30.10.2001

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.**sanco75**.D(01)
CSTEE/01/plen.min.30.10.2001

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

Minutes of the 27th PLENARY MEETING

30 October 2001
Centre Albert Borschette, rue Froissart 36, B-1040 Brussels

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

Apologies were received from Profs. Kyrtopoulos and Vighi and Dr Lambré.

Prof. Van Leeuwen declared his wish not to participate in the discussions on agenda point 4 given his close knowledge of the subject due to the fact that it is about a submission by the Netherlands.

2. Adoption of the draft agenda

The draft agenda was adopted.

3. Approval of the draft minutes of the 25th and 26th CSTEE plenary meeting

Both draft minutes were adopted with minor editorial amendments.

4. *Justification of the Dutch request for derogation under article 95(5) of the EC Treaty - provisions of the Directive 94/60/EC concerning Creosote*

The Working Group chairman made a presentation starting with an 'historical' account of events leading to the discussions and conclusions arrived at during the WG meeting held the day before. The draft text submitted was discussed at length and several editorial corrections made. In general focus was put on 'old' wood data as opposed to 'new' as it meant a worst case approach scenario. One important conclusion seemed to be, on a *'prima facie'* basis, that indeed the circumstances invoked by the submitter M. State are there, although whether or not these are specific to this M. State may remain an open question.

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

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium - Office: B-232, 6/57.
Telephone: direct line (+32-2)2994634, switchboard 299.11.11. Fax: 2957332.
Telex: COMEU B 21877. Telegraphic address: COMEUR Brussels.

Internet: jorge.costa-david@cec.eu.int

5. *Health effects of Radio Frequency and Electromagnetic fields*

The Working Group chairman drew the CSTEE's attention to the main documents considered by the WG and the CSTEE and contributions received, including last minute ones, from CSTEE/WG members. He also drew the committee's attention to the fact that, rather than producing an altogether new review, drawing on raw data, the WG set out to consider existing evidence; this approach was largely determined by the time constraints that the WG and the CSTEE had to face (need to produce an opinion before 30 November 2001). He reminded the committee about the nature of the mandate to the committee (questions A and B of the terms of reference). He then presented, step by step, the draft produced by the WG.

The committee decided that any recommendations it could make relative to this domain, to the extent that this was not part of the mandate, they will be part of a separate document which the CSTEE will elaborate later.

The committee made very exhaustive comments on the draft, requiring clarification on some numerous aspects of it; the draft would subsequently be largely improved linguistically given the perceived need to avoid to the extent possible misinterpretations of the committee's conclusions.

The draft was finally adopted as a CSTEE opinion. It is available in:

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

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

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

a) *Di(isononyl)phthalate (DINP)* (HH and Env)

Regarding the human health effects part the critical effect called *spongiosis hepatis* was now considered as an effect relevant enough to be considered as the critical endpoint. This was previously considered by the CSTEE but, contrarily to the case of the kidney weight increases, the dose response curve could not be calculated before – a lower benchmark has since been calculated. The CSTEE is now of the opinion that this approach is justified.

The critical conclusion seems to be that applying a benchmark dose of 12 mg/kg/d for the hepatic effects yields a MOS value of 29 for combined consumer exposure of children aged 0.5-3 years thus warranting risk assessment conclusion iii). The Human Health and Environmental parts would finally be adopted as CSTEE opinions. They are available in:

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

b) *Di(isodecyl)phthalate (DIDP)* (Env)

Some important statements were made by the committee such as the problems associated with the potential underestimation of the bioconcentration and bioaccumulation of this chemical in that it may have consequences for the risk characterisation for humans exposed through the environment. The CSTEE also expressed the view that a risk assessment on the most relevant metabolite (monoisodecylphthalate) was needed. In the end the draft presented and discussed was adopted as a CSTEE opinion without other major issues raised. It is available in:

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

c) *Butadiene* (HH and Env)

The draft opinion on the Human Health part was presented by the CSTEE *rapporteur* for this substance. In general the RAR was deemed to be of good quality. However there was disagreement with conclusion iii) being reached for all exposure scenarios since the rationale behind conclusion iii)b for workers and iii)a for consumers and indirect exposure via the environment was not clear, as they are not qualified by any quantitative cancer risk estimates. However, since the importance of this distinction [iiia) and iiib)] seems to be destined to be dropped from the TGD this statement may become redundant soon. The CSTEE further stressed that the exposure to Butadiene should be kept as low as possible.

