Minutes of the Scientific Steering Committee Meeting of 18-19 February 1999

1. Welcome, apologies, introductory remarks, declaration of interest in relation to the current agenda

Prof.Dr.Pascal welcomed the participants. Apologies were received from Prof.Dr.A.Osterhaus (for 19.02.99), Prof.Dr.K.Jones (for 18.02.99), Prof.Dr.V.Silano, Prof.Dr.P.James and Prof.Dr.R.Kroes. The list of participants is attached as annex 1.

No member declared an interest in any of the point of the agenda which could conflict with his independence.

2. Approval of the agenda

The draft agenda was slightly modified and approved. It is attached as annex 2.

3. Approval of the minutes of the meeting of 21-22 January 1999

The draft minutes of the meeting of 21-22 January 1999 were approved without changes.

4. Work plan for the SSC

4.1. Progress on multidisciplinary matters:

a. *"Considerations for the evolution of scientific advice to address emerging health issues*".

Prof.Dr.W.Klein reported on the Working Group meeting which was held on 17 February 1999. A task distribution was agreed upon between the members, along the lines of the mandate described in the minutes of the 10-11 December 1998 meeting. Further progress will be reported on at the March meeting.

b. *Harmonisation of risk assessment procedures*

No progress was made. Three Scientific Committees have now provided their contributions. A draft document will be prepared also on the basis of the contributions from the secretariats, for discussion by the working group on 17 March 1999.

The possible enlargement of the mandate as to include a case study on harmonised risk assessment procedures for GMOs (ref.: SSC meeting of 21-22 January 1999), will also be discussed at that occasion.

c. *Resistance to antimicrobials*

The rapporteur provided the SSC with a feed-back from the WG meeting of 16 February 1999 and on the way it is responding to the SSC's suggestions on the draft report presented on 21-22 January 1999. Contributions - including on the implications for the environment of the use of antimicrobials - were received from several SSC members. The draft report is being finalised. It is expected to have the final draft report and draft opinion available for discussion at the SSC meeting of 22-23 April 1999.

4.2. Multidisciplinary matters relating to TSE/BSE

a. *General report of the work of the TSE/BSE ad-hoc group*.

Prof.Dr.M.Gibney, chairman of the TSE/BSE *ad hoc* Group, provided a summary report on the activities of the Group since last meeting. For most issues presented by Prof.Gibney, the corresponding details are provided in Section (b) hereafter.

b. *Reports on specific issues*:

b.1. "Fallen stock": The risk of infectious agents or non conventional transmissible agents entering the human food or animal feed chains via raw material from fallen stock, exotic/zoo animals, fur animals, dead animals, condemned materials, dead fish sick animals and laboratory animals and including the environmental aspects of disposal of potentially BSE infected materials and animals

Prof.Dr.M.Vanbelle, rapporteur of the Working Group "Producst" reported on the progress made by the Working Group since its meeting of 15 December 1999 and on the (present) general content of the draft report. He confirmed that a draft opinion would be ready for discussion by the SSC at its meeting of March 1999.

A short discussion was held and suggestions were made towards the Working Group. These will be discussed at the next WG meeting of 24 February 1999.

b.2. Intra-species recycling of animals waste.

A draft report has still not been adopted by the WG. It is now expected that a draft will be available for discussion by the SSC at its meeting of 18-19 March 1999.

b.3. Safety of gelatine (update of the opinion of 26-27 March 1998)

The opinions on the safety of hydrolysed proteins (adopted on 23-24.10.98) and on the possible use of the "133°C/20'/3 bars" production standard (see previous section) contain a number of conclusions which have also implications for the opinion on the Safety of gelatine, adopted on 26-27 March 1998. The latter opinion needed therefore to be updated to take into account also the use of hides from healthy animals and the possible use of the "133°C/20'/3 bars" production standard.

The opinion also needed minor updates so as to include the final report on the INVERESK inactivation study, which became only available after the adoption.

An updated draft opinion was presented and adopted It is attached as Annex 3.

b.4. The possible vertical transmission of Bovine Spongiform Encephalopathy.

