EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C2 - Management of scientific committees; scientific co-operation and networks
Scientific Committee on Toxicity, Ecotoxicity and the Environment

CSTEE/GEN2/Minutes 12.06.2003 Final

SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE) 38TH PLENARY MEETING

Held on 12 June 2003
in Brussels

DRAFT MINUTES

1. WELCOMING ADDRESS, APOLOGIES FOR ABSENCE, DECLARATIONS OF INTEREST

Prof. Bridges welcomed the participants to the meeting. Prof. Cantelli Forti, Prof. Janssen, Prof. Skåre, and Prof. Soares sent their apologies.

Declarations of interest:

Prof. Greim mentioned that one of his former colleagues worked on the report on the risks to health and the environment posed by the use of organostannic compounds. The members of the committee agreed that Prof. Greim would not participate to the discussion on this point. No other declarations of interests were made.

2. ADOPTION OF THE DRAFT AGENDA

The draft agenda was adopted as written in Annex I. A few points were discussed in a different order to better adjust to the time availability of some participants.

3. APPROVAL OF THE DRAFT MINUTES OF THE 37TH PLENARY MEETING

The draft minutes of the 37th CSTEE plenary meeting were adopted with minor corrections and are available at:
http://europa.eu.int/comm/food/fs/sc/sct/out185_en.pdf

4. NEW REQUESTS FROM COMMISSION SERVICES

Examination of a report on alternative non-animal methods for chemical testing

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Mr. Vogelgesang (DG ENV) introduced a request for consultation of the CSTEE for their opinion on a report entitled "Action to end animal toxicity testing" published by two animal welfare non-governmental organisations. The report lists a number of toxicity tests with animals, which are claimed to be replaceable, by available *in vitro* tests. The CSTEE is invited to assess the overall scientific quality of the report and to comment on the adequacy of the non-animal alternative methods proposed to carry out appropriate risk assessment, classification and labelling of industrial chemicals for each endpoint considered in the report.

The Secretariat clarified that a joint working group was created with members of the three non-food scientific committees to ensure a consistent approach whatever the uses of the chemicals (pesticides, additives etc.) and the various existing legislative frameworks (e.g. cosmetics).

Risk of sensitisation of humans to nickel by piercing post assemblies

DG ENTR commissioned a study to evaluate the current scientific knowledge on stainless steels used in body piercing with respect to nickel release and the ability of such steels to cause allergic dermatitis to nickel. Directive 94/27/EC seeks to prevent nickel sensitisation by restricting the use of nickel and its compounds that come into close and prolonged contact with the skin. The authors of the report finally recommended that the existing requirement of a maximum nickel content of 0.05% by mass in post assemblies be replaced by a migration limit of 0.2 $\mu g/cm^2$/week (in accordance with the specified standard method EN 1811). The CSTEE is asked to comment on the findings, conclusions and recommendations of the report.

A working group was set up. An external *ad hoc* expert on nickel tolerance will be invited to join the working group.

A risk assessment on Nickel under regulation 793/93 is ongoing. The final opinion of the CSTEE will be provided to the Rapporteur of the Risk Assessment Report on nickel for their consideration.

Risks to health and the environment from PAHs in extender oils and tyres

Mr. Hadrich explained that the Commission was currently considering a proposal for a Directive relating to restrictions on the marketing and use of certain PAHs in extender oils and tyres. PAHs, as constituents of extender oils, can remain in the tyres during the production process and be incorporated into the rubber matrix. The CSTEE is asked to assess the potential risks to humans and to the environment posed by the emissions of PAHs into the environment as a consequence of the abrasion of the tyre tread. DG ENTR provided background documents published by Member States or industry.

A working group was set up. Additional expertise on emissions may be needed.

