

Minutes of the Scientific Steering Committee Meeting of 20-21 January 2000

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

Prof.Dr.Pascal welcomed the participants. He apologised Prof.W.Bridges and Prof.K.Jones and (for 21 January) Prof.R.Kroes and Prof.M.Gibney. The list of participants is attached as annex 1.

Declarations of interest:

At the occasion of the first meeting in 2000, the participants completed and signed the "Annual Statement of Member's Interest and Declaration Concerning Confidentiality" (Annexes 1 and 2 to the Rules of Procedure of the SSC). The other members will have to send these forms, duly completed, by mail to the SSC secretariat.

No member declared an interest in any of the items on the agenda of this specific meeting.

2. Approval of the agenda

Items 4.d (White Paper on Food Safety) and 5.2.k (The safety of UK bone-in beef) were added to the draft agenda. The final agenda is attached as annex 2.

3. Approval of the minutes of the meeting of 9-10 December 1999

The minutes of the meeting of 9-10 December 1999 were adopted with minor changes. They are made available on the Internet as a separate document.

4. Multidisciplinary matters not relating to TSE/BSE

4. Progress on multidisciplinary matters:

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

Prof.W.Klein introduced the first version of the draft report and opinion "Emerging health issues - The case of genetically modified plants". The document was discussed in detail and several suggestions were made to the Working Group. The Chairman recalled the original intention to reflect, inter alia, on ways and means to deal with scientific advice requested for up-coming fears, sometimes based on speculative science, as defined by the WG. On the basis of the discussion, an updated draft will be prepared, for discussion at a next SSC meeting (probably March or April 2000). The SSC recommended focusing more on the general question and using the GMO-case as illustrative example.

b. Harmonisation of risk assessment procedures

Mr J.L.Jouve (DG-SANCO), on behalf of Prof.Bridges, reported that, since last SSC meeting, no Working Group meetings were held. However, the preparation of contributions to the various reports of the sub-groups and of the Working Group itself is following its course.

c. Possibly emerging fields of concern with respect to health and consumer protection

At the last meeting, it was agreed that this topic will be a permanent point on the agenda. All members should provide the secretariat with their contributions planned for the coming meetings in order to allow preparing a list/inventory of possibly emerging fields of concern with respect to health and consumer protection. In annex 3 an initial list of possible fields for concern is given. This list is the result of an initial brainstorming and has not yet been discussed. It is not

ranked in terms of priority or in any other way.

d. White paper on Food Safety

The Commission's *White Paper on Food Safety* was briefly presented to the SSC. An initial discussion was held. Amongst other concerns raised, the SSC's expressed scepticism regarding the feasibility of the schedule for the Action Plan on Food Safety.

Chapter 4: *Towards establishing a European Food Authority* was discussed in somewhat more detail but the SSC decided that it wished to have a much more in-depth discussion. It wants to prepare comments and concrete suggestions for the Commission, based on their collective experience in relation to provision of scientific advice to the Commission but also at national and (other) international level. These comments and suggestions will be submitted as a joint document from the SSC members.

This in-depth discussion will be held at the meetings of 2-3 March and of 13-14 April. Significant time will be allocated to this issue. In preparation of the March meeting, Prof Kroes drafts a first list of issues to be possibly addressed by the SSC. Contributions should directly be sent to him by e-mail.

5. Multidisciplinary matters relating to TSE/BSE

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

Prof.V.Silano, who chaired the last meeting of the TSE/BSE ad-hoc group, reported on the meeting of the TSE/BSE ad hoc Group of 13 January 2000. All items addressed by the group are dealt with in detail under point 5.2 of these minutes.

5.2. Reports on specific issues

a. Safety of ruminant blood (progress report)

The working Group met on 12 January 2000. Progress is according to schedule and a draft opinion is still expected to be ready for discussion by the SSC at its meeting of March or April 2000.

b. Quantitative assessment of safety of products (progress report).

The software package for the quantitative assessment of residual infectivity in bovine-derived processed products is not yet available. A draft opinion on the safety of the vertebral column for the production of gelatine and tallow (as a by-product of the degreasing process) will therefore not be ready for discussion before April 2000.

The software will also be used in preparing an opinion on the safety of UK bone-in meat (see item 5.2.k).

c. Handling and storage of possibly BSE contaminated MBM (progress report).

The awaited information from France was finally received and has been translated. The rapporteur will now include this info in his draft report.

d. Update of the opinion on the Safety of gelatine (February 1999).

- Recently, Inveresk Research International (1999) ¹ concluded a study "Validation of a NaOH treatment in the manufacturing process for bovine gelatine to show reduction of scrapie agent". The results are reported on in the Inveresk report number 16032 [project N° 856000 of 20.04.99]). This report was made available to the SSC.