The Working Group finalised its report and an initial version of a draft opinion has been prepared. However, no consensus has been reached so far on the exact formulation of a number of conclusions. An additional meeting of the working group has therefore been scheduled for 4 March 1999. Following discussion by the TSE/BSE *ad hoc* Group on 11 March, the discussion and possible adoption of the opinion is therefore now scheduled for the SSC meeting of 18-19 March 1999.

b.5. Safety of tallow derived from bones as a by-product in the gelatine production.

On request from DGVI, the SSC is addressing the issue of the safety with respect to TSE infectivity of tallow derived from bovine bones as a by-product of the gelatine production. The specific hazards are linked to the fact that such tallow seems to be processed according to lower standard than the "133°C/20'/3 bars" conditions defined by the SSC in its opinion on meat-and-bone meal and to the possible presence of the vertebral column in the raw material.

The Working Group has carried out a quantitative risk assessment and an opinion will be drafted by the TSE/BSE ad hoc Group and submitted to the SSC at its meeting of March 1999.

b.6 Human exposure risk (HER).

The SSC was informed on the progress made and requested the TSE/BSE ad-hoc group to closely follow this important matter.

b.7. Safety of blood: feed back from the Scientific Committee Medicinal Products and Medical Devises (SC-MPMD) following the Hill *et al* paper (Lancet, 1999, **353**: 183-189).

Following the request of the SSC (January 1999 meeting), the SC-MPMD evaluated the Hill *et al* paper in detail. The study seems to demonstrate clearly that the promoting role of B lymphocytes does not depend on the production of PrP^{c}, a general prerequisite for the multiplication of TSE agents. Therefore, it seems less probable that lymphocytes carry directly TSE infectivity. This finding has already been discussed in the SC-MPMD opinion of October 1998. The new findings shed some additional doubts on the usefulness of leukodepletion. It is expected that further sudies will focus on the role of the follicular dentritic cells in pathogenesis. The question as to how the TSE agents reach these cells have to be addressed.

An opinion is expected to be adopted by the SC-MPMD at its March meeting.

b.8. Safety of skins: feed back from the Scientific Committee Medicinal Products and Medical Devises (SC-MPMD) following the Pammer *et al* paper (American Journal of Pathology, 1998, **153**: 1353-1358).

Following the request of the SSC (December 1998 meeting), the SC-MPMD evaluated the Pammer *et al* paper on human keratinocytes expressing cellular prion-related proteins in vitro and during inflammatory skin disease. In summary, Pammer *et al* unequivocally demonstrate the presence of PrP^{c} in the skin. By this finding, they extent the range of tissues known to express PrP^{c}. The majority of observations seems to support the opinion that skin does not contain TSE infectivity in significant amounts. However, as there are still some open questions there is the need for studies investigating the presence of PrP^{Sc}, the pathologic form of the prion protein, in the skin. The methods are easily available. Until those studies are completed, there is no sound justification for a change in policy regarding the use of hides and skins for the preparation of gelatine.

An opinion is expected to be adopted by the SC-MPMD at its March meeting.

b.9. Manual for the assessment of geographical BSE risk (adoption of the final opinion, integrating also the comments received in January 1999).

The SSC was informed on the comments received on the preliminary opinion and the modifications proposed by the WG-"Sourcing", which analysed the comments and recommended to suppress the semi-quantitative risk assessment. The WG-"Sourcing" had also brought forward a clarification for the process to conclude on the geographical BSE-risk from the propagation risk and the processing risk, which was supported by the TSE/BSE ad-hoc group and finally accepted by the SSC. After an intensive discussion the opinion was finally adopted, integrating the proposed modifications.

b.10 First discussion of the draft report and opinion on criteria determining BSE-status categories, taking account of the geographical BSE-risk, the human exposure risk and the OIE recommendations.

The SSC discussed on the issue without arriving at a final conclusion. It accepted, however, the basic concept that the BSE-status will be established on the basis of the geographical BSE-risk *and* other factors, still to be determined. It asked the TSE/BSE ad-hoc group to continue the discussion and provide as soon as possible a discussion paper on the matter.

b.11 Monitoring of the evolution of the BSE epidemic in the UK.

The Commission invited the Scientific Steering Committee to address the following two questions:

- *How does the SSC assess the current and expected (1999-2004) evolution of the number of BSE cases (epidemic) in the UK, in the light of the OTMS ("Over thirty Months Scheme") and of the selective culling programme. Are the*

current numbers of cases in line with the scientific expectations?