Revision of the SCTEE opinion on SCCPs

The CSTEE had issued two opinions on SCCPs: on the initial risk assessment report under Regulation 793/93 (November 1998), and then following a Parliament request to evaluate whether new available scientific evidence might call for a modification of the conclusions of the Community risk assessment (December 2002). The CSTEE

concluded that the review of the new data on SCCPs did not lead to a change in the conclusions of the Community risk assessment.

However, as a follow up of Directive 2002/45/EC on the restriction of the use of SCCPs, the Community risk assessment report on SCCPs was recently revised using the revised Technical Guidance Document (2003) and other available information to issue a more complete assessment of the remaining uses of SCCPs not currently subject to restrictions in Directive 2002/45/EC. The report highlighted potential risks to the soil and to the marine environment in relation to the likely PBT properties of SCCPs . Despite the provisional character of the report, the CSTEE will be asked whether they agree with the conclusions given on the report or not.

The request should be treated as urgent with regards to Article 95 (4) and (6) of the Treaty, whereby the Commission has to approve or reject the justification of the national provisions notified by the Netherlands within a limited delay.

The working group that was previously set up to discuss the PBT approach will convene to respond to this request. The need for additional expertise will be assessed when the report is received early July.

Risks posed by Mercury in products

W. Hehn explained that DG Enterprise commissioned a study whose aim was to estimate present and future use of mercury and to characterise the risks to health and the environment posed by mercury in certain products, covering their entire cycle (production, use, waste treatment, emissions).

To allow the Commission to decide whether further restrictions on marketing and use of certain applications of mercury in products are needed under Directive 76/769/EEC, the CSTEE is asked for its opinion on the conclusions of the report and particularly on the results and reliability achieved by the use of the refined EUSES (European Union System for the Evaluation of Substances) model to predict the mercury concentrations in the three main environmental compartments (air, terrestrial and aquatic). The opinion of the CSTEE will be an important element in the preparation of the Commission comprehensive strategy on mercury.

A working group was set up.

Regulation 793/93

The Committee identified rapporteurs to review the final draft risk assessment reports on the substances mentioned from point 4f to 4k of the agenda.

Particular attention was drawn to the risk assessment of cadmium, as the conclusions reached will have implications on a few important pieces of legislation (e.g. Directives on cadmium in fertilisers, batteries). Any potential weaknesses should be pointed out. An appropriate external *ad hoc* expert was identified.

5. REGULATION 793/93 ON EXISTING SUBSTANCES (ESR): STATUS REPORTS/ OPINIONS (HUMAN HEALTH AND/OR ENVIRONMENT)

Aniline (ENV)

The draft opinion on the environmental part of the risk assessment report was discussed. The rapporteur explained that he could agree with most of the conclusions of the report, although minor points of disagreement were identified. The low reliability of the PNECsoil justifies the need for additional toxicity tests on soil organisms, which is in contradiction with the conclusion ii) reached in the report for the soil compartment. The use of a more stringent PNEC for the aquatic environment, i.e. use of the lowest NOEC value of the long-term studies on Daphnia to derive the PNEC, was discussed.
The draft opinion was adopted with some changes and is available at:
http://europa.eu.int/comm/food/fs/sc/sct/out186_en.pdf

3,4-Dichloroaniline (HH)

Due to technical problems the draft opinion on the human health risk assessment of 3,4-dichloroaniline could not be circulated among the committee. It will be soon circulated for review prior to the next plenary meeting.

Chromium Trioxide, Sodium Chromate, Sodium Dichromate, Ammonium Dichromate, Potassium Dichromate (ENV)

A working group meeting took place the day before the plenary meeting to discuss the points of concern raised at the last plenary meeting on the results of the environmental risk assessment of chromates : (a) the effects of the reduced form of Cr(VI) were not assessed, (b) the possible toxic effects of natural background concentrations were ignored, (c) consequently the added risk approach was incorrectly applied, (d) environmental factors e.g. pH, bioavailability were not taken into account (d) lack of references were missing in support to a few assumptions made. A final draft opinion including will be presented at the next plenary meeting.