As the results are relevant for the SSC-opinion on the Safety of gelatine (26-27 March 1998; updated in April 1998 and February 1999), the TSE/BSE *ad hoc* Group evaluated the document. Prof.M.Vanbelle reported on the findings of the TSE/BSE ad-hoc group. Following discussion, the SSC concluded that the described NaOH treatment step might be an

acceptable alternative for the liming *step* in the overall gelatine production process as described in the above mentioned SSC-opinion on the Safety of gelatine. However, the SSC once more underlined that a final assessment can only be made once a similar inactivation experiment is carried out with spiked bone material (see: SSC opinion on the Safety of Gelatine). The SSC further recommended continuing the studies aiming the assessment of the TSE infectivity inactivation for the process as a whole.

The SSC updated its opinion on the "Safety of Gelatine" accordingly (annex 4).

- In March 1998 the SSC recommended in its opinion on the Safety of Gelatine *"that research on the elimination and inactivation of TSE, including BSE, agents during the gelatine manufacturing process should also be carried out on raw material really used for gelatine production and for the production process as a whole, starting with the degreasing step of infected material, and not as individual research studies covering each of the production steps separately and that the results should be compared with the above results.* Following this recommendation, the association GME (Gelatine Manufacturers Europe) prepared a protocol for a study *" Evaluation of the inactivation/removal effect of the gelatine manufacturing process on TSE infectivity"*. Copies were sent to the SSC secretariat and made available, on request, to members of the SSC and of the TSE/BSE *ad hoc* Group.

It is not within the mandate of the SSC to comment on the protocol nor to approve it. However, it was agreed to provide the protocol to some experts previously involved in the preparation of the SSC-opinion on the Safety of Gelatine. Their possible comments will be sent to GME without further discussion by the SSC.

The SSC is looking forward to receive the final results of this study that it considers of prime importance.

e. Recent JRC report (November 1999) on the processing of meat-and-bone meal (report from the TSE/BSE *ad hoc* Group).

As a follow-up to its earlier validation studies on appropriate heat treatments of animal meals, the Joint Research Centre conducted a study on the *Prevention of Epidemic Diseases by appropriate Sterilisation of Animal Waste*. Given the importance of the matter, and in line with its discussions of January 1999, the SSC, at its meeting of 9-10 December 1999, invited the TSE/BSE *ad-hoc* group to comment on the report. A working group of independent experts reviewed the report, and the rapporteur, Prof. Vanbelle, reported to the TSE/BSE *ad hoc* Group. Following the suggestion of the TSE/BSE *ad-hoc* group, the SSC concluded as follows:

- So far, no methods were available to check the heat treatment used for the production of ruminant-derived meat and bone meal. The method described in the report is an improvement in the countries and regions where the conditions under which it can be applied (see below) are regularly met.
- The test may become, after further validation, a useful additional part of verification and control protocols for verifying the appropriateness of processing equipment in rendering plants (effective wet sterilisation carried out at least at 133°C/ 20/3 bars), provided a sample of appropriate test material is available to be processed.
- For certain operational purposes, such as on-the-spot checks of compliance with rendering conditions of "133°C/20/3 bars" or *a posteriori* verification of already processed meat-and-bone meal, the method is, as indicated in the study, still subject to a number of major limitations.
- However, the control of heat treatment and the identification of inappropriate heat treatment of ruminant materials in animal meals are essential elements to secure any BSE eradication policy. It is therefore important to further develop such methods..
- Some of the recommendations proposed to the European Commission are considered most important. They provide additional support to some of the essential recommendations in the SSC opinions on meat-and-bone meal (March 1998), gelatine (last update February 1999), and on "Fallen stock" (June 1999). Examples are the recommendations regarding wet sterilisation as opposed to dry sterilisation, batch processing as opposed to continuous processing, stirring of the material (to reach the desired conditions in every point of the autoclave), and as regards to how to verify the heat treatment conditions inside the equipment.

The SSC finally recommended that the detailed review by the *ad hoc* Group of the JRC report should be provided to the JRC.

f. "Human Exposure Limit Line" (discussion and possible adoption of an opinion).

The working Group met on 15 December 1999. Progress is according to schedule and a draft opinion is expected to be ready for discussion by the SSC at its meeting of March 2000. This report will also address issues such as the infective dose for humans, repetitive exposure and species barrier. The Working Group has already taken due account of, amongst many other papers, the recent publication of *Scott et al, 1999. Compelling transgenetic evidence for transmission of bovine spongiform encephalopathy prions to humans. Proc Natl Acad Sci USA, 96 (26): 15137-15142.*

g. TSE and culling

The working group met on 15 December 1999. Progress is not according to schedule, because not all the required information could be collected in due time. A draft opinion is hoped to be ready for discussion at the earliest for the SSC meeting of March 2000.

h. Origin of BSE

A draft report of the working group is expected for March 2000. A first discussion may therefore be held in April or May 2000.

