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

Minutes of the 26th PLENARY MEETING

held on

11 September 2001 in Centre Albert Borschette, rue Froissart 36, B-1040 Brussels

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

The CSTEE chairman welcomed participants to this plenary, the fist one since the summer break.

Apologies were received at the CSTEE secretariat from Profs. Cantelli-Forti, Dybing, Soares, Van Leewen and Vos.

No declarations of interest were made by any CSTEE member.

2. Adoption of the draft agenda

The draft agenda was adopted.

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

The adoption of the draft minutes of the 25th CSTEE plenary meeting was postponed.

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

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

a) *Hydrogen Peroxide*

Opinions on the Human Health and Environmental parts were adopted. They are available in:

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

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b) *Styrene*

The opinion on the Environmental part was adopted. It is available in:

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

c) *N-Vinyl pyrrolidone*

The opinion on the Environmental part was adopted. It is available in:

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

d) *Di(isononyl)phthalate (DINP)*

Several technical points were raised but in the absence of several committee members, namely the CSTEE *rapporteur* for the Human Health part of this RAR, the committee considered that the adoption as a CSTEE opinion of the draft text submitted was dependent on CSTEE confirmation once a new, edited version, would be circulated to the committee by the secretariat.

e) *Butadiene*

A presentation was made by the CSTEE *rapporteur* on the environmental part of the RAR. This being a gas, the RAR was somewhat different. In general the emissions section was deemed to be well covered. In the exposure assessment part there may be a problem in that a big river was used in the exposure assessment for the aquatic compartment (emission data instead of default data) with too large a flow (300x larger compared with the TGD), therefore probably 'diluting' the chemical. Other possible methodological problems were also addressed, *e.g.* whether the data used was realistic or not since it seemed to be dependent upon whether M. States knew where the emission sources were located. The CSTEE *rapporteur* suggested that a table should be made available with a list of all European production sites with data on production relative to all European production and use, sites of wastewater treatment plants and receiving water. The *rapporteur* undertook to incorporate comments of CSTEE members in view of possibly adopting the opinion at the next CSTEE plenary.

The CSTEE *rapporteur* for the Human Health part also presented the conclusions arrived at so far on the HH part of the RAR. Among the aspects addressed were: (i) quality of epidemiological and toxicological data; (ii) differences of sensitivity between mice and rats in inhalation studies; (iii) differences in metabolic patterns; (iv) the implications of extrapolations to humans and (v) implications of there not being references to quantitative cancer risk estimates made in the RAR. Differences in RA conclusions iiia) and iiib) for the different groups (general population versus workers) were also seemingly not properly explained in the RAR. Parallels with the evaluation of Acrylamide were made.

f) *Cyclohexane*

A presentation on the Environmental part of the RAR was made by the responsible CSTEE *rapporteur*, highlighting points on: (i) ready biodegradability; (ii) assumptions on emissions; (iii) extent to which the TGD was followed; (iv) exposure assessments; (v) sites considered; (vi) PNEC derivation; (vii) lack of atmospheric risk assessment/characterisation, etc. The CSTEE *rapporteur* will prepare a new draft, incorporating comments from CSTEE members in view of possibly adopting the opinion at the next plenary.

A brief presentation on the Human Health part of the RAR was also made by the CSTEE *rapporteur* commenting on: (i) exposure assessment; (ii) less than ideal way in which

tabulated data was put in the RAR; (iii) complexity of the toxicokynetic chapter; (iv) considerations on carcinogenicity through genotoxic mechanisms, etc. As was the case for the Environmental section the CSTEE *rapporteur* undertook to prepare a new draft on the HH part, incorporating comments from CSTEE members in view of possibly adopting the opinion at the next plenary.

A point was raised on whether the CSTEE should comment on a possible distinction between conclusion iii-a) and iii-b). An ECB official explained that in the framework of technical meetings in the ECB in Ispra the tendency has been to express this distinction in a slightly different way (in terms of magnitude of the risk, qualitatively, or, if possible, quantitatively). For this reason this difference may disappear in the future. In the case of Cyclohexane this distinction may not be relevant.

g) *Dodmac*

A first presentation was made by the CSTEE *rapporteur* for the human health part of this substance. Adoption of the opinion was postponed to the next CSTEE plenary.

The committee was made aware of submissions from Industry on the RAR for this substance. This triggered a more general discussion and the point was made that the rules agreed between the ECB and the CSTEE secretariat have to mean that normally such submissions should be made during the preparation of the RAR and not when the CSTEE peer reviews the final risk assessment report. Obviously distinctions have to be made between internal Industry information and reports published in peer reviewed scientific publications. An important point was made by the ECB representative in that, if the M. State *rapporteur* for a particular substance is provided data which will be deemed to have a significant impact on the conclusion, that M. State can request a new discussion at an ECB technical meeting; this rule makes submissions to the CSTEE by Industry late in the process as *de facto* redundant.

The committee finally concurred that good information could be looked at by the committee on top of the RARs from the ECB. Decisions have however to be made on a case by case basis.

h) *Di(isodecyl)phthalate (DIDP)* (ENV)

The draft distributed, and in principle adopted by the committee, will have to be reviewed in the light of the more general discussions on DINP, given the possible implications/extrapolations of conclusions on it to other phthalates.

