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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,
SANCO.C.2/JCD/jcd.sanco80.D(01)
CSTEE/00/.min.07.12.2001

**SCIENTIFIC COMMITTEE ON
TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)**

**Minutes of the
28th PLENARY MEETING**

7 December 2001

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

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

Apologies for absence have been received from Profs. A. Soares, P. Calow, Cantelli-Forti and C. Jansen.

No declarations of interest were made by any committee member.

2. Adoption of the draft agenda

The draft agenda was adopted.

3. Approval of the draft minutes of the 27th CSTEE plenary meeting

The adoption of the draft minutes was postponed.

**4. Health effects of Radio Frequency and Electromagnetic fields –
recommendations of the CSTEE for research**

An account made by the CSTEE secretary was made on the so-called Luxembourg conference held on 30 November 2001. Further terms of reference are still to be submitted by DG SANCO to ensure a follow up to the CSTEE opinion on the subject adopted on 30 October 2001. Various options were discussed but no final decisions made in terms of scope of the final document and a CSTEE schedule of meetings for finalising the activity on *recommendations for research*; the WG chairman took the task of trying to gather in the meantime contributions from WG experts and other external experts.

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The representative of DG SANCO/G thanked the committee for its opinion on the subject adopted at the previous CSTEE plenary. He took the opportunity to express the wish of DG SANCO that a more in depth expression of the committee's views would be welcome on the questions asked previously. In this regard the current CSTEE's position was compared with that of the SSC in its opinion of 1998 (when the SSC endorsed the ICNIRP guidelines proposed and, in order to cover for possible long term carcinogenic effects, further endorsed the adding of a safety factor of 50 to such guidelines). The DG SANCO representative considered that a similar approach by the CSTEE now would be welcomed. The WG chairman replied saying that some of the requests implied asking the committee views which clearly would be of a risk management nature and that it was his understanding that the committee's remit does not include those. Several CSTEE members supported him on this.

The DG SANCO representative informed that in principle there would be no need to essentially change the formulation of the questions as submitted at the occasion of the previous mandate but a new set of terms of reference would be submitted soon to the committee specifying better what is required.

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

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

a) Butadiene (Env)

The CSTEE *rapporteur* for the Environmental section presented the draft he had prepared. Some data submitted at the margins of the RAR report itself were commented upon; these were basically comments from the M. State *rapporteur* to the draft CSTEE text and the committee raised again the issue of the difficulties posed by such an iterative process. For future reference it was suggested that, to the extent that such comments may be dealt within the timeframe set for the CSTEE opinion, they should be taken account of, if not then a different approach may be necessary. The draft would finally be adopted as a CSTEE opinion. It is available in:

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

b) Cyclohexane (HH and Env)

The Human Health draft was presented but its adoption postponed for the next CSTEE plenary given the need for some substantial changes particularly as regards the genotoxic effects of the substance. In the absence of the CSTEE *rapporteur* for the Environmental part of the RAR the discussion on this section had to be postponed.

c) Dodmac (HH and Env)

Essentially reservations were expressed about the lack of carcinogenicity data for this high production volume study and the bits of the RAR on such end point extensively discussed. The CSTEE decided that its opinion on this chemical should specifically address the RARs shortcomings in this regard. Prof. Van Leeuwen informed the committee about the experience of NL with this chemical, in particular as regards how the risks posed by it were addressed by that M. State. He also commented on how the TGD should be used in the assessment of chemicals such as this one. The decision was taken that both sections, Human Health and Environment should be revisited at the next plenary meeting.

d) Bis(2-ethylhexyl)phthalate (DEHP) (HH and Env)

The RAR was in general considered to be of a very high quality. The *rapporteur* for the human health part described the draft text prepared for the meeting in detail in particular the critical health effects [in this regard the relative merits of the main studies that were behind the RAR of this substance (Arcadi, Poons + Schilling) were considered in detail]. Issues such as indoor saturation with phthalate vapours, conclusions drawn from rat studies with very high doses and the extrapolation to humans, relative pertinence of studies considered and respective usefulness/value of each were all addressed in detail.