For information the secretariat made available to all members, the latest communication by Parish & Parish (2000) *BSE is a non-transmissible disease*, which it received on 19.01.00. This communication should be taken into account by the WG-origin of BSE.

i. Geographical risk: update and further discussion.

- Prof.V.Silano introduced the draft update of the "Opinion on a method for assessing the Geographical BSE-Risk (GBR) of countries of regions" that was finalised by the TSE/BSE *ad hoc* Group at its meeting of 13 January 2000.

The draft was discussed in detail and amended. A final version was eventually adopted. It is attached as Annex 5.

- During the discussion on the issue the SSC identified the need to prepare an overall summary opinion on the geographical BSE risk in the European Union. This opinion should be based on the geographical BSE risk assessments that presently were being finalised for 14 Member States (Greece excluded). It should also establish the link with the SSC opinions on

- Specified Risk Materials (December 1997);
- Human Exposure Risk (December 1999); and
- Human Exposure Limit Line (forthcoming).

As far as possible, it should further look into the impact of intra-community trade of bovine derived foodstuffs on the vCJD-risk outside the UK.

j. The possibility of an immune or auto-immune pathogenesis of BSE and TSE

The SSC had been made aware of a publication suggesting an auto-immune theory for the origin of BSE (Ebringer, 1999). The SSC secretariat compiled, with significant help from the SEAC secretariat that closely follows the subject, a dossier on the issue, including also the paper *Tiwana et al, 1999. Infection and Immunology, 67: 6591-6595.*

A member of the TSE/BSE *ad hoc* Group evaluated the dossier. His report (see annex 5) was discussed by the *ad hoc* Group on 13/01/2000 and transmitted to the SSC. Following discussion, the SSC fully endorsed the *ad hoc* Groups recommendation that, as it presently stands, immune or autoimmune pathogenesis is probably not relevant as a hypothesis for the aetiology of BSE. Nevertheless the SSC recommended that the *ad hoc* group would closely monitor

any new developments that could come forth on this topic and should remain to stay in close contact with SEAC on the issue.

k. The safety of UK bone-in beef: question, mandate and first discussion.

End December 1999, the UK decided to lift the bone-in beef ban. This decision was based on a risk assessment carried out by the Chief Medical Officer in July 1999 and an additional epidemiological study of the epidemic and the corresponding expected numbers of cases for 1999 and following years. Subsequently the UK Government invited the Commission to follow the UK in its decision.

The Commission requested detailed information on the risk assessment and decided to consult the SSC on this matter. A question will be transmitted to the SSC in due time. Special emphasis will be put on the use of the vertebral column.

A copy of the *Supplementary information for the SSC on background to the recent decisions on bone-in beef*, addressed on 7 January 2000 by the UK-MAFF to the SSC secretariat, was made available by fax to all SSC and TSE/BSE *ad hoc* Group members on 10-11 January 2000. It contains 3 annexes: a , a summary of the results of the above epidemiological study and a copy the *Bone-in beef and cattle bones: further advice to Government from the Chief Medical Officer*.

Following discussion, it was agreed that:

- The SSC secretariat should request from the UK authorities a copy of the complete epidemiological study on which the decision to lift the bone-in ban is at least partly based.
- The SSC, when addressing this question, would also take into account the outcome of the pending opinion on the Human Exposure Limit Line. Of particular importance will be issues such as bovine to human species barrier, minimal infective dose for humans, and possible cumulative effect of repeated exposures (to small doses) at regular intervals.

As soon as the Commission's question is made available, the TSE/BSE *ad hoc* Group shall prepare a draft opinion to be provided for discussion to the SSC meeting of 13-14 April or 25-26 May 2000.

6. Organisational matters

No organisational matters were discussed.

7. Co-ordination

a. Reports of the Chairmen of the 8 Scientific Committees.

The chairmen of all Scientific Committees provided written reports on the activities of their committees since the last SSC meeting (9-10 December 1999; see annex 7)

b. Structure of opinions and technical reports.

This point was again referred to another meeting for further discussion.

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

As a follow-up to her intervention at the meeting of 9-10 December 1999, Mrs.P.Colombo informed the participants of the Commission intentions regarding the classification of animal waste types. The draft is to a large extent based on the SSC opinions on "Fallen stock", "Intra-species recycling", "Safety of meat-and-bone meal", "Organic fertilisers", "Safety of tallow" and "Safety of gelatine".