6. INFORMATION ON THE WATER FRAMEWORK DIRECTIVE AND CSTEE INVOLVEMENT

Mr. D'Eugenio (DG ENV) was invited to present the Water Framework Directive (2000/60/EC) and explain at which stage the CSTEE would be involved.

Mr. D'Eugenio made a detailed presentation on the Water Framework Directive, whose main purpose is to protect all waters, surface and ground waters in a holistic way. The implementation timetable was described until 2015, by which date the status of 'good quality' water should be achieved. The activities include information exchange and raising awareness, the development of thirteen Guidance documents and four Technical reports, the development of geographical information systems, testing studies in pilot river basins (manual for integrated river basin management).

Further information can be found at the following website addresses:
Water policy: http://www.europa.eu.int/comm/environment/water
WFD Circa information exchange platform:
http://forum.europa.eu.int/Public/irc/env/wfd/home
Guidance documents: http://forum.europa.eu.int/Public/irc/env/wfd/library

Mr. D'Eugenio clarified that DG ENV has a co-ordination role to support the implementation of the Directive. The Guidance documents are neither formal nor Commission documents. They are prepared by experts from Member States or Candidate countries or NGOs etc... and aimed at creating a common understanding

among Member States experts and include useful tools and best practices on various practical issues in relation to the implementation of the Directive (economic analysis, pressure and impact analysis, intercalibration). They should be integrated in a manual in 2005.

Prof. Calow expressed nevertheless some concern that such guidance documents may be used and finalised without ensuring an appropriate scientific approach.

Further to the fruitful and useful collaboration with the CSTEE in the past, Mr. D'Eugenio confirmed the willingness to consult the CSTEE on key scientific elements in the policy preparation. The CSTEE will be consulted on environmental quality standards for priority substances in the near future. The CSTEE may also be consulted on the first report on intercalibration that will be issued by end 2003. Data are currently collected. DG JRC will compare the systems between Member States. Mr. D'Eugenio proposed to join again at one of the meetings of the CSTEE next year to update the members on any progress. Mr. D'Eugenio was finally gratefully thanked for the useful and complete explanations given.

7. ONGOING REQUESTS FOR OPINION FROM THE CSTEE BY COMMISSION SERVICES

Studies relating to the quality of drinking water in selected European countries

The changes required at the last plenary meeting on the draft opinion on the two studies concerning the quality of drinking water in selected European countries were reviewed in detailed by the Committee. It was concluded that, although the studies provided were comprehensive, the results obtained could not give a full picture of the variability of drinking water throughout Europe. Furthermore the study design did not allow the identification of the different potential pollution sources. Future studies should also include other geographical areas, where the raw water quality and purification techniques may be different. Smaller waterworks should also be included.

It was strongly suggested that the CSTEE should be consulted before such studies are launched to ensure that the study designs would cover all necessary scientific aspects in the most appropriate way.

The opinion was adopted with a few additional changes and is available at:
http://europa.eu.int/comm/food/fs/sc/sct/out187_en.pdf

Phosphate based household detergents and eutrophication

The working group could not convene before the week following this plenary meeting and succeeded only recently to find an appropriate expert knowledgeable on substitutes to phosphate-based detergents. It was agreed that the opinion should be adopted in November at the latest due to its implications.

Study on the risks to health and the environment posed by the use of organostannic compounds

The CSTEE was asked for an opinion on the risks posed by organostannic compounds to human health and the environment from food and non-food sources. The opinion relating to the food sources and prepared by a working group of the EFSA Panel on contaminants has been delayed. The working group proposed the

revised opinion relating to the risks from non-food sources for adoption. A consolidated opinion will then be prepared when the EFSA opinion is finalised.