Regarding the environmental part, the draft was presented by the *rapporteur* in detail. It indicated that the RAR for the environmental was of unequal quality overall, with parts well backed but with others less so. The key points were felt to be the need to justify some assumptions such as most aspects of risk characterisation for aquatic environment, on sediments and bioaccumulation and, for the terrestrial environment, the soil and secondary poisoning.

The importance of hazard identification was emphasised because of the problems posed by possible bioaccumulation through the food chain implying a need for a model of biomagnification like for other phthalates; it was pointed out that this information comes from hazard assessment and it is for this reason that the current TGD models may not be enough in this chemical for a proper risk assessment.

The decision was taken to table the draft opinions on both sections (Human Health and the Environment) at the next plenary even though the ones discussed at the current plenary were close to the finalised stage.

e) 3,4-dichloroaniline (HH and Env)

A draft on the Human Health part was briefly discussed but its adoption postponed to a forthcoming CSTEE plenary.

f) N-Vinyl pyrrolidone (HH)

The draft opinion was adopted. It is available in:

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

g) Naphthalene (HH and Env)

The *rapporteur* for the Human Health part of this substance presented the revised draft text which was extensively discussed. Among other issues were considered the specific conclusions allowed for from animal studies (mouse) *vis à vis* other species, the respective implications on possible extrapolations and genotoxicity/carcinogenicity considerations.

Given the nature of the discussion it was felt that a revised draft should be tabled at the next plenary for adoption.

h) Ethyl acetoacetate (HH and Env)

i) Trichloroethylene (HH and Env)

j) Tetrachloroethylene (Env)

Provisional tentative conclusions were described by the *rapporteurs* but the adoption of final opinions was postponed to the next CSTEE plenary.

k) Bis(pentabromophenyl)ether (HH and Env)

l) Methyl acetate (HH and Env)

No drafts were ready for being discussed on substances **h), k) and l)**.

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

No new information was made available by the competent Commission service(s).

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

1. 'Environmental exposure'

The *rapporteur* for this subWG made a brief presentation of the collation of comments so far. Expertise in modelling was still considered necessary but an expert has in the meantime been found and included in the working group. In response to a question from a CSTEE member, differences of approach between procedures in the TGD and that used for agricultural products were described. Expert input on *release* was also deemed necessary.

2. 'Marine risk assessment'

In the absence of the *rapporteur* for this sub-working group the CSTEE secretary informed that he had requested, by 14 December, comments to the draft prepared following the working group meeting of 30 November 2001. Conclusions stemming from the WG meeting were seemingly not fully included in the draft presented and therefore CSTEE members expressed the view that the draft does indeed need some in depth analysis and possibly changes before such an adoption. After consideration of any changes deemed necessary a new draft should be prepared and considered at a forthcoming WG meeting, in principle on 8 January 2002, with an adoption by the plenary the day after, even though this was considered an optimistic scenario by some members.

3. 'Environmental effects assessment'

The members of this subworking group having decided to devote their attention to section 2. first no discussion took place on this specific subsection.

4. 'Human health exposure assessment'

Given the lack of the 2nd version of this part of the TGD revision the sub working group *rapporteur* was unable to make any progress. The ECB representative informed that a meeting of the relevant technical working group was taking place on this very day in Ispra and as such its conclusions, which will be the backbone of the new version, are not ready yet. Regarding occupational health there is also no new version available even though the ECB working group chairperson indicated that it might be available by the end of November 2001. The CSTEE will be provided with copies of these in due course.

5. 'Human Health effects assessment'

The *rapporteur* for this subworking group informed the committee about the outcome of its meeting, the conclusions of which are in a draft text made available to the CSTEE before the meeting. Comments have been received and the draft is near completion and it should be in principle adopted at the next plenary.

As a final comment it was agreed that the various bits being assessed by the CSTEEN need not necessarily be adopted all at the same time given expected differences in terms of possible progress on the various parts and that the sooner they will be made available the better.

7. *Environmental impact evaluation of Alkaline processes used for animal by-product treatment*

The CSTEEN chairman reminded the committee of the background to this agenda item the importance of which is linked to the fact that the Commission is under enormous pressure to steer work on options of dealing with millions of tons of meat and bone meal which are waiting for solutions other than incineration.

