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EUROPEAN COMMISSION
DIRECTORATE-GENERAL HEALTH AND CONSUMER PROTECTION
Directorate C - Scientific Opinions
Unit C2 - Management of Scientific Committees; scientific co-operation and networks
Scientific Committee on Toxicity, Ecotoxicity and the Environment

Brussels,
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CSTEE/00/MinPlen.20.07.2001

**Minutes of the 25th PLENARY MEETING
of the
SCIENTIFIC COMMITTEE ON
TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)**

held on

20 July 2001 in

**Centre Albert Borschette, rue Froissart 36,
B-1040 Brussels**

1. Welcoming address, apologies for absence, declarations of interest

Apologies were received from Profs. A. Soares, J.Vos, B. Terracini, S. Kyrtpoulos and J. U. Skäre.

Prof. Bo Jansson declared his involvement on the activities of the 'Marine risk assessment' group that took place under the auspices of the European Chemicals Bureau and that drafted the respective part of the so-called *Technical Guidance Document* (see agenda point 4.D). The committee noted that this fell into the definition of 'non-personal and specific' type of involvement.

2. Adoption of the draft agenda

The draft agenda was adopted. The order of some points was somewhat changed to address travelling needs of some committee members and availability of Commission officials.

3. Approval of the draft minutes of the 24th CSTEE plenary meeting

The draft minutes were approved with some minor editorial corrections. They are available in:

http://europa.eu.int/comm/food/fs/sc/sct/outcome_en.html#minutes

4. Regulation 793/93 on Existing substances (ESR):

A brief debate took place on the legitimacy/convenience of contacts between CSTEE members and the authors of 793/93 RARs submitted to the CSTEE for peer review. The CSTEE secretary informed of the debate that had taken place during the CAs meeting in Stockholm on the issue. It was concluded that the ECB has to be used as the relayer of information for this sort of contacts. On the other hand the current *status quo* of the CSTEE consultation on Reg. 793/93 RARs does as yet not include earlier involvement of the scientific committee before final RARs are submitted, but this is foreseen to change.

The CSTEE secretary informed that separate CSTEE opinions will from now on be adopted for the Human Health and Environmental parts of the 793/93 Regulation RARs.

A. Status reports/opinions on:

a) 1,2,4-Trichlorobenzene (Human Health & Environment)

The contributions of various members were noted and most of them were integrated in the final draft that was finally approved as the CSTEE opinion. It is available on:

http://europa.eu.int/comm/food/fs/sc/sct/outcome_en.html

b) Hydrogen Peroxide (Human Health & Environment)

A first discussion on the RARs of this chemical took place and the contributions of CSTEE members were noted. A long discussion took place on extrapolation of PNEC aquatic to PNEC soil, the difficulties in the discussion of which caused a postponement of the adoption of the draft on the environmental part.

Regarding the human health part it was pointed out that there is no good data so far on inhalatory toxicity on humans and animals. There is no relevant long-term study on inhalation and no definite study in humans on exposure to inhalation to evaluate NOAELs either. It would look as if the relevance to the human situation of available studies is not clear. This should be acknowledged as well as the usefulness of animal studies to the human situation. Reprotoxic effects were thought to be addressed in a way that led the committee to express doubts about this part of the report and consequently committee members were asked to take an even more in depth look at this part of the RAR.

Rapporteurs for both sections (HH and ENV) of the RAR undertook to provide final draft versions for adoption at the next CSTEE plenary.

c) Styrene (Environment)

The CSTEE *rapporteur* described the contributions received (in particular on *exposure* and the *terrestrial environment* parts) and provided first general impressions on the RAR. He undertook the task of integrating comments in a final draft opinion for adoption at the occasion of the next CSTEE plenary.

d) N-Vinyl pyrrolidone

As in c).

B. Status reports/opinions (Environment) on:

e) Di(isononyl)phthalate (DINP) and f) Di(isodecyl)phthalate (DIDP)

Amended versions of the draft opinions which had been worked out the day before (19 July 2001) during the meeting of the subgroup 'Environment' of the 'Phthalates' CSTEE working group were distributed and the debate took place using these as a reference. In

general the RARs were thought to be good and that the TGD had been used properly in the RARs of these chemicals, even though the WG expressed doubts about the usefulness of the TGD in this kind of chemicals which can be considered to be quite specific. Some possible problems due to the biopersistence of these chemicals were noted.