The committee did not agree either with the RAR in that there is no need for further information or testing regarding the possibility of inhalatory sensitisation and toxicity for reproduction, conclusion i).

The draft opinion on the Human Health part 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

The draft on the Environmental part was discussed but its adoption deferred to the December 2001 CSTEE plenary meeting.

d) *Cyclohexane* (HH and Env)

A presentation of the main conclusions as drafted by the CSTEE *rapporteurs* for the Human Health and Environmental parts was made. An ECB representative read a commentary by the FR M. State *rapporteur* to the initial CSTEE draft on the environmental part but such a statement lead the committee to question procedurally whether any views put forward by the committee could start a round of endless back to back discussions between the CSTEE and the M. State rapporteur and/or the technical meeting. The committee endorsed the view that in order to react to such comments it needed advance notice of them.

As a more general comment the CSTEE secretary reminded that at some point, in the case of the future RAs to be submitted to the CSTEE for opinion, it is to be expected that every RA will deserve two rounds of opinions of the CSTEE per substance, one to be called an interim opinion which will allow the M. State *rapporteur* and the relevant ECB technical meeting to react, and a 2nd, and final, opinion on the final Risk Assessment report, which presumably will have taken into consideration the CSTEE's comments made during the 1st opinion.

Given the extensive nature of the comments made (various pages of text) the committee requested that these be provided to the committee for its consideration. Given the above it was agreed that more in depth discussions were needed and the adoption of the documents as CSTEE opinions was postponed to the December 2001 CSTEE plenary meeting.

e) *Dodmac* (HH and Env)
f) *Bis(2-ethylhexyl)phthalate (DEHP)* (HH and Env)
g) *3,4-dichloroaniline* (HH and Env)
h) *N-Vinyl pyrrolidone* (HH)
i) *Naphthalene* (HH and Env)

j) *Ethyl acetoacetate* (HH and Env)
k*) Trichloroethylene* (HH and Env)
l) *Tetrachloroethylene* (Env)

Given the lengthy discussions on some of today's agenda items discussions on chemicals **e)** to **l)** were postponed to the following CSTEE plenary.

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

No feedback was available to be given from any of the pertinent Commission service(s).

C. 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'*.

The WG chairman explained to the committee how the group set out tackling this task and the conclusions of the WG meeting held the day before. To start off this activity, discussions on subsections 1 and 2 were merged into the same sub-group but it was acknowledged that this approach could pose problems since expertise needed for the very in depth discussions per section should be different. The work schedule for the WG is aiming to have an opinion submitted and adopted by the CSTEE at the January 2002 CSTEE plenary meeting. Different responsibilities allocated to the different WG members were also described. A tentative WG meeting was scheduled for the end of November 2001. Once the contributions will start being received they will be merged into one single document which will include exposure considerations as well. It was also suggested that both exposure sections, human and environment, could be discussed into one single sub-group, the conclusions of which could be fed into the more general discussion document. The same logic would apply to the human health part.

Volunteers for the various areas/tasks were tentatively short-listed. The WG chairman then described the main aspects of the documents looked at by the WG and the provisional views which will be discussed in a more in depth manner during the November 2001 WG meeting. A table of contents will be produced to structure better the contributions to be received; such a table of contents would change as and when justified, also in the light of what already is being perceived as a significant problem in that the documents being peer-reviewed by the CSTEE are changing more or less constantly as TGD technical meetings organised under the auspices of the ECB in Ispra take place. The WG chairman specifically requested that the minutes of the current plenary meeting should explicitly emphasise that the TGD and its revision is an extremely important document, the final format and content of which will have major implications on how risk assessments, and logically its conclusions, will take form.

The CSTEE secretary raised the problem of distribution of documents for this opinion request and pointed out that any updates to the documents may be assessed in the ECB web-site the password for which has been made available by the ECB already. The ECB representative informed that by the end of November 2001 updates of the different sections will be available in the ECB web-site.