- *In the light of the confirmed 1998 incidence, is it necessary to continue OTM Scheme for animals falling under the Date Based Export Scheme*

The questions will be addressed by the TSE/BSE ad hoc Group, who will prepare a draft report and draft opinion for discussion by the SSC.

5. Organisational matters:

No organisational matters were discussed.

6. Co-ordination:

a. Recombinant Bovine Somatotropine (BST)

A detailed feed-back was given by the chairpersons of the SC-Veterinary Measures relating to Public health (addressing veterinary public health aspects) and the Scientific Committee Animal Health and Animal Welfare (addressing the animal health and animal welfare aspects).

Draft reports of both Committees are in an advanced stage and it is expected to have the opinions available by March 1999. It appears that no conflicts exist between the two reports and the possibility of preparing a common introduction will be considered. It was confirmed to provide the SSC with a copy of the opinions immediately following their adoption.

b. EMEA s for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products.

Prof.Dr.K.Jones, chairman of the SC-Medicinal Products and Medical Devises, reported on the evaluation of the EMEA s carried out by his Committee at its meeting of 10 February 1999 and on the inputs provided by the TSE/BSE *ad hoc* Group at its meeting of 11 February 1999. A joint paper had been prepared and was, after discussion and amendments, also adopted by the SSC. It is attached as Annex 5.

c. reports of the Chairmen of the 8 Scientific Committees.

The chairmen of Scientific Committees reported on the activities of their committees since the last SSC meeting (21-22 January 1999). A summary of their reports is given in annex 6.

7. Information by the Commission services on matters related to consumer health.

Due to a lack of time, this agenda item was postponed until the next meeting.

8. Any other business

-M Rateau (Commission) informed the SSC on the "European Day of the Consumer" which will be held on 15 March 1999. The day is organised by the Economic and Social Committee (ECOSOC), in collaboration with the European Commission. Venue is the headquarters of the ECOSOC, 2 rue Ravenstein, 1000 Bruxelles. The conference will start at 14h30' and last until 18h00'. The programme and additional information will be sent by ECOSOC to all the SSC members.

- Internal SSC seminar on molecular biology, neuropathology and testing for prion-related diseases.

Due to a lack of time, the TSE/BSE *ad hoc* Group did not discuss this item at its meeting of 11 February. It was therefore postponed until the next meeting.

- Monitoring by the SSC of ongoing research in the field of TSEs

The secretariat raised this issue and was supported by the SSC as to its usefulness. However, questions were raised concerning the capacity of the secretariat and the TSE/BSE ad-hoc group to organise that additional task. DG XII signalled that it is reflecting on providing access to interim reports but that there are legal problems which are not yet solved.

- Exploitation of scientific opinions

A preliminary discussion was held on the exploitation by the Commission of scientific opinions adopted by its Scientific Committees. No conclusions were drawn, but it was decided to continue the discussion at a next SSC meeting.

The meeting ended on Friday 19 February 1999, at 13h30.

The next meeting will be held in Brussels, on 18-19 March 1999.

***Annex 1*: List of participants of the Scientific Steering Committee meeting of 18-19 February 1999**

List of presence

***Members of the SSC**:*

Prof. Georges Bories, Prof. W.Bridges (not present on 18 February morning), Prof. F.Garrido Abellán, Prof. Michael J. Gibney, Prof. Anthony Hardy, Prof. Philip James (not present), Prof. Keith H.Jones (not present on 18 February), Prof. Fritz H.Kemper, Prof. Fritz H.Kemper, Prof. Werner Klein, Prof. Ib Knudsen, Prof. Robert Kroes (not present), Prof. Albert Osterhaus (not present on 19 February), Prof. Gérard Pascal, Prof. Marcel Vanbelle, Prof. Martin Wierup

***Participants from the Commission*:**

DG III: M.P. Darchy, A. North, O. Rothe, Mr Silva

DG V H. Buchow

DG VI T. Chalus, M. Lahrssen, C. Micmacher, I. Peutz, L. Terzi

DG XI V. Matzeit

DG XII A. Fabre

DG XXIV: S. Clarke, J. Costa David, T. Daskaleros, W. De Klerck, M. de Sola, C.Diez, J.Kreysa, M. Lauridsen, G.Morrison, J.J. Rateau, A. Sanabria, W. Schuller, A. Somogyi, R. Vanhoorde, J. Vergnettes, P.Vossen