While the draft opinions were generally considered to be good, because CSTEE members had had no time to consider them in detail it was agreed to postpone their adoption to the following CSTEE plenary in September 2001.

C. State of play regarding other substances evaluated under the ESR

The CSTEE secretary informed the committee of his attending the respective Competent Authorities meeting in Stockholm, from the 25 to 27 June where a new document, in the meantime sent by mail to the CSTEE, with the current *status quo* for the RARs was presented. Committee members' attention was drawn to the fact that the role of the CSTEE is now clearly and explicitly acknowledged by means of two columns that have been inserted in the mentioned document.

The CSTEE secretary informed that RARs on other chemicals would be submitted soon to the CSTEE. DODMAC, Naphthalene, Butadiene and Cyclohexane were specifically mentioned. DEHP was expected also. CSTEE *rapporteurs* were appointed for the Human Health and Environmental sections of each.

D. Input of the CSTEE into the revision of the 'Technical Guidance Document' in support of Regulation 793/93

The secretariat could so far not further the initiative and action decided at the previous plenary *i.e.* that the CSTEE should receive from the ECB the final reports of some ECB WGs working on the TGD revision and that these should be looked at by some CSTEE subgroups, *i.e.* Human Health effects, Marine risk assessment and Exposure. Suggestions for membership of the respective CSTEE working group were noted.

The ECB informed the CSTEE secretariat that the final reports as cleared by the respective groups in Ispra should be sent very soon. The committees were reminded that there should be at least four different groups, *i.e.* Marine risk assessment, Exposure assessment, Human Health effects and Environmental risk assessment. Two committee members further undertook to provide the co-ordinates of external experts to collaborate on the reports on Marine risk assessment and Environmental risk assessment.

5. JRC report on results of the validation of methodologies for determining the release of DINP from toys and childcare articles - for opinion

The CSTEE *rapporteur* presented the draft of the proposed CSTEE opinion on the latest version of the JRC report. Some aspects of the report on which the CSTEE expressed the view that better information would be convenient were mentioned such as *e.g.* (i) information on the kinds of problems that participating laboratories had during the course of their participation; (ii) problems with simulation of the worst case *in vivo* study; (iii) need for a factor to be applied to reach the levels experienced in a worst case situation.

It was pointed out that currently the validation applies to DINP only, extrapolation to other plasticisers being as yet not established.

The submitted draft was finally approved as the CSTEE opinion. It is available on:

http://europa.eu.int/comm/food/fs/sc/sct/outcome_en.html

The JRC representative commented on the CSTEE opinion saying that the JRC knew from the start about the 'problems' mentioned by the committee but time constraints did not help accomplish the validation addressing those. More detailed comments were made on some of the specificities of the validation task carried out by the JRC overall. The feedbacks from laboratories were essentially complaints about time constraints and funding problems. The JRC representative undertook to answer, where possible, to the information requests of the CSTEE (among others some raw, tabulated data, not included in the report submitted for CSTEE opinion).

The DG ENTR representative welcomed the work of the JRC, the CSTEE opinion and informed that the Commission services will now have to consider the available information before a final risk management decision can be made. In principle the committee can expect to be consulted again in the future on some outstanding issues, *e.g.* correction factors, new guidance values dependent on the NOAEL, etc.

**6. Endocrine Disrupting Chemicals (EDCs):
3rd presentation by representatives of the *Fraunhofer-Institut für Umweltchemie und Oekotoxikologie*, Schmallenberg, Germany, of the final results of their research project relating to the development and validation of a test method for the identification of endocrine disrupting chemicals**

Representatives of the *Fraunhofer-Institut* presented the final result of their research project. The committee were reminded of two other interim presentations on this research project; the previous presentations had taken place, the 1st at the 9th CSTEE plenary meeting, 5th of May 1999 and the 2nd at the 16th CSTEE plenary meeting, 19th of June 2000.

It was explained that the aim of the study was contributing to the development of testing strategies for EDCs but it had been made clear from the outset that the focus would be on oestrogen compounds due to the complexity of endocrinic modes of action and time constraints. The representative of the *Fraunhofer-Institut* informed that the report (of which the CSTEE had received a paper copy by mail) was a final draft version. The very final version would be provided later for information of the committee.