The rapporteurs reiterated the issues raised at the last plenary meeting and concluded with a list of information gaps on: antifoulings, a few organotin compounds, some organotin containing products, measured emission factors for industrial processes and consumer products, some exposure routes (indoor air, dust, toys), levels in the food chain and wildlife species, additivity of some organotin compounds, immunotoxicity endpoint for wildlife, literature coverage.

The opinion was adopted provided that some clarifications would be provided (calculation of TBT uptake from cycling shorts padding, exposure in paddling pool, missing data to calculate children exposure) and that the final text would be circulated to the whole committee.

The opinion will be available at the website address:
http://europa.eu.int/comm/food/fs/sc/sct/out188_en.pdf

Study on heavy metals and organic compounds from wastes used as organic fertilisers

The working group identified some issues at their first meeting such as the lack of a clear definition of compost, the selection criteria for the compounds considered, the basis for the threshold values used, the lack of data on organic chemicals, the lack of consideration of different types of soil. They will meet in two weeks to discuss first drafts of individual contributions. A draft opinion will be presented at the next plenary meeting.

Prof. Calow drew the attention of the committee to the presence GMOs in wastes, which may become an issue to consider in the future.

Study on the risks posed by the use of copper containing anti-foulings on pleasure crafts

The working group could not convene before the week following the plenary meeting. They will report back at the next plenary meeting.

Report on the risk assessment of organic chemicals in toys/Risks posed certain elements in toys

The combined working group will convene the day following the plenary meeting to discuss the background information provided and which chemicals are of concern. They will report back at the next plenary meeting.

Studies on scientific evaluation of substances showing evidence or potential for endocrine disruption

The first meeting of the working group will take place the week following the plenary meeting. They will report back at the next plenary meeting.

8. ISSUES IDENTIFIED BY THE CSTEE

Persistence, bioaccumulation and toxicity criteria

Following the proposal by the CSTEE to discuss the definition and use of the PBT criteria as well as possible alternative approaches for persistent substances, Mr. Blainey (DG ENV) clarified it was actually not the intention to submit a request for consultation to the CSTEE on this issue, although a consultation in the future was nevertheless not excluded. The revised Technical Guidance Document has indeed just been published (http://ecb.jrc.it/cgi-bin/reframer.pl?A=ECB&B=/tgdoc/). Furthermore, the REACH (Registration, Evaluation and Authorisation of Chemicals) proposal, which include PBT criteria, is now available for consultation on the Internet. The CSTEE members agreed to prepare comments on REACH with regards to PBT criteria.

Comments to REACH

Prof. Dybing presented a draft text, where deficiencies with regards to the use of vertebrate animals were identified in the REACH proposal. Although the CSTEE supports and encourages research to reduce, refine or replace the use of laboratory animals, the current REACH proposal seems to underestimate the need to use vertebrate animals for appropriate chemical testing, whose purpose is to ensure and enhance human and animal health and protection of the environment. Animal toxicity data are necessary to perform meaningful risk assessment (e.g. identification of NOAELs or risk specific doses, which cannot be achieved with available *in vitro* methods).

The CSTEE was concerned that, although the REACH proposal was an improvement to the existing system, there was a risk to end up with hazard identification rather than with a proper risk assessment.

Prof. Tarazona pointed out that the use of aquatic vertebrates was less considered that those of other vertebrate animals. Although some alternative methods have already been suggested, they are also far from being able to predict ecologically relevant sublethal endpoints.

Prof. Calow will prepare a draft section on PBT and vPvB assessments to be added in the final comments.

Last, a section will be included on what the CSTEE would be willing to advise further on.

The revised text will be circulated again among the committee members for comments before it is put on the Internet (http://europa.eu.int/comm/enterprise/chemicals/chempol/contributions/public.htm)

The final comments can also be found as Annex III to these minutes.

Endocrine disruption

Due to technical changes in the procedure, the preparation of the call for tender by DG SANCO/B to support a systematic review of epidemiological evidence of temporal changes of sperm quality and associated risk factors has been delayed. It will not be an open call, the proposal will be sent to five Institutions.