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

The ECB representative announced the next batch of RARs to be submitted to the CSTEE for peer review. Were mentioned in particular ***Bis(2-ethylhexyl)phthalate (DEHP)*****(HH and Env)*****; 3,4-dichloroanyline* (HH and Env)*; N-Vinyl pyrrolidone* (HH)*; Naphthalene* (HH and Env)*; Ethyl acetoacetate* (HH and Env)*; Trichloroethylene* (HH and Env)*; Tetrachloroethylene* (Env*).**

CSTEE *rapporteurs* for all (HH and Env) were appointed.

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

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

Since the drafts were received at the CSTEE secretariat from the ECB relatively recently the activity will start only after this plenary. It was tentatively agreed that the Working group(s) should meet in the eve of the next CSTEE plenary meeting.

The ECB representative informed that ideally the CSTEE position should have been made available already since the results would be useful for a technical meeting scheduled for the 23/24 October. However the EC will try to accommodate the CSTEE's comments even if they will arrive after that.

The ECB representative also informed that all key documents can be retrieved from the relevant ECB website. The CSTEE will be provided with the necessary password so that any relevant document may be looked at by the committee.

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

The draft prepared by the CSTEE *rapporteur* was presented. The three uses covered were described. Links with the former CSTEE position in 1998 (Atkins report) were made. It was reminded that the CSTEE had highlighted that report's shortcomings. The reservations expressed then were related to total human exposure in that the former report did not cover well the full range of human exposure; the issue of the NOAELs was also addressed.

The relevance of these reminders is related to the fact that the Atkins report was used now as a basis for preparing the report that the CSTEE is now expressing an opinion on. The previous Atkins report was completed with new data and specific references are made to the former CSTEE's comments. It would look as if there is an increased transparency in this current report *vis à vis* the former one.

It was pointed out that the three specific cases of uses considered should be seen in the light of the overall Cadmium uses. The conclusions have therefore to be viewed in the context of a more comprehensive risk assessment, covering other uses. It was surprising to see how little data was provided from certain quarters (*e.g.* factories).

The effects' assessment for the environment are extensively described and the Belgian report used was considered a good basis given its comprehensiveness. There was very little information on occupational exposures however. Overall the conclusions seem rather more acceptable than the ones in the previous Atkins report. However, given the limited focus of the uses considered a false sense of safety may be conveyed.

Problems were also found with agreeing with conclusion of no risk for soil and sediments since even for the only three uses considered not all emission sources were apparently addressed in the report.

The ECB representative informed that the main Cadmium risk assessment (in the framework of Reg. 793/93) may be ready by the end of the year and therefore any shortcomings that the current report being assessed by the committee may have, may have a solution then.

A DG Enterprise representative reminded that the reasons behind this targeted report were related to the accession provisions of the three most recent EU M. States; this of course posed problems in terms of the comprehensiveness of the report. However given the time limit (end of 2002), this meant that the EC could not wait for the full report to be ready (even though it would look as if the full, comprehensive, report will be ready before that).

Indicating what was left out in the report, that a more complete risk assessment should have, would perhaps be a means of making the point that this new report looked at by the CSTEE cannot be considered as a complete risk assessment. The point was also made that there may be a risk that a limited risk assessment may not be very helpful as a basis for risk management.

Finally research on bioavailability was also deemed necessary by the committee.

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

The working group chairman described the rate of progress, including that stemming from working group meetings, the last one of which had taken place one day before this plenary meeting.

Some data used by the working group in the review were described. It was noted that there were no major disagreements in the WG on the interpretation of the available studies.

It was noted that the opinion request is not only on whether the SSC opinion of two years ago ought to be reviewed on cause-effect relationships and spectrum of effects in the body but also on whether new exposure limits should be proposed.

A tentative schedule of activities ahead for the working group was proposed. Overall it would look as if the prospects for adopting the opinion at the next plenary are good.

The CSTEE secretary reminded the committee of the link that Commission services have established between this opinion and the upcoming conference in Luxembourg on the subject, scheduled to 30 November 2001. For this reason it is very important that the opinion be adopted at the next plenary on 30 October 2001.

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

The 1st vice-chairman commented on his participation in the activities of the SCF working group debating the issue of Dioxins in food. Of main interest to the CSTEE representatives was the use by the SCF working group of an uncertainty factor of 3.5 for inter-individual differences between males and females, leading to the ADI that the SCF finally came to adopt.

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

a) *Endocrine disruption (Human health)*

In the absence of the working group chairman the discussion on this topic was postponed.

b) *Indoor climate*

A representative of the JRC made a presentation of the activities that the JRC is carrying out on this topic. He undertook to send to the CSTEE secretariat a complete set of documents which have been produced in the framework of the concerted action *'Indoor quality and its impact on man'* now called *'Urban air, indoor environment and human exposure'*, the main reasons for this change being to follow trends in this area of work.

The chairman welcomed the presentation and commended the collaboration/input of the JRC into this activity, bearing in mind that the CSTEE will try to avoid duplication of effort.