Annex 2*: *agenda of the Scientific Steering Committee Meeting of 18-19 February 1999

1. Welcome, apologies, introductory remarks, declarations of interest

2. Approval of the agenda

3. Approval of the minutes of the meeting of 21-22 January 1999.

4. Work plan for the SSC

4.1. Progress on multidisciplinary matters:

a. "Considerations for the evolution of scientific advice to address emerging health issues" (progress report)

b. Harmonisation of risk assessment procedures (progress report)

c. Resistance to antimicrobials (feed-back from the WG)

4.2. Multidisciplinary matters relating to TSE/BSE

a. Report by the chairman of the TSE/BSE ad-hoc group.

b. Reports on specific issues:

Production systems and products.

b.1. "Fallen stock": The risk of infectious agents or non conventional transmissible agents entering the human food or animal feed chains via raw material from fallen stock, including environmental aspects of disposal of potentially BSE infected materials and animals (introduction of the draft report).

b.2. Intra-species recycling of animal waste (introduction of the draft report).

b.3. Safety of gelatine (adoption of the update of the opinion of 26-27 March 1998).

b.4. The possible vertical transmission of Bovine Spongiform Encephalopathy (progress report)

b.5. Safety of tallow derived from bones as a by-product in the gelatine production (progress report).

Human exposure risk.

b.6. First discussion of the draft report and opinion.

b.7. Safety of blood and skins: feed back from the Scientific Committee Medicinal Products and Medical Devises following various Lancet papers.

Geographical risk.

b.8. Handbook for the assessment of geographical BSE risk (adoption of the final opinion, integrating also the comments received in January 1999).

b.9 First discussion of the draft report and opinion on criteria determining BSE-status categories, taking account of the geographical BSE-risk, the human exposure risk and the OIE recommendations.

b.10 Monitoring of the evolution of the BSE epidemic in the UK.

5. Organisational matters.

6. Co-ordination:

a. Recombinant Bovine Somatotropine (BST): progress reports from the Scientific Committees Veterinary Measures related to Public Health and Animal Health and Welfare.

b. Briefing on the Commission's activities related to hormones.

b. EMEA s for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products.

c. reports of the Chairmen of the 8 Scientific Committees.

7. Information by the Commission services on matters related to consumer health.

8. Any other business.

- internal SSC seminar on molecular biology, neuropathology and testing for prion-related diseases.

Annex 3:

Scientific Report and Opinion on **The Safety of gelatine** *adopted by the Scientific Steering Committee at its meeting of 18-19 February 1999*

Version updated at the SSC meeting of 18-19 February 1999, following the adoption of the following opinions:

- The safety of hydrolysed proteins produced from bovine hides (22-23.10.98).

- The safety of bones produced as by-product of the Date Based Export Scheme. (22-23.10.98)

- Evaluation of an alternative process for the production of gelatine regarding its equivalency with commonly used industrial gelatine production processes in terms of its capacity of inactivating/eliminating possible TSE infectivity in the raw material. (22-23.10.98)

- Evaluation of the *"133°/20'/3 bars heat/pressure conditions"* for the production of gelatine regarding its equivalency with commonly used industrial gelatine production processes in terms of its capacity of inactivating/eliminating possible TSE **infectivity in the raw material. (21-22.01.99)**

(This annex was distributed separately)

Annex 4:

Opinion of the Scientific Steering Committee on a method to assess the Geographical BSE-risk (GBR) of countries or regions. Adopted on 18-19 February 1999.

(This annex was distributed separately)

***Annex 5*:**

Comments on:

1. The EMEA Committee for Veterinary Medicinal Products: Draft for Guidance for minimising the risk of transmitting animal spongiform encephalopathy agents via veterinary medicinal products

2. The EMEA Committee for Proprietary Medicinal Products: Draft for Guidance for minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products

Formulated by the Scientific Committee for Medicinal Products and Medical Devices (SC-MPMD) at its meeting of 10.02.99 and by the Scientific Steering Committee (SSC) at its meeting of 18-19.02.99, following consultation of the TSE/BSE ad hoc Group.