The CSTEEN chairman pointed out that insofar as the committee was being asked to approve a commercial process an opinion from the CSTEEN could create a precedent for being under pressure to approve other ones. In principle what the CSTEEN could do would be to provide a framework for evaluating various procedures which could then be dealt with by Commission services directly. Such an approach was submitted to the consideration of the SSC at its previous plenary meeting of and its members were of the opinion that this was the approach they would favour. A draft framework was already produced and this was being considered. It would also look as if the issues to do with the possibility that dioxins could be formed in significant quantities with such processes had not been fully considered but since this cannot be dismissed, such processes need to be evaluated from this standpoint. The possibility of forming a small working group to deal with these issues was considered where dioxin formation would be assessed alongside other issues. Committee members took the task of informing the secretariat about possible additions to the working group.

8. *Member States' assessments of the risk to health and the environment from cadmium in fertilisers*

The DG ENTR (service of the Commission that submitted the opinion request) representative explained the series of steps linked to this dossier, its political aspects and the importance of the CSTEEN opinion before Commission services can present a risk management proposal. Essentially the data on which an opinion was requested are a series of M. States reports. The environmental concerns are the focus of this opinion request. The membership of the former Cadmium working group was reminded but given the focus of it on human health concerns the composition was expanded to cover better the need for a proper environmental assessment. It was agreed that the working group should imperatively meet in January 2002, ideally before the January CSTEEN plenary.

9. *Participation of the CSTEEN in activities/working groups of other scientific committees of the Commission*

M. Vighi informed of his involvement in the WG of SCAN. Claude Lambré informed on his involvement on an SCF WG on risk assessment polycyclic aromatic hydrocarbons in diets and of his being appointed as co-ordinator for a scoop task on collection of occurrence data of PAHs in foods.

10. Emerging issues identified by the SSC and for which the CSTEE is the ‘lead’ committee:

a) *Endocrine disruption (Human health)*

The WG chairman informed of the prospects of the CSTEE’s activities on endocrine disruption. Prof. Terracini will be member of the WG to strengthen the epidemiology part and he may start addressing the issue of purported changes in sex ratios. He also described the most recent papers on the subject sent to the CSTEE secretariat for distribution among CSTEE members; they address issues such as exposure to natural hormones (Dutch report), to low doses (peer review report), etc, workshop in Aromsburg (18-20 June 2001) the report of which is available.

A tentative working group meeting was scheduled for 8 January, to be confirmed later.

b) *Indoor climate*

A WG meeting was provisionally scheduled for 8 January 2002. The CSTEE chairman commented on the substantial data package received from the JRC recently. WG members were invited to identify other documents that could be useful for the committee to take on this subject.

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

None reached the CSTEE secretariat and none was provided at the plenary.

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

No new submissions reached the CSTEE secretariat either.

13. 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 informed the committee about the upcoming activities under the auspices of the SSC, namely the development of procedures for different committees to express their opinions (drafts will be circulated as soon as they’re available). The chairman informed that one of the conclusions was (recommendation of the task force) that when a committee is looking at an issue and a working group generate a report, the working group then becomes the ‘owner’ of that report and it is not up to the committee to modify that report but it is up to the committee to use it in the formulation of its opinion. This could be a substantial change for some committees that had developed a particular, and different, working line, but not so much to the CSTEE.

Dr. José Tarazona informed about a meeting the following week of the harmonisation of environment risk assessment work group.

b) *Cross committee’s collaboration*

No particular issue was to be commented upon under this agenda item.

14. Arrangements for the next (29th) plenary meeting of the CSTEE and scheduling of plenary meetings for the year 2002

As agreed the next CSTEE plenary will take place on 9 January 2002. The following dates for other CSTEE plenary meetings were set (so far only for the 1st half of 2002):

22 February

8 April

22 May

27 June

15. Any other business

Prof. Kees van Leeuwen informed about his appointment as Director of the JRC Institute for Health and Consumer Protection. The appointment is to take effect on 15 January 2002. This new set of circumstances may force him to resign from the CSTEE since it would look as if such a new status may be incompatible with his CSTEE membership. He will however maintain his membership till the taking up of his new duties and will continue to contribute during the next month or so, particularly on the TGD revision activity by the CSTEE.