Indoor air quality

A few projects similar to the proposal developed by the CSTEE on the health impact of indoor air quality are ongoing or about to start through EU funding e.g. DG SANCO, DG RDT. It was then suggested to avoid duplication of work and rather

wait for preliminary and intermediate results of these studies to better identify gaps, where the CSTEE involvement would be the most beneficial.

Mr. Kephalopoulos updated the Committee on the progress of the INDEX project lead by DG JRC. The aim is to create a network of European leading scientists in this area of indoor air pollution and the herewith associated health impacts. It will help identifying priorities and assessing the need for a Community strategy and action plan. The project will focus on 5-6 major compounds for which indoor air exposure limit would be proposed. The intermediate report is expected in June and will be circulated to the CSTEE for information.

9. PARTICIPATION OF THE CSTEE IN ACTIVITIES/WORKING GROUPS OF OTHER SCIENTIFIC COMMITTEES OF THE COMMISSION OR EFSA

The collaborative work on the environmental effects of coccidiostats in animal feed between of a few members of the CSTEE and the new EFSA Panel on animal nutrition is still ongoing. Meetings are planned in June and July 2003.

A comparative table between the assessment of the CSTEE and the SCF on phthalates was prepared for the establishment of the list of plastics additives in food contact material. Two members of the CSTEE participated to the last EFSA Scientific Committee meeting, where the matter was discussed. The conclusions of the CSTEE were taken up, except regarding benchmark doses.

10. UPDATE ON THE LATEST MEETINGS OF THE SSC ON MATTERS OF INTEREST TO THE CSTEE

Prof. Bridges informed the participants that the report on the harmonisation of risk assessment procedure was finished and published on the Internet. A publication on the BSE activities in the last six years is also available.

11. NEXT PLENARY MEETINGS OF THE CSTEE

The next meetings of the Committee will take place on 10 September 2003 and 13 November 2003. A tentative date has been fixed also on 8 January 2003, in case the new scientific committees would not be in place by that date.

12. ANY OTHER BUSINESS

Mr. Daskaleros (DG SANCO) presented the Action Plan of EIS-CHEMRISKS, the European Information System on the risks from chemicals released from consumer products/articles. The purpose is to build knowledge and develop an infrastructure for the collection and assessment of information on human exposure to chemicals released from consumer products/articles. It is the intention to consult the CSTEE before any related documents (emerging issues, exposure scenarios, priority action plans) are finalised. Within this framework a first workshop was organised in May 2003 on the safety aspects of tattoos and piercing. The CSTEE will also be informed of the dates of other forthcoming workshops in 2003-2004 (clothing/textiles, toys, personal hygiene products, computer devices, automotive components). Mr.

Daskaleros encouraged the members of the committee to contact the responsible person, Mr. Papameletiou (DG JRC), should they have any comments or suggestions on the informative document distributed.

Mr. Pickering (DG ENTR) informed the members of the committee that an interservice consultation took place the day before this meeting to discuss the draft legislative on cadmium in fertilisers. The opinion issued by the CSTEE in September 2002 on this matter was used as a basis. The draft legislation proposal will be put on the Internet for consultation in about a month.

Prof. Terracini asked about the final conclusions of the Conference on "Application of the Precautionary Principle to EMF", which took place on 24-26 February 2003, in Luxemburg. The summary reports of the Conference are available on the WHO website at the following address:
http://www.who.int/peh-emf/meetings/Lux_PP_Feb2003/en/

Two documents prepared by Prof. Cantelli Forti on lead in candle wicks and indoor PCBs were distributed for information.

Prof. Bridges closed the meeting with thanking the participants for their contributions.

Annex I: Agenda.

Annex II: List of Participants.