The presentation was followed by a question time period during which committee members enquired about such varied aspects as: histology; population dynamics; acute to chronic ratio of EDCs; false negatives with the proposed screening; possibilities of extrapolation to different species bearing in mind differences in sexual behaviour and reproductive strategies across such species; aspects of experimental designs; species comparability; consequences over later generations of test species; possibility of developing a pre-screening based on *e.g.* QSAR approaches to identify completely unknown chemicals that have EDC effects (the DG JRC representative informed about progress on the use of QSAR in trying to identify EDCs - they will be published soon); possibility of incorporating metabolism systems in *in vitro* screens, etc.

The *Fraunhofer-Institut* representatives welcomed comments from the CSTEE and informed that the final version of the report would certainly address some of them. The CSTEE chairman also commended the *Fraunhofer-Institut* for their work.

7. Report on "Cadmium used as a Colouring Agent or a Stabiliser in Polymers and for Metal Plating - Risks to Health and Environment"

In the absence of the *rapporteur* for this opinion request only the exposure and environmental parts of the report could be addressed by the responsible CSTEE members and already on the exposure side - even though with a targeted risk assessment this was not totally unexpected - it would look as if the report only considers exposure from the applications under consideration, whereas the ESR risk assessment still under way, seems to be considering all other applications, including natural background concentrations.

Clarification was also requested on the possible degree of overlap, if any, between the study submitted to the CSTEE for peer-review and the major Cadmium risk assessment still ongoing under the responsibility of Belgium (the Member State nominated *rapporteur* for this substance, in the framework of Regulation 793/93).

A representative of DG Enterprise explained that the obligations of the Commission to review before 2003 the legal provisions on Cadmium polymers for stabilising PVC and for plating meant that it could not wait for the ESR Cadmium RAR to be finalised, hence the reason why the report, now submitted to the CSTEE for review, was requested. Conclusions in the study will be considered in the light also of the CSTEE opinion once it is available.

8. Health effects of Radio Frequency and Electromagnetic fields – progress report

A short account on progress so far, basically stemming from the conclusions arrived at at the WG meeting held the month before, was provided. WG members were then given a series of tasks to accomplish, to be ready before the next WG meeting scheduled for 10 September 2001.

A JRC representative provided information on the JRC's activities in the field and will attempt to be present at future meetings of the CSTEE. The CSTEE EMF/RFF WG chairman will be kept informed about the JRC's activities. The CSTEE secretary informed that Prof. Ahlbom's contribution into this exercise was secured. In spite of other commitments he promised to drop them in favour of attending the working group meeting scheduled for 10 September 2001.

9. Revision of the CSTEE position paper on "Exposure data" (in the light of public comments received)

The WG chairman described comments received, subsequent to publication in the DG SANCO website of the CSTEE opinion for a period of *circa* one month, during which public comments had been invited. He informed that practically all could be endorsed and that the CSTEE opinion was changed accordingly. The opinion will now be put in the DG SANCO website as the final CSTEE opinion. The CSTEE secretary informed that the secretariat will try to have this opinion published as an OPOCE document.

10. Participation of the CSTEЕ in activities/working groups of other scientific committees of the Commission

a) Toxicity of minerals such as Cu and Zn in animal feed regarding the possible environmental impact of these minerals – activity of the SCAN

The CSTEЕ secretary informed that to the extent that the CSTEЕ involvement was dependent on the SACN secretariat taking the initiative, this agenda point would be dropped from future CSTEЕ plenary meeting agenda's until the CSTEЕ secretariat is informed of the need to activate a CSTEЕ participation.

b) Other

The 1st vice-chairman of the CSTEЕ commented on the participation of some CSTEЕ members on the activities of the SCF working group that addressed the subject '*Dioxins and dioxin like PCBs in food*'. At stake had been the issue of derivation of NOAEL on the basis of the acceptable daily intake and the use of an uncertainty factor to compensate for gender differences in human toxicokinetics, something on which the participating CSTEЕ members had expressed reservations (and informed the SCF and its secretariat accordingly). The committee noted the adoption by the SCF of the opinion on the risk assessment of dioxins and dioxin-like PCBs in food, on 30 May 2001.

The CSTEЕ also discussed briefly what course of action to take in cases of differences of opinion between committees.

