



## 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

CSTEE/00/DraftMinutes.22.05.2002

#### SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE) 31st PLENARY MEETING

**22 May 2002, all day, starting at 10H00 in  
Centre Albert Borschette, rue Froissart 36,  
B-1040 Brussels**

#### - Minutes -

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

Apologies were received from Profs. G. Cantelli Forti, E. Dybing, A. Soares, K. Victorin and M. Vighi.

No declaration of interest was submitted by any CSTEE member in respect of any of the points in the draft agenda.

##### 2. Adoption of the draft agenda

The draft agenda was adopted.

##### 3. Approval of the draft minutes of the 30<sup>th</sup> CSTEE plenary meetings

The draft minutes of the 30<sup>th</sup> CSTEE plenary meeting were adopted with minor editorial corrections.

##### 4. Health effects of Radio Frequency and Electromagnetic fields:

The chairman of the WG on "Radio Frequency and Electromagnetic Fields" presented a draft report including a draft reply to question B. Several questions were raised by the Committee members, in particular regarding the description, in the ICNIRP guidelines, of the margins of safety used establishing limit values. It was also noticed that results of the new long-term studies in animals reproducing the only experimental conditions in which a tumour excess had been found previously would become available within the next two weeks. The Chairman of the WG summarised in a new document the questions and comments formulated by the plenary (see annex III). The document will be submitted to members of the WG.

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

###### A. Status reports/opinions (Human Health and/or Environment):

###### Opinions were adopted on the following substances and sections:

###### a) 3,4-dichloroaniline (HH) – for opinion

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium - Office: G-1.-01/48.  
Telephone: direct line (+32-2)2955185, switchboard 299.11.11. Fax: 2957332.  
Telex: COMEU B 21877. Telegraphic address: COMEUR Brussels.

Internet: arturo.sanabria-tienza@cec.eu.int

- b) *Bis(pentabromophenyl)ether* (Env) – for opinion
- c) *Methyl acetate* (Env) – for opinion
- d) *Bisphenol-A (4,4'-isopropylidenediphenol)* (HH and Env) – for opinion

The draft opinion on the first substance will be discussed at the next plenary meeting.

With regard to *Bis(pentabromophenyl)ether* (Env) the Committee decided it was not necessary to revise its opinion.

The opinions on *Methyl acetate* (Env) and *Bisphenol-A* (HH) were adopted with minor editorial corrections.

After an initial discussion, the adoption of the environmental part of the latter substance was deferred to the next plenary meeting.

The opinions are available in:

[http://europa.eu.int/comm/food/fs/sc/sct/out143\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/sct/out143_en.pdf)

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

No new information was yet available on which chemicals being evaluated under the ESR would be submitted in the near future for CSTEE opinion.

Mr Hansen of JRC will communicate the progress on different substances at the next plenary meeting.

## **6. Input of the CSTEE into the revision of the 'Technical Guidance Document' in support of Regulation 793/93 - Status reports/opinions of subgroups on:**

1. *'Environmental exposure'*
2. *'Marine risk assessment'*
3. *'Environmental effects assessment'*
4. *'Human health exposure assessment'*
5. *'Human Health effects assessment'*

The Committee expressed its concern that the comments made by the SCTEE had not been taken into account in the document presented by the JCR. As the TGD is already in the final stage of consultation it seemed unlikely that they could be incorporated subsequently.

The Committee agreed, nonetheless, to finish its report on the environmental effects assessment.

The representative of JCR, Mr Hansen, said that certain comments made by the SCTEE were taken into account in the document although not all. Nevertheless he promised to inform the technical group about the concerns of the Committee in order that the necessary changes can be included in the document. He promised further feedback to the CSTEE at some later date.

## **7. Member States' assessments of the risk to health and the environment from cadmium in fertilisers – progress report**

The working group chairman informed the committee that a meeting of the WG was held in February but no great progress was made due to the amount of work involved in assessing many of the papers sent.

He said that he could probably present a paper on the subject at the next plenary meeting.