The SC-MPMD and the SSC consider that the EMEA Guidances for minimising the risks of transmitting animal spongiform encephalopathy agents largely comply with conditions for safe sourcing, removal of specified risk materials, appropriate production processes, intended end-use or application, avoidance of cross-contamination, etc., listed in the various TSE-related scientific opinions adopted since November 1997 by the European Commission's Scientific Committees. (See attached list).

However, the Committees wish to point at the following sections in both s, which are considered to be open for possible misinterpretation or which need to be further elaborated in detail:

a. *Regarding the collection of source materials*. The documents consider that the substitution of ruminant source materials by material from other species which are recognised to suffer from TSEs, *other than as a result of experimental challenge*, would not normally be acceptable.

The SC-MPMD and the SSC consider that precautions should be taken to possibly exclude sourcing from animals that that in practice may have been exposed to TSE infectivity, for example via feed, and are experimentally susceptible to TSEs. For most, if not all, of such animal species, a TSE-specific surveillance system does indeed not exist, and they can not therefore automatically be considered as "safe".

b. *Regarding the geographical sourcing of the animals*. The SC-MPMD and SSC recommend that in the criteria referring to imports of animal materials and to feeding practices, a time component be introduced, specifying since when certain imports or feeding practices should have been banned. The SC-MPMD and the SSC consider that, in order to be fully effective, these bans should have been enforced for a period which is at least equal to 8 years. (8 years corresponds with the upper end of the BSE incubation period).

c. *Regarding process validation,* the SC-MPMD and the SSC wish to point at the fact that, in all their opinions related to the safety of bovine derived products, they have emphasised on the need that the [expected, claimed, assumed] infectivity reduction capacity of production processes be validated by appropriate experiments. In the absence of the results of such experiment(s), and if the intended end-use implies direct human consumption, it may even be recommendable not to acknowledge certain production processes as resulting in an acceptable level of clearance of infectivity, even if they look similar to other processes for which such experiments have been carried out.

d. *Regarding the age of animals*. The s recommend sourcing from young animals, because clinical TSE has not been diagnosed in young animals. Whilst recognising that it is for the time being difficult to exactly specify the age of animals which could be safely sourced, the SC-MDMP and SSC recommend that, for ruminants, the age should be fixed at 30 months for bovines and at 12 months for ovines and caprines.

e *Regarding the conditions which should apply to gelatine,* the SC-MPMD and SSC recommend that the conditions listed in the SSC opinion on the Safety of Gelatine, adopted on 26-27 March 1998 and amended on 18-19 February 1999 (sections related to the production of gelatine and to its end-use in registered pharmaceutical products, for parenteral use and as a reagent in the manufacture of pharmaceuticals), should also be specified in detail in the s for Guidance.

f. Footnote (9) referring to the sourcing of bovine bones for the production of gelatine, would need to be further clarified.

Scientific justifications: sources

The above statements are resulting from the exploitation of the following scientific opinions adopted by the Scientific Committee Medicinal Products and medical Devices and the Scientific Steering Committee:

- Listing of Specified Risk Materials: a scheme for assessing relative risks to man (SSC, 9 December 1997)

- Opinion of the Scientific Steering Committee on defining the BSE risk for specified geographical areas (SSC, 22-23 January 1998)

- Final Opinion on the contents of a "Complete dossier of the epidemiological status with respect to TSEs". (SSC, 19-20 February 1998)

- Opinion on BSE risk (SSC, 26-26 March 1998)

- Opinion on the Safety of Gelatine (SSC, 26-26 March 1998, updated 18-19 February 1999)

- Opinion and report on the equivalency of alternative products to intestines of animal origin for use as surgical sutures (SC-MPMD, 16 September 1998.

