the Environment

CSTEE/00/Plen.age.01.04.2003 Final

<p style="text-align: center;">SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE) 37TH PLENARY MEETING</p>

*1st April 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 36th CSTEE plenary meeting
- (4) Regulation 793/93 on Existing substances (ESR): Status reports/opinions and new request (Human Health and/or Environment)
 - (a) *Aniline* (ENV, HH) – for adoption (HH) or discussion (ENV)
 - (b) *3,4 Dichloroaniline* (HH) – for discussion
 - (c) *Chromium trioxide, Sodium Chromate, Sodium Dichromate, Ammonium Dichromate and Potassium Dichromate* (ENV) – for discussion
 - (d) *Sodium Perborate* (ENV) – for discussion
- (5) Requests for opinion from the CSTEE by Commission services on:
 - (a) Studies relating to the *quality of drinking water in selected European countries* – for adoption
 - (b) Questions arising from a study on *Risks to Health and the environment related to the Use of Lead in Products* – for adoption
 - (c) *Phosphate based detergents and eutrophication* - new request
 - (d) Risks to health and environment posed by the use of *Organostannic compounds* – for discussion
 - (e) Study on *Heavy metals and organic compounds from wastes used as organic fertilisers* – for discussion
 - (f) Risks to environment posed by the use of *copper containing anti-foulings on pleasure craft* – new request

- (g) CEN Report on the risk assessment of *organic chemicals in toys* – new request
 - (h) Risks posed by *heavy metals in toys* – possible new request
 - (i) *Alternatives to animal testing* – possible new request
 - (j) Two studies on substances showing evidence of or *potential of endocrine disruption* – new request
- (6) Emerging issues identified and for which the CSTEE is the leading committee:
- (a) *Endocrine disruption (Human Health)*
 - (b) *Indoor air quality*
 - (c) *PBT*
- (7) Participation of the CSTEE in activities/working groups of other scientific Committees of the Commission
- (8) Update on the latest meetings of the Scientific Steering Committee on matters of interest to the CSTEE
- (9) Next plenary meeting (38th) of the CSTEE.
- (10) Any other business

Annex II

<p style="text-align: center;">SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE) 37TH PLENARY MEETING</p>

*Held on 1st April 2003
in Brussels*

LIST OF PARTICIPANTS

MEMBERS OF THE CSTEE:

Prof. Jim BRIDGES, Prof. Peter CALOW, 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 (afternoon), Prof. José TARAZONA, Prof. Katarina VICTORIN and Prof. Joseph VOS.

Apologies: Prof. Giorgio CANTELLI FORTI, Prof. Janneche SKÅRE, Prof. Benedetto TERRACINI and Prof. Marco VIGHI.

EUROPEAN COMMISSION:

CSTEE Secretariat (DG Health & Consumer Protection):

Mrs. G. FONTANESI, Ms. V. ROLLAND

DG Health & Consumer Protection:

Mr. T. DASKALEROS

DG Enterprise:

Mr. W. HEHN, Ms. E. GUSTAFSSON, Ms. K. GRODZKI, Mr. S. PICKERING

DG Environment:

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

DG Research:

Mr. C. SEARLE, Mr. J. PULLICINO

DG JRC:

Mr. L. BONTOUX, Mr. S. KEPHALOPOULOS, Ms. S. MUNN

DG MARKET:

Mr. H. INGELS