



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,

SANCO.C.2/JCD/jcd.sanco59.D(01)

CSTEE/00/plen.min.12.06.2001

MINUTES OF THE 24th PLENARY MEETING OF THE SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)

12 June 2001, 10H00

Brussels, Belgium

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

No declarations of interest relative to the agenda points of this 24th CSTEE plenary were submitted by any CSTEE member. All CSTEE members attended this plenary.

2. Adoption of the draft agenda

The draft agenda was adopted.

3. Approval of the draft minutes of the 22nd and 23rd CSTEE plenary meetings

Both draft minutes were adopted. Those of the 23rd CSTEE plenary with a comment added under agenda point 3, to the effect that the committee expressed concern over the issue of resources available to the CSTEE secretariat.

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

A. Status reports/opinions (Human health & Environment) on:

a) *Methyl oxirane (propylene oxide)*

The draft opinion was adopted. It is available in:

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

b) *Toluene*

The draft opinion on 'Toluene' was adopted. It is available in:

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

c) *1,2,4-Trichlorobenzene*

The discussion on this chemical was postponed, as the adoption of an opinion on this chemical was not urgent.

d) *Acrylic acid*

The draft opinion was adopted. It is available in:

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

e) Hydrogen Peroxide

Same conclusion as in c).

f) Di(isononyl)phthalate (DINP)

The adoption of both the Human Health and Environment parts of the draft opinion on 'DINP' remained pending the need to obtain clarification on some original data in one of the studies considered in the RAR (Human Health part) and the need expressed by the committee to held a working group meeting to address the 'Environment' part (together with the 'Environment' part of DIDP).

g) Di(isodecyl)phthalate (DIDP)

The draft opinion on the Human Health part was adopted. It is available in:

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

h) Styrene

Same conclusion as in c).

i) N-Vinyl pyrrolidone

Same conclusion as in c).

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

The representative of the European Chemicals Bureau present in the meeting undertook to provide an update more formally as soon as the number of new elements of information would justify this. In the meantime the CSTEER should expect to receive the final RARs for the following substances: Cyclohexane, Dimethyldioctadecylammonium chloride (DODMAC), Naphthalene and DEHP. CSTEER *rapporteurs* for all four were nominated.

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

See also connection, below, with issues to be addressed under agenda points 7 and 16. Committee members also gave their agreement to the public dissemination, in the DG SANCO web site, of the CSTEER position paper on 'Margins of safety' adopted by the committee at the 22nd CSTEER plenary meeting on 6/7 March 2001, initially intended to be used only as an internal CSTEER working document. Interest from various quarters in its content however justified this change of stance.

The ECB representative that attended this meeting informed the committee about the activities being carried out by the various working groups formed for revising the so-called 'Technical Guidance Document'. Apparently the various subgroups responsible for different bits of the revision process would finalise their drafts in July 2001.

The CSTEER will receive those when they are ready and the bits mentioned would be then be looked at by some CSTEER subgroups, i.e. *Human Health effects assessment*, *Marine risk assessment*, *Exposure assessment* and *Environmental effects*.

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

A JRC representative attended this CSTEEN plenary in view of presenting the final version of the report on "*Validation of methodologies for the release of Diisononylphthalate (DINP) in saliva simulants from toys*" (a draft version of the report had been presented by the same representative at the previous CSTEEN plenary in April). A copy of this final version would be sent to the members of the CSTEEN and Commission services; a pdf format version would also be available on a special JRC web site. The terms of reference were in the meantime submitted by DG Enterprise in view of the possible use of the test method(s) under scrutiny for regulatory purposes (Directive 76/769 on limitations of marketing and use of certain dangerous substances and preparations).

The representative of DG Enterprise informed the committee that various options are of course still open for regulating the use of phthalates. If the method(s) scrutinised by the JRC turn out to be useful, a solution may be possible for toys and childcare articles by means of a labelling provision as had been proposed under the Portuguese presidency. Subsequently committee members were informed of the questions in the terms of reference submitted to the committee on the subject of this JRC report.

The CSTEEN secretariat should now check what working arrangements are necessary in view of ensuring that a draft opinion is ready if possible for the 25th CSTEEN plenary on 20 July 2001.