**8. Request for an opinion from the SCTEE on certain questions arising from a study on *Risk to Health and the environment related to the Use of Lead in Products***

A working group was established.

The group will meet before the next plenary meeting.

**9. Questions to the CSTEE relating to *scientific evidence of risks to health from chromium VI in cement***

The rapporteur explained the document drafted by the working group at its last meeting.

Several members made observations and the Chairman proposed to adopt the conclusions. The rest of the document with these and other observations made by the members will be adopted by written procedure.

The Committee agreed.

**10. Justification of a notification by The Netherlands to introduce national measures concerning wood treated with copper substances.**

The representative of Directorate General Environment requested a speedy opinion taking into account the nature of the measures proposed by The Netherlands.

The Chairman promised to give an opinion as quickly as possible and proposed the formation of a working group to deal with the subject.

**11. Emerging issues identified by the SSC and for which the CSTEE is the 'lead' committee:**

**a) *Endocrine disruption (Human health)***

A member of the Committee agreed to draft a report on the subject of sperm quality which could be presented at the plenary meeting of September.

**b) *Indoor climate***

The Chairman informed the Committee that the working group dealing with the subject met on 21<sup>st</sup> May and created a Task Force with several groups ( Regulations, Science, Priorities, Examples) due to the diversity of the subject.

The composition of the groups and the timetable were agreed in the meeting and figures in Annex IV.

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

Two requests for opinions were received, one concerning nickel in coins and another concerning chrysotile asbestos.

The Committee has already dealt with the issue of nickel in coins in the past . No new questions had yet been provided by Commission Services.

Concerning the second question the Committee agreed that the members of the previous working group should deal with this request.

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

No information was available from Commission services on the follow-up given to CSTEE opinions adopted in the recent past.

**14. Participation of the CSTEE in activities/working groups of other scientific committees of the Commission**

Committee members informed the committee about their recent involvement in other scientific committees' activities. In particular information was provided on the foreseen involvement on the risk assessment on PAH's in the SCF.

**15. 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 chairman informed the Committee that working documents on quantitative risk assessment and quality of life, together with a number of environmental papers are all being finalised and would soon be available for public consultation.

**b) Cross-committee collaboration**

On the subject of future collaboration with EFSA, the chairman informed the Committee that a detailed document, aimed at sining up the future harmonisation and co-ordination strategy, is currently being written. This document will be made available to Committee members who express a wish to consult it and to contribute to its preparation.

***c) Environmental impact evaluation of Alkaline processes used for animal by-product treatment***

The CSTEE chairman reported that, regarding the evaluation of alkaline processes used for animal by-products treatment, an opinion has been produced by the SSC and is available for consultation on the SSC website.

**16. Arrangements for the following plenary meetings of the CSTEE**

The Committee agreed to meet in plenary session on the following dates:

27 June 2002

24 September 2002

31 October 2002

17 December 2002

**17. Any other business**

The Chairman proposed to send a letter to Mr. Byrne, Commissioner of the UE dealing with the Scientific Committees, requesting more help from the Commission in the form of human resources, taking into account that when the Committees first started work the SCTEE was helped by 3 officials but now only one official has charge of this Committee and he was also responsible for a second Scientific Advisory Committee.

The Committee agreed.

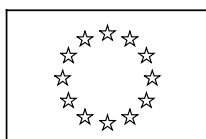
The draft letter was distributed at the end of the meeting and was signed by the Chairman and the two Vice-chairmen on behalf of the Committee.

The Committee also expressed its concern at the request formulated by the Commission services to certain members asking them to provide draft documents that had been discussed in working groups in order to send them to third parties that had requested them in accordance with the principle of public access to documents.

The Chairman said that for the future these requests should be addressed to him or the Secretary to the Committee rather than to the members. He agreed to write to Mr Wagstaff on behalf of the Committee to explain the position of the CSTEET.

- Annexes:**
- I.** Draft agenda.
  - II.** List of participants.
  - III.** Questions and comments formulated by the plenary on item 4.
  - IV.** Working Groups on Indoor Climate.