- Opinion on the risk of infection of sheep and goats with Bovine Spongiform Encephalopathy agent. (SSC, 24-25 September 1998)

- Opinion on the risk quantification for CJD transmission via substances of human origin. (SC-MPMD, 21 October 1998)

- Preliminary opinion on a method to assess the geographical BSE-risk of countries or regions (SSC, 10-11 December 1998)

- Report and Scientific Opinion on the evaluation of the " *133°/20'/3 bars heat/pressure conditions*" for the production of gelatine regarding its equivalency with commonly used industrial gelatine production processes in terms of its capacity of inactivating/eliminating possible TSE infectivity in the raw material. (SSC, 21-22 January 1999)

Annex 6: **Reports from the secretariats of Scientific Committees on the major activities and milestones since the SSC meeting of 24-25 September 1998.**

Scientific Committee Food

No plenary sessions of the SC-Food have been held since the last SSC meeting, hence no new opinions have been adopted. A number of working groups meetings has taken place.

Scientific Committee on Plants

After three Working Groups met concurrently on 3 February 1999, the Scientific Committee on Plants held its 11 th Plenary Meeting on 4 February at which one opinion was adopted and discussions progressed on a further eight drafts.

The opinion adopted was:

Plant Protection Products

- Opinion of the Scientific Committee on Plants regarding the inclusion of azimsulfuron in Annex I to Directive 91/414/EEC concerning the placing of plant protection products on the market.

The Committee is completing draft opinions on two plant protection products, isoxaflutole and fenarimol, and a further opinion on the relationship between the elimination or strong reduction in the use of plant protection products in the cultivation of fruits and vegetables and the presence of mycotoxins and heavy metals.

Plant GMOs

The dossier on a modified starch potato by Amylogene is being evaluated and questions for further clarification were addressed to the company. Although a draft opinion was being prepared on a herbicide tolerant and insect resistant (Bt) maize from Dekalb, the new owners, Monsanto, have since withdrawn the application and work has ceased. Opinions are being written on 3 requests from Member-States invoking Article 16 (the Safeguard Clause) on GMO plants. A draft opinion on the proposed protocol for monitoring European corn borer resistance to Bt should be adopted at its next Plenary meeting on 4 March.

Scientific Committee on Animal Nutrition (SCAN)

Since the last SSC plenary, the SCAN plenary met on 25 January.

SCAN adopted an update of the SCAN opinions of Enzymes on one hand and on Microorganisms on the other hand.

Some other reports that had been expected for adoption at the January plenary had to be postponed to the next plenary.

New questions have been submitted to SCAN, in particular on copper compound. As such a question concerns several committees (SCF, SCTEE), SCAN agreed to involve members of these committees for a better co-ordination.

Scientific Committee Veterinary Measures relating to Public Health

The SC-VMPH has been addressing the following issues:

1. Cooling of carcasses during transport;

In principle the Committee agreed on a draft report. However, in order to avoid any misunderstanding, a final draft will be circulated to the members with a view to its formal adoption at the next plenary.

2. Working Group on the complementary risk assessment on the use of hormones.

All members of the Committee agreed with the composition of the Working Group as well as with its overall balance.

3. *Bovine Somatotropine (public health aspects);*

The Committee discussed the general concept of the draft report and considered the possible direct and indirect impact on consumer health with a view to the adoption of the report at the plenary of 15-16 March. Cross-references to the part of the report that is addressing animal welfare and animal health aspects were considered.

4. Revision of ante- and post- mortem inspection procedures for an alternative inspection system for the slaughter of pigs;

Substantial progress has been made on this issue is and it is expected to have a final draft report available for discussion in plenary in May.

5. Evaluation of microbiological criteria and temperatures for storage and transport of products of animal origin intended for human consumption:

- partim microbiological criteria;

Contrary to earlier planning, an additional working group meeting will be necessary. It is foreseen to have the draft report finalised by April.

6. *Listeria.*

A working group including expertise from the SCF has been set up to address the issue of listeria in ready to eat food. The first working group meeting is scheduled for 22 March.

7. *Prevalence and methods of control of cysticercosis;*

The draft report is in a progressed stage. It is expected to have the final draft report ready by April.

Scientific Committee Cosmetic and non-Food Products

Prof. Kemper, the chairman, reported on the topics dealt with since the last SSC meeting.

One plenary meeting and a series of Working Parties took place, during which the following items were discussed:

1. Alternatives to animal testing : further to the approval of the first alternative methods to animal testing (in vitro test to assess skin corrosivity and to assess photo-toxicity) and to the adoption of a status report on the use of alternative methods to animal testing in the safety evaluation of cosmetic ingredients or mixture of ingredients, a press release on the issue has been prepared and sent to the Cabinet of Mrs Bonino.