11. Strategies for dealing with emerging issues identified by the SSC and for which the CSTEЕ is the 'lead' committee:

a) Endocrine disruption (Human health)

In the absence of the WG chairman no discussion on this agenda point took place.

b) Indoor climate

The debate on this agenda item was preceded by an introductory remark made by the CSTEЕ chairman who explained that the CSTEЕ involvement on this topic was the direct consequence of the SSC's view that a range of emerging issues, while cross-cutting more than one committee's fields of competence, should still be tackled under the co-ordination of individual committees.

Contributions on this subject sent by of some CSTEЕ members in advance of the meeting were described. The composition of the CSTEЕ was discussed and members, including external experts, were proposed. A tentative working group was formed.

Aspects to be considered when the CSTEЕ tackles this subject in practice are **(i)** Possible overlap with activities of other scientific committees/group/fora, and avoid duplication; **(ii)** Extreme wide scope of the exercise; **(iii)** Ensure that composition of the CSTEЕ working group covers the major areas.

A representative of the JRC also commented on the current JRC activities in this field. He sought clarification on the scope of the CSTEЕ exercise and was informed that, in principle, it should also address physical aspects, noise, etc. and not only atmospheric pollutants. However, the CSTEЕ chairman informed that in any case a final answer on the scope can only be provided later, once the WG and the CSTEЕ endorse a proposal; likewise the composition of the WG can be enlarged as it progresses. He also pointed out that this activity can last as long as the rest of the life of the current term of the CSTEЕ.

12. Feedback from the relevant services of the Commission on the follow up to the opinions adopted previously by the CSTEE

No feedback was provided by any Commission service.

13. Strategies for dealing with additional opinion requests submitted by other DGs of the Commission

Apart from the ones under the 793/93 ESR programme previously mentioned no information was received at the secretariat on new opinion requests to be submitted to the CSTEE soon.

14. Update on the latest meetings of the Scientific Steering Committee on matters of interest to the CSTEE

a) Harmonisation of Risk Assessment Task Force and Working groups

The CSTEE chairman provided information on the status quo of activities; for the most part members of the various Working groups are drafting the sections of the reports for which they have been made responsible. In principle these should be checked in September 2001. The CSTEE secretary reminded the CSTEE that they still could comment on the document sent on the '*format for adopting opinions by scientific committees*'.

15. Arrangements for the next (26th) plenary meeting of the CSTEE

The meeting was confirmed for 11 September 2001. The EMF/RFF working group will meet the day before. The venues will be confirmed later.

16. Any other business

A. The problems faced during the evaluation of the **Human Health part of the DINP RAR** (Reg. 793/93) were addressed by the committee, particularly those posed by the so-called Exxon and Aristech studies and the derivation of NOAELs by both. A proposal was put forward to use a so-called 5% benchmark dose (38mg/kg bw/day) that takes account of the shape of the dose/response curve. The benchmark concept addresses the problem posed by the slope of the dose/response whose calculation is being attempted. Only when this info is available will it make sense to define a MOS. The dose spacing in both the Ariston and the Exxon studies made the assignment of a NOAEL rather uncertain and the benchmark concept would help circumvent the problem in an adequate, and scientific, way. The kidney weight increase was still, at this point in time, considered by the CSTEE to be the relevant health endpoint. Some committee members pointed out that the benchmark concept being a new approach a note should be added explaining better why the committee resorted to using it here. Another advantage of this method is on the lesser need to carry out animal testing. In general committee members expressed support to the benchmark approach.

The consideration the committee now gave to this new approach is also the reason why the conclusions could not be fully in line with the conclusions of the CSTEE in the opinion it adopted in 27 November 1998 (*Opinion on Phthalate migration from soft PVC toys and child-care articles – Data made available since the 16th of June 1998*). The re-evaluation of the database however, made this change necessary, particularly as the benchmark approach is now more widely recognised. The consequences of this new

approach cannot however be automatically endorsed in the conclusions the committee reaches on the test methodology for DINP release from toys and childcare articles.

The committee agreed to postpone the adoption of the opinion on the DINP RAR (Human Health) given the various aspects that need to be taken into consideration as well as the need to redraft various aspects of the current draft properly.

B. Given the move of the CSTEE secretariat to new premises some changes are to be expected as regards venues for WG meetings; in the future most of the WG meetings will take place in the new premises. Plenary meetings should still take place in the Borschette building as before.