Annex I



**EUROPEAN COMMISSION**

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

Brussels,  
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CSTEET/00/plen.age.22.05.2002

**SCIENTIFIC COMMITTEE ON  
TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEET)  
31st PLENARY MEETING**

**22 May 2002, all day, starting at 10H00 in  
Centre Albert Borschette, 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 30<sup>th</sup> CSTEET plenary meeting**
- 4. Health effects of Radio Frequency and Electromagnetic fields:**
  - i) Recommendations of the CSTEET for research – status report**
  - ii) New opinion request from DG SANCO – status report**
- 5. Regulation 793/93 on Existing substances (ESR):**
  - A. Status reports/opinions (Human Health and/or Environment) on:**
    - a) 3,4-dichloroaniline (HH) - for opinion**
    - b) Bis(pentabromophenyl)ether (Env) – for opinion**
    - c) Methyl acetate (Env) - for opinion**
    - d) Bisphenol-A (4,4'-isopropylidenediphenol) (HH and Env) - for opinion**
  - B. State of play regarding other substances evaluated under the ESR**
- 6. Input of the CSTEET into the revision of the ‘Technical Guidance Document’ in support of Regulation 793/93 - Status reports/opinions of subgroups on:**

1. *'Environmental exposure'*
  2. *'Marine risk assessment'*
  3. *'Environmental effects assessment'*
  4. *'Human health exposure assessment'*
  5. *'Human Health effects assessment'*.
7. **Member States' assessments of the risk to health and the environment from cadmium in fertilisers – progress report**
  8. **Request for an opinion from the SCTEE on certain questions arising from a study on *Risks to Health and the environment related to the Use of Lead in Products***
  9. **Questions to the CSTEE relating to *Scientific evidence of risks to health from chromium VI in cement***
  10. **Justification of a notification by The Netherlands to introduce national measures concerning wood treated with copper substances**
  11. **Emerging issues identified by the SSC and for which the CSTEE is the 'lead' committee:**
    - a) *Endocrine disruption (Human health)*
    - b) *Indoor climate*
  12. **Strategies for dealing with additional opinion requests, if any, submitted by other DGs of the Commission**
  13. **Feedback from the relevant services of the Commission on the follow-up to the opinions adopted previously by the CSTEE**
  14. **Participation of the CSTEE in activities/working groups of other scientific committees of the Commission**
  15. **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 collaboration
    - c) *Environmental impact evaluation of Alkaline processes used for animal by-product treatment*
  16. **Arrangements for the following plenary meetings of the CSTEE**
  17. **Any other business**

**SCIENTIFIC COMMITTEE ON  
TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)  
31st PLENARY MEETING  
22 May 2002  
Brussels**

**LIST OF PARTICIPANTS**

**CSTEE:**

Prof. James BRIDGES, Prof. Peter CALOW, Prof. Wolfgang DEKANT, Prof. Dr Helmut GREIM, Prof. Colin JANSSEN, Prof. Bo JANSSON, Prof. Soterios KYRTOPOULOS, Dr Claude LAMBRE, Dr José TARAZONA, Prof. Benedetto TERRACINI, Prof. Janneche Utne SKARE, Prof. Joseph VOS.

**EUROPEAN COMMISSION:**

**Health & Consumer Protection DG:**

Dr. A. SANABRIA

**Enterprise DG:**

P. BRUNERIE, S. PICKERING, D. HODRICK, W. HEHN, A. PEACE, G. INDIRLI, S. ERLER

**Joint Research Centre (Ispra):**

S. KEPHALOPOULOS, B. HANSEN

**RTD DG:**

T. KARJALAINEN

Questions and comments formulated by the plenary on Radio Frequency and Electromagnetic Fields.