Annex III: CSTEE comments on REACH

Annex I

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C2 - Management of scientific committees; scientific co-operation and networks
Scientific Committee on Toxicity, Ecotoxicity and the Environment

CSTEE/00/Plen.age.12.06.2003 Final

SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)
38TH PLENARY MEETING

12 June 2003, starting at 10h00
Building Demot 24
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 37th CSTEE plenary meeting

(4) New requests from Commission Services

(a) Animal testing
- Examination of a report on alternative *non-animal methods for chemical testing*
- Note prepared by Prof. Dybing: Reach - Use of vertebrate animals

(b) Risk of sensitisation of humans to *nickel* by *piercing post assemblies*
(c) Risks to health and the environment from *PAHs in extender oils and tyres*
(d) Revision of the SCTEE opinion on *SCCPs* – possible new request
(e) Risks posed by *Mercury in products* – possible new request
(f) Regulation 793/93 : *Cadmium* – possible new request
(g) Regulation 793/93 : *Edetic acid* (CAS No. 60-00-4) - HH and ENV
(h) Regulation 793/93 : *Tetrasodium ethylendiaminetetraacetate* (CAS No. 64-02-8) - HH and ENV
(i) Regulation 793/93 : *But-2-yne-1,4-diol* (CAS No. 110-65-6) – HH and ENV
(j) Regulation 793/93 : *Zinc metal* (CAS No. 7440-66-6), *Zinc oxide* (CAS No. 1314-13-2), *Zinc distearate* (CAS No. 557-05-1), *Zinc chloride* (CAS No. 7646-85-7), *Zinc sulphate* (CAS No. 7733-02-0), *Zinc phosphate* (CAS No. 7779-90-0) – HH
(k) Regulation 793/93 : *Methylenediphenyl diisocyanate (MDI)* (CAS No. 26447-40-5) – HH and ENV

(5) Regulation 793/93 on Existing substances (ESR): Status reports/opinions

(a) *Aniline* (ENV) – for discussion
(b) *3,4 Dichloroaniline* (HH) – for discussion
(c) *Chromium trioxide*, *Sodium Chromate*, *Sodium Dichromate*, *Ammonium Dichromate* and *Potassium Dichromate* (ENV) – for discussion

(6) Information on the Water Framework Directive and CSTEE involvement

(7) Ongoing requests for opinion from the CSTEE by Commission services on:

(a) Studies relating to the *quality of drinking water in selected European countries* – for discussion
(b) *Phosphate based detergents and eutrophication*
(c) Risks to health and environment posed by the use of *Organostannic compounds* – for adoption
(d) Study on *Heavy metals and organic compounds from wastes used as organic fertilisers – for discussion*
(e) Risks to environment posed by the use of *copper containing anti-foulings on pleasure craft*
(f) Report on the risk assessment of *organic chemicals in toys*
(g) Report on the assessment of the *bioavailability* of certain elements *in toys*
(h) Two studies on substances showing evidence of or potential of *endocrine disruption*

(8) Emerging issues identified and for which the CSTEE is the leading committee:

(a) *Endocrine disruption -Metaanalysis (Human Health)*
(b) *PBT*
(c) *Indoor air quality*

(9) Participation of the CSTEE in activities/working groups of other scientific Committees of the Commission or EFSA

(10) Update on the last meeting of the Scientific Steering Committee on matters of interest to the CSTEE

(11) Next plenary meetings of the CSTEE

(12) Any other business

Annex II

SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)
38TH PLENARY MEETING

Held on 12 June 2003
in Brussels

LIST OF PARTICIPANTS

MEMBERS OF THE CSTEE:

Prof. Jim BRIDGES, Prof. Peter CALOW, Prof. Dr. Wolfgang DEKANT, Prof. Erik DYBING, Prof. Dr. Helmut GREIM, Prof. Bo JANSSON, Prof. Soterios KYRTOPOULOS, Prof. Claude LAMBRE, Prof. José TARAZONA, Prof. Benedetto TERRACINI, Prof. Katarina VICTORIN, Prof. Marco VIGHI and Prof. Joseph VOS.