Finally the tentative calendar of events was described: 15 March-2nd commenting round with the final draft to be ready by 15 April 2002 for adoption by written procedure by the competent authorities but with the final comment of the CSTEE requested by the end of the year 2001, if possible.

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

The draft presented was extensively discussed and in general the committee was of the opinion that the report reviewed was significantly better than the previous one, so called Atkins report, also peer-reviewed by the CSTEE in 1998. Still many issues particularly on the environmental effects side were debated, such as the lack of information on long-term emissions of cadmium from landfills in that it constitutes a serious problem leading the committee to recommend that further research in this field as of high priority. As the cadmium releases from this potentially important exposure route are not considered in the presently peer-reviewed report, the expressions of risk may not reflect the true environmental risks of these cadmium uses. Furthermore the CSTEE also made the point that the results of the Report cannot be used in isolation, and that the importance of the possible risks of these cadmium uses should be evaluated in a broader context.

Regarding the human health effects side of the report the CSTEE recognised that a full re-evaluation of the NOAEL and ADI of cadmium cannot be carried out in the context of the present study and in such a context, it underlined that the publication of the final Risk Assessment Report on cadmium to be produced in the framework of Regulation 793/93 on Existing substances might help sort such difficulties out.

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

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

Prof. José Tarazona informed the committee about his participation in the expert Forum for the Water Framework Directive, in his capacity as an individual external expert of the Commission and not as a CSTEE member and in particular not as chairman of the CSTEE Working Group 'Water Framework Directive'.

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

a) *Endocrine disruption (Human Health)*

The committee decided that the activity of the Working Group on the Human Health part should start as soon as possible, ideally with a WG meeting before the end of the year if possible. WG membership was discussed and possible additions to the group considered. Low dose effects were deemed to be an area where the CSTEE should be focussing as well as on other more conventional aspects. The exposure assessment part was also deemed to be an important one. The date of 9 January 2002 was decided for a tentative meeting of the Working group.

b) *Indoor climate*
A tentative meeting was also set for the 9th of January, either during the morning or afternoon since only half a day was deemed necessary.

A note from the JRC representative was read to the CSTEE reiterating their willingness to collaborate with the CSTEE on the JRC co-ordinated European collaborative action on urban air indoor environment and human exposure.

The CSTEE chairman reminded the committee of the need to define the brief of the CSTEE very clearly for this activity.

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

No feedback was available to be provided by any Commission service representative.

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

i) Consultation of the CSTEE on *'Incineration of animal waste'*.

The representative of DG SANCO made a presentation on the issue and reminded that regarding disposal of animal waste there has not been an environmental problem as such so far because all of it has been transformed in meat and bone meal. But now, because of the BSE crisis, such material is accumulating and becoming an environmental emergency since there are on storage three million tonnes of meat and bone meal which cannot be disposed off; to make things worse there is a lack of capacity of 50% of this material for incineration and co-incineration and therefore alternative ways of disposal are being looked for which will not have a negative environmental impact.

Approving new incineration facilities are a problem in some Member States and there is thus an interest in new ways of disposal resorting to new techniques. Alkaline hydrolysis may be one option and the SSC has given a preliminary positive statement regarding the safety of these processes although conclusions regarding the validation of the inactivation of the prion are still missing. The SSC also considered that the environmental impact assessment of this technology should be addressed by the appropriate committee, the CSTEE.

The CSTEE chairman replied drawing the attention to the need to be clear about the roles of the SSC and the CSTEE. He had prepared a draft for the SSC which could not be considered. The CSTEE does not normally deal with TSEs as such and he requested that waste disposal be addressed by the CSTEE in a more broader sense.

The DG SANCO representative replied stating that the environmental legislation does not cover animal carcasses and the disposal of this type of waste. In the new legislation a link has been created but this type of technology has an environmental impact which should be addressed. In principle this is only one among other possible processes and what is required from the CSTEE is not an opinion on a company product but a view on a possible approach.

The CSTEE chairman indicated that first of all the committee should possibly look at what kind of environmental criteria should apply and to do this a set of questions to be addressed needed to be defined and DG SANCO would be consulted to do this.

ii) Consultation of the CSTEE relating to Member States' assessments of the risk to health and the environment from cadmium in fertilisers.