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

The WG chairman made a brief oral account of action taken so far. It was noted that the composition of the WG was revised (bearing in mind the expertise still lacking proposals for membership were put forward). These had been endorsed by the secretariat and the necessary contacts were established. The second meeting of the Working Group was to take place on 13 June, one day after this plenary.

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

Few comments were received following the publication in the DG SANCO website requesting 'public' comments on it. The committee will eventually revise its position paper in the light of those. This topic will be put in the next CSTEEN plenary agenda. Once adopted the new paper will be fed into the 'Harmonisation of risk assessment' exercise being carried out under the auspices of the Scientific Steering Committee.

8. Review of a draft CPMP discussion paper on Environmental Risk assessment of medicinal products.

The draft text previously prepared by the *rapporteur* was changed in the light of conclusions arrived at, at the occasion of the WG meeting that took place on 6 June 2001 in Brussels. The draft opinion so changed was adopted. It is available in:

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

9. (i) *Carcinogenic and non-carcinogenic effects of Cadmium and Arsenic in ambient air*

The draft opinion on ‘*Ambient Air Pollution by Cadmium Compounds*’ and that on ‘*Ambient Air Pollution by Arsenic Compounds*’ were adopted. They are available in:

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

(ii) *Derivation of limit values for PAH in ambient air*

The draft opinion on ‘*Ambient Air Pollution by Polycyclic Aromatic Hydrocarbons (PAH)*’ was adopted. It is available in:

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

10. Draft CSTEE opinion on the Report on “Assessment of the risks to human health posed by azo colorants in toys, writing inks and paper products, and analysis of the advantages and drawbacks of restrictions on their marketing and use” – for opinion

The CSTEE rapporteur for this opinion presented the last changes made to the draft and this was adopted. It is available in:

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

11. Submission(s) under article 95 of the Treaty:

i) *Ecotoxicological properties of Creosote*

The WG chairman undertook the task of producing quickly a first draft for comments. The committee confirmed that the request from the Netherlands (for derogation from the provisions of Directive 94/60/EC in order to prohibit the use of wood treated with creosote in contact with groundwater) was indeed a complex issue. The CSTEE concluded therefore that the PAH exposure as a result of leaching into the groundwater was of no such threat to human health that immediate measures have to be taken. The draft opinion on ‘*Creosote*’ was adopted. It is available in:

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

12. 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*

On behalf of the SCAN secretariat the CSTEE secretary informed that this SCAN activity has yet to start. Committee members will be informed when its intervention will be deemed necessary.

13. Strategies for dealing with emerging issues identified by the SSC and for which the CSTEE is the ‘lead’ committee:

a) *Endocrine disruption (Human health)*

The CSTEE ‘Endocrine disruptors’ WG chairperson presented a document which had been recently sent to the CSTEE for information (*National Toxicology Program’s Report of the “Endocrine Disruptors Low Dose Peer Review” organised by the*

National Institute of Environmental Health Sciences, National Toxicology Program – Executive summary).

CSTEE members were also reminded about the strong focus on 'Endocrine disruption' characterising the next EC Research Framework programme.

b) Indoor climate

A draft table of contents was presented at the occasion of the previous CSTEE plenary meeting. In the light of comments, some changes were made to it. Another draft prepared by another committee member was in the meantime made available. Committee members were asked to reflect on its content and send comments and identify key issues for a new discussion of the topic at the occasion of the next CSTEE plenary.

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

No information was provided on any specific opinion request adopted by the CSTEE that might have been the object of a Commission proposal recently.

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

Apart from the last four ones under the Existing substances Regulation (see point 4, above) the CSTEE secretariat has been informed of none.

16. 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 presented the *document "Presentation of opinions and glossary of terms"*. Committee members were reminded about the convenience in respecting the 'standard' format when elaborating their draft opinions.

b) Cross committee's collaboration

Apart from the one mentioned in 12.a) there was only the recent involvement of some CSTEE members in the activities of the SCF WG addressing the update of the SCF opinion on 'Risk assessment of Dioxins and of Dioxin-like PCBs in food'; a new SCF opinion was adopted on 30 May 2001 based on new information made available since the adoption by the SCF of its opinion on the subject on 20 November 2000. A brief oral account by the committee members concerned was given.

17. Arrangements for the next (25th) plenary meeting of the CSTEE

The date was confirmed for 20 July 2001.