***Apologies**:* Prof. Giorgio CANTELLI FORTI, Prof. Colin JANSSEN, Prof. Janneche SKÅRE and Prof. Amadeu SOARES.

EUROPEAN COMMISSION:

CSTEE Secretariat (DG Health & Consumer Protection):

Ms. V. ROLLAND and Mrs. G. FONTANESI

DG Health & Consumer Protection:

Mr. T. DASKALEROS

DG Enterprise:

Mr. D. HADRICH, Ms. E. GUSTAFSSON, Ms. K. GRODZKI, Mr. W. HEHN, Mr. S. PICKERING

DG Environment:

Mr. M. BLAINEY, Ms. M. BRÄTTEMARK, Mr. J. D'EUGENIO, Mr. J. VOGELGESANG

DG Research:

Mr. T. KARJALAINEN

DG Joint Research Centre:

Mr. L. BONTOUX, Mr. S. KEPHALOPOULOS, Ms. S. MUNN

DG Internal Market:

Mr. H. INGELS

SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)
38TH PLENARY MEETING

Held on 12 June 2003
in Brussels

CSTEE COMMENTS RELATED TO EXPOSURE ASSESSMENT, THE USE OF VERTEBRATE ANIMALS FOR THE TESTING OF CHEMICALS, AND PBT AND VPVB ASSESSMENT ACCORDING TO THE NEW CHEMICALS LEGISLATION (REACH)

Introduction

The Enterprise Directorate-General and the Environment Directorate-General have very recently finalised the draft of a new chemicals legislation (REACH – Registration, Evaluation and Authorisation of Chemicals) to implement the policy set out in the Commission's White Paper of February 2001 on the 'Strategy for a future Chemicals Policy' (http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/reach.htm). The objective of this legislation is to afford a high level of protection for humans and the environment against exposures to general chemicals. The CSTEE would hereby like to contribute to the internet consultation regarding the REACH proposal.

Exposure assessment

To evaluate the risks to human health and to the environment requires information on both hazard and exposure. Hazard cannot be equated with risk.

Use of tonnage manufactured as a reliable surrogate for exposure is unsound. On the one hand, a chemical may be manufactured in higher quantities than 10 tonnes, but because it is only used as an intermediate in making other products, human and environmental exposure will be low. On the other hand, for some chemicals some consumer groups may be extensively exposed, although the chemicals are produced in amounts less than one tonne.

Where tonnage is used as a surrogate for exposure assessment it is essential that this is total tonnage of the chemical (and of closely related chemicals) within the EU. If there are a number of manufacturers/importers of the chemical it is not appropriate to consider simply the amount that an individual manufacturer will produce in applying REACH.

Use of vertebrate animals

In the explanatory note of the essential features of REACH it is stated that substantial efforts have been made to minimise animal testing. Although this is a commendable position from an ethical standpoint, it can be seriously questioned from a health safety viewpoint. Throughout the consultation document concerning REACH, one is presented with the view that the use of vertebrate animals should be avoided without the qualifier that data from such use are essential for risk assessment.

As stated in the Society of Toxicology's animals in research public policy statement of 1999, 'research involving laboratory animals is necessary to ensure and enhance human and animal health and protection of the environment. In the absence of human data, research with experimental animals is the most reliable means of detecting important

toxic properties of chemical substances and for estimating risks to human and environmental health'. Research with experimental animals should allow for decisions aimed at preventing harmful human and environmental exposures.

In regard to human health protection, it is a specific deficiency in the REACH system that no requirement for testing for general toxicity after repeated dosing (such as the 28-day oral test in rats) is formulated for the manufacturing tonnage threshold below 10 tonnes per producer/importer per annum (Annex V). Usage below 10 tonnes could under specific circumstances lead to significant exposures to humans and the environment. Also, since the manufacturing threshold is per producer/importer, the total volume thus can be larger.