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

The committee was made aware by a JRC representative about an addendum/explanatory note, intended to fill the gaps noted in the former CSTEE opinion on *'Validation of methodologies for the release of DINP in saliva simulant from toys'*; the *addendum* also helps justify some of the choices that had to be made by the JRC.

The point was also made that the toys used in the 'validation' were actually from production lines and not made specifically for the 'validation'. The committee was asked to provide input on whether this *addendum* fills the gaps mentioned.

The committee was also made aware of the 'Greenpeace' stance (made public in their website) on the CSTEE opinion on *'Validation of methodologies for the release of DINP in saliva simulant from toys'*. No decision was taken on this occasion on whether a reaction from the CSTEE to the 'Greenpeace' paper should take place. Committee members were asked to consider this and provide feed back to the secretariat on how they feel about it.

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

i) *Consultation of the CSTEE on the 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 committee was reminded by the CSTEE secretary that this consultation is the natural follow up to the opinion adopted by the committee back in June this year. Basically the committee is being asked to consider the 'Dutch' evidence not previously made available. These will be sent in earnest during the forthcoming days.

ii) Consultation of the CSTEE on *'Incineration of animal waste'*

A presentation was made by the desk officer of the Commission responsible for the dossier. The committee was asked whether it can assist in the evaluation of the environmental impact of alternative ways to incineration when disposing of animal

waste, The current legislation on disposal of animal waste in relation in particular to the risk of dissemination of BSE is imposing the incineration of animal carcasses; for other risk material, co-incineration or landfill is also allowed, after a pre-treatment to high temperatures. However, since some M. States have a lack of capacity for incineration or co-incineration, alternative ways of disposal have to be found, which are safe, in terms of BSE risks but which should not pose undue environmental risks either. The legislation foreseen accepts this but any process has to be scientifically validated. Furthermore the SSC has expressed the view that any alternative method of disposal should be validated by the appropriate scientific committee, hence this upcoming opinion request.

The matter is complicated by a peculiarity in that the environmental legislation (framework waste directive, incineration of waste directive, landfill directive) all exclude from their scope the incineration of animal carcasses. Given that this vacuum on the environmental impact of the disposal of animal carcasses has to be filled, a scientific opinion from the CSTEE may provide a solution to this emerging environmental problem.

Some CSTEE members volunteered in principle to participate in this activity, perhaps with members of other scientific committees.

Because of the consternation caused by the events in New York City when this meeting was being held the session was closed without a discussion of the remaining agenda points (11, 12 and 13).

11. 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

12. Arrangements for the next (27th) plenary meeting of the CSTEE

13. Any other business

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SCIENTIFIC COMMITTEE ON
TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)
26th PLENARY MEETING

11 September 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 CSTEE plenary meeting**

4. **Regulation 793/93 on Existing substances (ESR):**
   - **A. Status reports/opinions (Human health & Environment) on:**
     - **a)** ***Hydrogen Peroxide***
     - **b)** ***Styrene***
     - **c)** ***N-Vinyl pyrrolidone***
     - **d)** ***Di(isononyl)phthalate (DINP)***
     - **e)** ***Butadiene***
     - **f)** ***Cyclohexane***
     - **g)** ***Dodmac***
   - **B. Status reports/opinions (Environment) on:**
     - **h)** ***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 - Activities of subgroups on:**
     - **1.** ***'Environmental exposure'***
     - **2.** ***'Marine risk assessment'***
     - **3.** ***'Environmental effects assessment'***
     - **4.** ***'Human health exposure assessment'***
     - **5.** ***'Human Health effects assessment'*****.**

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

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

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

8. **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*

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

10. **Strategies for dealing with additional opinion requests submitted by other DGs of the Commission**
    i) ***Consultation of the CSTEE on the justification of the Dutch request for derogation under article 95(5) of the EC Treaty - provisions of the Directive 94/60/EC concerning Creosote***
    ii) Consultation of the CSTEE on *'Incineration of animal waste'.*

11. **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
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12. **Arrangements for the next (27th) plenary meeting of the CSTEE**

13. **Any other business**

SCIENTIFIC COMMITTEE ON
TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)
26th PLENARY MEETING

11 SEPTEMBER 2001, 10H30
Brussels, Belgium

LIST OF PARTICIPANTS

CSTEE:

Prof. James BRIDGES, Prof. Peter CALOW, Prof. Wolfgang DEKANT, Prof. Helmut A. GREIM, Prof. Colin JANSSEN, Prof. Bo JANSSON, Prof. Soterios KYRTOPOULOS, Dr. Claude LAMBRÉ, Dr. José V. TARAZONA, Prof. Benedetto TERRACINI, Prof. Janneche Utne SKARE, 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, Messrs Giovanni INDIRLI and Alastair PEACE

JOINT RESEARCH CENTRE (BXL):

Mr Laurent BONTOUX

JOINT RESEARCH CENTRE (ISPRA):

Mrs. Catherine SIMONEAU, Messrs Sazan PAKALIN, Stylianos Kephalopoulos and Demostenes PAPAMELETIOU