C. The CSTEE chairman informed the committee that he was still waiting a response from Commission services on the issue of the scarce resources available to the CSTEE secretariat.

Without any other business the meeting was closed.



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**SCIENTIFIC COMMITTEE ON
TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)
25th PLENARY MEETING**

**20 July 2001, all day, starting at 10H00 in
Centre Albert Borschette, rue Froissart 36,
B-1040 Brussels**

- Final AGENDA -

- 1. Welcoming address, apologies for absence, declarations of interest**
- 2. Adoption of the draft agenda**
- 3. Approval of the draft minutes of the 24th CSTEE plenary meeting**
- 4. Regulation 793/93 on Existing substances (ESR):**
 - A. Status reports/opinions (Human health & Environment) on:**
 - a) *1,2,4-Trichlorobenzene***
 - b) *Hydrogen Peroxide***
 - B. Status reports/opinions (Environment) on:**
 - c) *Styrene***
 - d) *N-Vinyl pyrrolidone***
 - e) *Di(isononyl)phthalate (DINP)***
 - f) *Di(isodecyl)phthalate (DIDP)***
 - C. State of play regarding other substances evaluated under the ESR**
 - D. Input of the CSTEE into the revision of the 'Technical Guidance Document' in support of Regulation 793/93**
- 5. JRC report on results of the validation of methodologies for determining the release of DINP from toys and childcare articles - for opinion**
- 6. Endocrine disrupting chemicals:**

3rd presentation by representatives of the *Fraunhofer-Institut für Umweltchemie und Oekotoxikologie*, Schmallenberg, Germany, of the final results of their research project relating to the development and validation of a test method for the identification of endocrine disrupting chemicals (the first presentation took place at the 9th CSTEE plenary meeting, 5th of May 1999 and the 2nd at the 16th CSTEE plenary meeting, 19th of June 2000).

7. **Report on "Cadmium used as a Colouring Agent or a Stabiliser in Polymers and for Metal Plating - Risks to Health and Environment" – progress report**
8. ***Health effects of Radio Frequency and Electromagnetic fields* – progress report**
9. **Revision of the CSTEE position paper on "Exposure data" (in the light of public comments received)**
10. **Participation of the CSTEE in activities/working groups of other scientific committees of the Commission**
 - a) *Toxicity of minerals such as Cu and Zn in animal feed regarding the possible environmental impact of these minerals* – activity of the SCAN
 - b) Other
11. **Strategies for dealing with emerging issues identified by the SSC and for which the CSTEE is the 'lead' committee:**
 - a) *Endocrine disruption (Human health)*
 - b) *Indoor climate*
12. **Feedback from the relevant services of the Commission on the follow up to the opinions adopted previously by the CSTEE**
13. **Strategies for dealing with additional opinion requests submitted by other DGs of the Commission**
14. **Update on the latest meetings of the Scientific Steering Committee on matters of interest to the CSTEE**
 - a) Harmonisation of Risk Assessment Task Force and Working groups
 - b) Cross committee's collaboration
15. **Arrangements for the next (26th) plenary meeting of the CSTEE**
16. **Any other business**

**SCIENTIFIC COMMITTEE ON
TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)
25th PLENARY MEETING**

**20 July 2001, 10H30
Brussels, Belgium**

LIST OF PARTICIPANTS

CSTEE:

Prof. James BRIDGES, Prof. Giorgio CANTELLI FORTI, Prof. Wolfgang DEKANT, Prof. Erik DYBING, Prof. Helmut A. GREIM, Prof. Colin JANSSEN, Prof. Bo O. JANSSON, Dr. Claude LAMBRÉ, Dr. José V. TARAZONA, Prof. Cornelis Van LEEUWEN, Prof. Katarina VICTORIN, Prof. Marco VIGHI.

EUROPEAN COMMISSION:

HEALTH AND CONSUMER PROTECTION DG:

Messrs. Jorge COSTA-DAVID and Panagiotis DASKALEROS.

ENTERPRISE DG:

Mrs. Lena PERENIUS.

RESEARCH DG:

Mr Rolf OSTROM

JOINT RESEARCH CENTRE:

Mrs. Catherine SIMONEAU, Messrs Peter PART and Dimitrios KOTZIAS

FRAUNHOFFER INSTITUT:

Drs Andrea WENZEL and Christoph SCHÄFERS.