The Step 4 of Annex IV relates to the generation of new data. Here it is stated than new tests on vertebrates should only be conducted or proposed as a last resort when all other data sources have been exhausted. Given the considerable lack of necessary animal toxicity data in order to perform meaningful risk assessments for many existing chemicals, this gives a false impression that one will be able to conduct such risk assessments based on other data sources.

Human health risk assessments rely heavily on the identification of NOAELs (DNELs in REACH terminology) or other surrogates for toxicity thresholds for chemicals with dose thresholds, or risk specific doses (points of departure) for non-threshold chemicals, derived from long-term studies with laboratory animals. *In vitro* studies cannot for the foreseeable future identify NOAELs or risk specific doses.

Ethical concerns related to the use of aquatic vertebrates are less considered than those for birds and mammals. However, some alternative approaches have been suggested. A key difference in the risk assessment arena is that environmental risk assessment focuses on generic endpoints, mostly survival, growth and reproduction, as well as the consequences for population dynamics. Although some *in vitro* tests have shown correlation with acute lethality assays, the current ability for predicting ecologically relevant sublethal endpoints is far from being possible.

PBT and vPvB assessments

We note that under Point 44 (Title VIII; Chapter 1) PBT and vPvB criteria are to be used for identifying substances subject to authorisation (for inclusion in Annex XIII). In an Opinion on the "Revision of the 1996 Technical Guidance Document (TGD) in support of Commission Directive 93/67EEC on risk assessment for new notified substances and Commission Regulation (EC)1488/94 on risk assessment for existing substances" (January 2002) the CSTEE expressed the view that "The PBT approach … is not a risk assessment… it is based on the intrinsic properties of chemicals …*but that*… the PBT approach would be useful as a means of prioritising substances for further action".

We understand that this is the intention as part of the authorisation process and that it will be for manufacturers, importers or downstream users to demonstrate through risk assessment and socio-economic analyses that authorisation can be justified.

However, the CSTEE wishes to raise the following further points:

- What sort of risk assessment will be necessary to balance the concerns arising from the PBT/vPvB assessments? There is currently no appropriate advice in the revised TGDs for new and existing chemicals. Without a general framework being clearly

defined it is possible that there will be a tendency for chemicals that are committed to Annex XIII to be subject to management action on the basis of hazard criteria alone rather than a risk assessment.

- We note that the criteria used in defining PBT and vPvB in Annex XII are similar to those defined in the revised TGD (see above). The CSTEE has already expressed concerns about suggested methodology and definitions included in the revised TGD in its Opinion of January 2002 and believes that these need careful reappraisal before final inclusion in the legislation.

- We understand that PBT criteria are being used in various other regulatory contexts. To avoid confusion it will be important to ensure that there is consistency between these and where this is not the case that there are good scientific grounds for differences. We are unsure if this is the case.

CSTEE would be very willing to advise further on these matters and, in conclusion, believes that the following issues need further attention from a scientific perspective:

1.What general form will risk assessments need to take for substances that are listed in Annex XIII?

2.To what extent can thresholds of concern in P and B and T be defined in a scientifically defensible way?

3.What methods should be used to measure P and B and T?

4.To what extent are the PBT criteria used in the draft legislation consistent with those used in other regulatory contexts?

Conclusions

The CSTEE strongly supports the policy of using research animals in a responsible manner and encourages research designed to reduce, refine or replace the need for laboratory animals. However, in order to afford a high level of protection from chemical exposures, the use of vertebrate animals for testing of chemicals is essential.

The CSTEE expresses concerns about suggested methodology and definitions for PBT and vPvB, and believes that these need careful reappraisal before final inclusion in the legislation. It will be particularly important to develop guidance for the risk assessment of PBT and vPvB substances in synchrony with their use as prioritisation criteria.