### 1. Biological findings included in the process of setting limit values

(Guidelines have been published in Health Physics 1998, vol 74/4)

- CSTEE acknowledges that the use of findings other than *established health effects* (p. 495) "would not provide a scientific basis in order to establish limit values". Guidelines do not provide an indication of the weight given to health effects which are only "suggested" by the scientific evidence (such as epidemiological findings regarding childhood leukemia and ELF) in the decisions on margins of safety.
- It seems that restrictions for ELF have been established on the basis of nerve and muscle tissue stimulation by electric currents which are induced in the cells. This is a thresholded effect (p. 501) The relevance of this outcome to health effects is not clear.
- CSTEE noted that the statement that "only biological effects that had been established to occur from at least two independent studies were to be considered for the determination of limit values" appears in the report of the Working Group but not in the ICNIRP guidelines. Has the exclusion of finding based on only one investigation been the policy of ICNIRP?
- CSTEE would also like to know what is the present state of the long-term experiments on transgenic mice intended to test the reproducibility of findings by Repacholi et al. in the Emu-Pim1 strain (Radiat Res 1997;147:631-640)

### 2. Safety factors

- At page 508, the guidelines spell out the general variables which have been considered in the development of safety factors for high-frequency fields (effects under severe environmental conditions, existence of highly sensitivity population subgroups, conditions of exposure). Where in the guidelines is the corresponding indication is given for ELF?
- CSTEE expected a more detailed description of the individual safety factors which have been introduced and the rationale for each of them. This is what CSTEE usually do in risk assessment for chemicals, where the final safety factor is derived from the multiplication of separate safety factors taking into account different sources of uncertainty.



- The ICNIRP document on the use of the guidelines <http://www.icnirp.org/Documents/Use.htm> states that "Numerically uncertain relationships between established effects and exposure levels result in higher safety factors and vice versa". What is intended as "numerically uncertain relationships"? Was the principle applied to the uncertainties of the epidemiological findings (which are only partly "numerical")? .
- The same document states that "in the new (?) ICNIRP guidelines the safety *factors* vary from approximately 2 to > 10" and that less conservative safety *factors* have been applied to indirect effects (italics of mine, plural in the original text). How many *factors* for each limit value? How were they combined in order to obtain an overall safety factor?
- It was noticed that safety factors between 2 and 5 have been adopted for ELF on the basis of biological signals and induction of currents. The document also says that the criteria which have been used lead to an overall safety factor of 100 or greater with regard to life threatening conditions (cardiac extrasystoles, respiratory failure etc). The basis of this estimate are not very clear. CSTEET has previously provided examples of circumstances requiring a safety factor higher than 100 and circumstances justifying a safety factor lower than 100 ([http://europe.eu.int/comm/food/fs/sc/sct/out110\\_en.html](http://europe.eu.int/comm/food/fs/sc/sct/out110_en.html)>

### 3. A system of health protection

- The paragraphs regarding *regulation* and *providing information* refer to a unanimously accepted use of scientific findings and CSTEET is unanimously ready to endorse them. Some concern was expressed by some CSTEET members on the paragraphs *individuals* and *local public authorities*, which imply choices in risk management. (This is mentioned here for the information of the WG members. No questions addressed to the WG have been asked)

### 4. Recommendations for research

- The plenary has taken notice with much interest of annex 2 to the WG report (i.e. the WHO document "EMF research priorities" [http://www.who.int/peh-emf/research\\_agenda/agenda\\_priorities.htm](http://www.who.int/peh-emf/research_agenda/agenda_priorities.htm). Whereas the whole document can be endorsed by CSTEET, an indication of priorities might be useful.

ANNEX IV

Working Groups on Indoor Climate.

*WG “Regs”:*

Prof. G. Cantelli Forti (Chairperson), Dr C. Cochet, Dr D. Papameletiou , Dr B. Seifert, Dr H. Vuorelma.

*WG “Science”:*

Dr C. Lambré (Chairperson), Dr M. Jantunen, Dr S.Kephalopoulos, Dr T. Lindvall, Dr L. Molhave, Dr Pickering.

*WG “Priority”:*

Prof. E. Dybing (Chairperson), Prof. J. Bridges (CSTEE Chairman/Member), Dr M. Kryzynowski, Dr B Maynard, Dr B. Seifert.

*WG “Examples”:*

To be notified.