The terms of reference for starting this activity were reminded but for sheer lack of time the committee could not have started working on this activity yet.

12. 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 information was given that meetings of these two groups were scheduled for the near future.

b) Cross committee's collaboration

Due to his absence from the last SSC plenary the CSTEE chairman could not comment on major topics under discussion at that meeting.

13. Arrangements for the next (28th) plenary meeting of the CSTEE

The next CSTEE plenary meeting was confirmed for December 7, 2001 in Brussels. The CSTEE secretary confirmed that from now on the CSTEE WG meetings will take place in the new premises of Directorate SANCO/C in rue de Genève in Brussels.

14. Any other business

The CSTEE chairman reminded the committee and Commission participants of some follow up on how to improve education and training of future risk assessors by means of creating Masters or PhD level courses at European level; a small group of Universities has set out to investigate what action to take to further this. CSTEE members were invited to show interest and contribute.

Without any other business the meeting was closed.

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.**sanco70**.D(01)
CSTEE/00/plen.age.30.10.2001

SCIENTIFIC COMMITTEE ON
TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)
27th PLENARY MEETING

30 October 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 25th and 26th CSTEE plenary meeting**

4. J***ustification of the Dutch request for derogation under article 95(5) of the EC Treaty - provisions of the Directive 94/60/EC concerning Creosote***

5. ***Health effects of Radio Frequency and Electromagnetic fields***

6. **Regulation 793/93 on Existing substances (ESR):**
   A. Status reports/opinions (Human Health and/or Environment) on:
   a) *Di(isononyl)phthalate (DINP)* (HH and Env)
   b) *Di(isodecyl)phthalate (DIDP)* (Env)
   c) *Butadiene* (HH and Env)
   d) *Cyclohexane* (HH and Env)
   e) *Dodmac* (HH and Env)
   f) *Bis(2-ethylhexyl)phthalate (DEHP)* (HH and Env)
   g) *3,4-dichloroanyline* (HH and Env)
   h) *N-Vinyl pyrrolidone* (HH)
   i) *Naphthalene* (HH and Env)
   j) *Ethyl acetoacetate* (HH and Env)
   k) *Trichloroethylene* (HH and Env)
   l) *Tetrachloroethylene* (Env)

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

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

9. Emerging issues identified by the SSC and for which the CSTEE is the 'lead' committee:
a) *Endocrine disruption (Human health)*
b) *Indoor climate*

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

11. Strategies for dealing with additional opinion requests submitted by other DGs of the Commission
i) Consultation of the CSTEE on *'Incineration of animal waste'.*
ii) Consultation of the CSTEE relating to Member States' assessments of the risk to health and the environment from cadmium in fertilisers.

12. 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

13. Arrangements for the next (28th) plenary meeting of the CSTEE

14. Any other business

SCIENTIFIC COMMITTEE ON
TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)
27th PLENARY MEETING

30 October 2001, 10H00
Brussels, Belgium

LIST OF PARTICIPANTS

CSTEE:
Prof. James BRIDGES, Prof. Peter CALOW, Prof. CANTELLI-FORTI, Prof. Wolfgang DEKANT, Prof. Erik DYBING, Prof. Helmut A. GREIM, Prof. Colin JANSSEN, Prof. Bo JANSSON, Prof. Amadeu SOARES, Dr. José V. TARAZONA, Prof. Benedetto TERRACINI, Prof. Janneche UTNE SKARE, Prof. Cornelis VAN LEEUWEN, Prof. Katarina VICTORIN, Prof. Joseph VOS.

EUROPEAN COMMISSION:
HEALTH AND CONSUMER PROTECTION DG:
Messrs. Jorge COSTA-DAVID and Panagiotis DASKALEROS.

ENTERPRISE DG:
Mrs. Lena PERENIUS, Mr Marinus BOGERS

JOINT RESEARCH CENTRE (ISPRA):
Messrs Sazan PAKALIN, Stylianos KEPHALOPOULOS, Mmes Kirsten VORMAN and Florence BERTHAULT