18. Any other business

The CSTEE was informed that its secretariat, together with all the other scientific committee's secretariats, will move from their current premises in 232, rue Belliard to new ones in rue de Genève in Brussels. This is an anticipation of the setting up of the future European Food Authority. More details would be provided to the committee as they would become known, i.e. date of move, extent to which this might affect the CSTEE's working arrangements, etc.



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**SCIENTIFIC COMMITTEE ON
TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)
24th PLENARY MEETING**

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

- Adopted AGENDA -

- 1. Welcoming address, apologies for absence, declarations of interest**
- 2. Adoption of the draft agenda**
- 3. Approval of the draft minutes of the 22nd and 23rd CSTEE plenary meetings**
- 4. Regulation 793/93 on Existing substances (ESR):**
 - A. Status reports/opinions (Human health & Environment) on:**
 - a) *Methyl oxirane (propylene oxide)*
 - b) *Toluene*
 - c) *1,2,4-Trichlorobenzene*
 - d) *Acrylic acid*
 - e) *Hydrogen Peroxide*
 - f) *Di(isononyl)phthalate (DINP)*
 - g) *Di(isodecyl)phthalate (DIDP)*
 - h) *Styrene*
 - i) *N-Vinyl pyrrolidone*
 - B. State of play regarding other substances evaluated under the ESR**
 - C. 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**
- 6. *Health effects of Radio Frequency and Electromagnetic fields* – progress report**
- 7. Revision of the CSTEE position paper on “*Exposure data*” (in the light of public comments received)**

8. **Review of a draft CPMP discussion paper on Environmental Risk assessment of medicinal products - for opinion**
9. (i) *Carcinogenic and non-carcinogenic effects of Cadmium and Arsenic in ambient air* – for opinion
(ii) *Derivation of limit values for PAH in ambient air* – for opinion
10. **Draft CSTE E opinion on the Report on “Assessment of the risks to human health posed by azo colorants in toys, writing inks and paper products, and analysis of the advantages and drawbacks of restrictions on their marketing and use” – for opinion**
11. **Submission(s) under article 95 of the Treaty:**
 - i) **Ecotoxicological properties of Creosote, NL notification – for opinion**
12. **Participation of the CSTE E 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
13. **Strategies for dealing with emerging issues identified by the SSC and for which the CSTE E is the ‘lead’ committee:**
 - a) **Endocrine disruption (Human health)**
 - b) **Indoor climate**
14. **Feedback from the relevant services of the Commission on the follow up to the opinions adopted previously by the CSTE E**
15. **Strategies for dealing with additional opinion requests submitted by other DGs of the Commission**
16. **Update on the latest meetings of the Scientific Steering Committee on matters of interest to the CSTE E**
 - a) **Harmonisation of Risk Assessment Task Force and Working groups: “Presentation of opinions and glossary of terms”**
 - b) **Cross committee’s collaboration**
17. **Arrangements for the next (25th) plenary meeting of the CSTE E**
18. **Any other business**

**SCIENTIFIC COMMITTEE ON
TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)
24th PLENARY MEETING**

**12 June 2001, 10H30
Brussels, Belgium**

LIST OF PARTICIPANTS

CSTEE:

Prof. James BRIDGES, Prof. Peter CALOW, Prof. Giorgio CANTELLI FORTI, Prof. Wolfgang DEKANT, Prof. Erik DYBING, Prof. Helmut A. GREIM, Prof. Colin JANSSEN, Prof. Bo O. JANSSON, Prof. Soterios A. KYRTOPOULOS, Dr. Claude LAMBRÉ, Prof. Amadeu SOARES, Dr. José V. TARAZONA, Prof. Benedetto TERRACINI, Prof. Janneche UTNE-SKÅRE, Prof. Cornelis Van LEEUWEN, Prof. Katarina VICTORIN, Prof. Marco VIGHI, Prof. Joseph G. VOS.

European Commission:

HEALTH AND CONSUMER PROTECTION DG:

Messrs. Jorge COSTA-DAVID and Panagiotis DASKALEROS.

ENTERPRISE DG:

Mrs. Lena PERENIUS.

JOINT RESEARCH CENTRE:

Mrs. Sharon MUNN, Mrs. Catherine SIMONEAU.