Besides its work on 'Alternatives', the Committee started the updating of its s of Guidance for Testing of cosmetic ingredients for their safety evaluation. This update concerns mainly the insertion of the recently adoption opinions concerning the above mentioned in vitro methods into the notes of guidance.

2. Hair Dyes : as reported during the previous SSC meeting, the special task force met from 1 to 4 February 99 and

wrote status reports on 40 hair dye files. The secretariat will now make a first selection to be presented to the next meeting of the Working Party 'Hair Dyes' of 11 March 99.

An opinion on hydroquinone as a hair dye constituent was adopted by the plenary.

3. Inventory : the committee adopted a status report on the inventory. The committee states that the information given for many entries in the inventory has to be improved and lists the priorities which must be incorporated in the 1 st update of the inventory as published in 1995.

4. Preservatives, Colorants & Fragrances : opinions were approved on the use of carbamide peroxide as a teeth bleaching products and on benzylhemiformal.

An opinion was adopted concerning the limitation and labelling of chemicals listed in Annex VI (= preservatives) of the cosmetics directive when they are used for purposes other than for a preservative function.

5. UV Filters : 7 opinions on UV filters were adopted during last plenary meeting of 17.2.99. 3 of these 7 substances were provisionally allowed for use in cosmetic sun screen formulations. Their adoption implies that no substances are listed any longer in part 2 (provisionally list) of Annex VII of the cosmetic directive.

A point was raised by a member of the committee concerning the safety of sun beds and whether this issue falls within the field of competence of the committee. As the Commission replied affirmative, a working party will be set up to this end.

Scientific Committee for Toxicity, Ecotoxicity and the Environment

Since the mentioned SSC meeting no CSTEE meetings took place, the next one foreseen being the plenary on the 4 th of March 1999.

A. The CSTEE has basically been busy finalising the opinion on ' ***Endocrine disrupting chemicals*** '. The WG chairman has now confirmed that the final version of the draft will be sent to the CSTEE secretariat either Friday, 19 th of February or by early next week (22 February). Copies will be immediately distributed among CSTEE members for final comments. Adoption is foreseen for the 4 th of March plenary.

B. Regarding the consultation of the CSTEE on the subject ***'Ground level ozone'*** , difficulties in finding a meeting date convenient to a majority of WG members have prevented the possibility of holding such a meeting before the next CSTEE plenary. It was agreed to try and get a draft produced on the basis of contributions of WG and CSTEE members with a view to it being presented at the next plenary for a first discussion. It is unlikely that a final opinion, answering fully the terms of reference, will be adopted then.

C. Since members received the substantial documentation package on citrates mentioned in the previous briefing for the attention of the SSC, no progress has been made on the subject of the consultation of the CSTEE on ' ***Substitutes of phthalates in teething rings and other child care articles intended to be put in the mouth*** '. During a M. States meeting (Directive 76/769 on limitations of the marketing and use of certain dangerous substances and preparations) organised by DG III and which took place on the 1 st of February 1999, the understanding was that more data needs to be collected and that Industry should collaborate with the Commission and M. Sates to help gather and provide it. However, since then, no data was made available to the CSTEE secretariat (it was agreed that DG III should centralise the receiving of data).

D. The CSTEE secretary has been following developments on the follow up by the competent Commission services subsequent to the adoption of a number of opinions by the CSTEE, namely those on ***Tin*** , ***Arsenic*** , ***Cadmium*** and ***Pentachlorophenol*** and ***Phthalates in toys*** .

a) In a meeting of the technical progress committee for Directive 76/769/EEC, held on the 12 th of February 1999, an adaptation to technical progress of the directive was voted favourably by qualified majority. It concerned ***Tin organic***

compounds , ***Pentachlorophenol*** and ***Cadmium*** . The basis of the proposal had been the reports commissioned by the competent Commission service (DG III), later peer-reviewed by the CSTEE.

b) On the subject of ***Phthalates migration from soft PVC toys and child-care articles*** following the adoption by the CSTEE of its opinion on the 27 th November 1998, the Commission is still considering risk management options.

E. The **next CSTEE plenary** is confirmed for the 4 th of March 1999.