It was confirmed that the prospect of the future management of the non-food scientific committees, one of which is the CSTEE, after the setting up of the Food Authority is that they will continue to be managed by DG SANCO. The current mandate of the CSTEE lasts till the end of 2003.



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**SCIENTIFIC COMMITTEE ON
TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)
28th PLENARY MEETING**

**7 December 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 27th CSTEE plenary meeting**
- 4. Health effects of Radio Frequency and Electromagnetic fields –
recommendations of the CSTEE for research**
- 5. Regulation 793/93 on Existing substances (ESR):**
 - A. Status reports/opinions (Human Health and/or Environment) on:**
 - a) *Butadiene* (Env) - for opinion**
 - b) *Cyclohexane* (HH and Env) - for opinion**
 - c) *Dodmac* (HH and Env) - for opinion**
 - d) *Bis(2-ethylhexyl)phthalate (DEHP)* (HH and Env) - presentation of RARs
and 1st discussion**
 - e) *3,4-dichloroaniline* (HH and Env) - presentation of RARs and 1st
discussion**
 - f) *N-Vinyl pyrrolidone* (HH) - presentation of RAR and 1st discussion**
 - g) *Naphthalene* (HH and Env) - presentation of RARs and 1st discussion**
 - h) *Ethyl acetoacetate* (HH and Env) - presentation of RARs and 1st
discussion**
 - i) *Trichloroethylene* (HH and Env) - presentation of RARs and 1st discussion**
 - j) *Tetrachloroethylene* (Env) - presentation of RAR and 1st discussion**
 - k) *Bis(pentabromophenyl)ether* (HH and Env) - presentation of RAR and 1st
discussion**
 - l) *Methyl acetate* (HH and Env) - presentation of RAR and 1st discussion**
 - B. State of play regarding other substances evaluated under the ESR**

6. **Input of the CSTEE into the revision of the ‘Technical Guidance Document’ in support of Regulation 793/93 - Status reports 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. *Environmental impact evaluation of Alkaline processes used for animal by-product treatment – progress report*
8. *Member States’ assessments of the risk to health and the environment from cadmium in fertilisers – progress report*
9. **Participation of the CSTEE in activities/working groups of other scientific committees of the Commission**
10. **Emerging issues identified by the SSC and for which the CSTEE is the ‘lead’ committee:**
 - a) *Endocrine disruption (Human health)*
 - b) *Indoor climate*
11. **Feedback from the relevant services of the Commission on the follow up to the opinions adopted previously by the CSTEE**
12. **Strategies for dealing with additional opinion requests submitted by other DGs of the Commission, if any**
13. **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*
14. **Arrangements for the next (29th) plenary meeting of the CSTEE and scheduling of plenary meetings for the year 2002**
15. **Any other business**

**SCIENTIFIC COMMITTEE ON
TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)**

28th PLENARY MEETING

7 December 2001, 10H00

Brussels, Belgium

LIST OF PARTICIPANTS

CSTEE:

Prof. James BRIDGES, Wolfgang DEKANT, Prof. Erik DYBING, Prof. Helmut A. GREIM, Prof. Bo JANSSON, Prof. Soterios KYRTOPOULOS, Dr. Claude LAMBRE, Dr. José V. TARAZONA, Prof. Benedetto TERRACINI, Prof. Janneche UTNE SKARE, Prof. Cornelis VAN LEEUWEN, Prof. Katarina VICTORIN, Prof. Marco VIGHI, Prof. Joseph VOS.

EUROPEAN COMMISSION:

HEALTH AND CONSUMER PROTECTION DG:

Messrs. Jorge COSTA-DAVID and Marc SEGUINOT

ENTERPRISE DG:

Mr. Philippe BRUNERIE

JOINT RESEARCH CENTRE (ISPRA):

Mrs. Kirsten VORMAN