Its objectives are to recast existing measures of animal by-products not destined for human consumption (MBM,

rendered fats, manure, etc.) and to ensure that only animal by-products derived from animals declared fit for human consumption can enter the animal feed chain.

It was agreed that the list would also be provided for information to the TSE/BSE *ad hoc* Group.

9. Any other business

The SSC members were informed that France had submitted, on 29 December 1999, a request to the European Court of Justice, against the Decision by which the Commission refuses to modify or repeal its Decision 99/514 lifting the embargo on the exportations of bovine meat from the United Kingdom.

The SSC had an exchange of views on the issue and suggested to prepare, as part of pro-active measures, a discussion paper on the hypothesis of "the 3rd route of transmission of BSE", in the light of the SSC opinion of 28-29 October 1999. The TSE/BSE ad-hoc group should embark on that subject.

Further on, the SSC felt the need to prepare a statement on the way the EC's Scientific Committees function. It should clarify that the adopted opinions are the result of a scientific exercise (risk assessment, with all its uncertainties), not the result of a "negotiation between positions" be it of representatives of Member States or of institutes.

The meeting ended on Friday 21 January 2000, at 14h00.

The next meeting will be held in Brussels, on 2 and 3 March 2000, starting at 10:00 and ending on Friday afternoon, 16:00. It will reserve significant time for a first orientative discussion on the White Paper on Food Safety.

Annex 1: List of participants of the Scientific Steering Committee meeting of 20-21 January 2000

List of presence

Members of the SSC :

Prof. Georges Bories, Prof. James W. Bridges (not present), Prof. Fulgencio Garrido Abellán, Prof. Michael Gibney (not present on 21 January 2000), Prof. Anthony R. Hardy, Prof. Philip T. James (not present on 21 January 2000 afternoon), Prof. Keith H. Jones (not present), Prof. Fritz H. Kemper, Prof. Werner Klein, Prof. Ib Knudsen, Prof. Robert Kroes (not present on 21 January 2000), Prof. Albert Osterhaus, Prof. Gérard Pascal, Prof. Marcel Vanbelle, Prof. Martin Wierup, Prof. Vittorio Silano

Participants from the Commission:

DG SANCO: B. Carsin, J.J. Rateau, C. Berlingieri, P. Colombo, W. de Klerck, C. Diez, J.L. Jouve, J. Kreysa, G. Morrison, W. Penning, A. Somogyi, J. Vergnettes, P. Vossen, A. Wilhelm

Stagiaires: L. Döbeli, A. Simmank

Annex 2: Agenda of the Scientific Steering Committee Meeting of 20-21 January 2000

1. Welcome, apologies, introductory remarks,

Declarations of interest (annual, written declaration).

2. Approval of the agenda

3. Approval of the minutes of the meeting of 9-10 December 2000.

4. Progress on multidisciplinary matters:

- a. "Considerations for the evolution of scientific advice to address emerging health issues" (discussion and possible adoption of an opinion)
- b. Harmonisation of risk assessment procedures (progress report)
- c. Possibly emerging fields of concern with respect to health and consumer protection (further discussion).
- d. White paper on Food Safety

5. Multidisciplinary matters relating to TSE/BSE

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

5.2. Reports on specific issues:

Production systems and products.

- a. Safety of ruminant blood (progress report)
- b. Quantitative assessment of safety of products (progress report).
- c. Handling and storage of possibly BSE contaminated MBM (progress report).
- d. Update of the opinion on the Safety of gelatine (February 1999) (for adoption).
- e. Recent JRC report (November 1999) on the processing of meat-and-bone meal (report from the TSE/BSE ad hoc Group).

Human exposure risk

- f. "Human Exposure Limit Line" (discussion and possible adoption of an opinion).

Geographical risk.

- g. Geographical risk: update and further discussion; opinion.
- h. TSE and culling (discussion and possible adoption of an opinion).
- i. Origin of BSE (progress report).

Other issues:

- j. The possibility of an immune or autoimmune pathogenesis of BSE.
- k. The safety of UK bone-in beef: question, mandate and first discussion.

6. Organisational matters.

7. Co-ordination:

- a. Reports of the Chairmen of the 8 Scientific Committees.
- b. Structure of opinions and technical reports.

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

9. Any other business.

Annex 3: Draft initial* list of possible fields for concern in the medium-term future (Listing as on 21.01.00**)

Factors predisposing for the emergence of infectious diseases:

- New viral diseases / prion diseases;
- Unexpected microbial diseases linked with (drinking) water;
- climatic change events: extreme weather events and results of increased temperatures;
- Xeno-transplantation;
- Upcoming diseases due to blood transfusion;
- Safety of vectors used in gene therapies
- Risk assessment of genetically modified viruses

Other fields:

- Macro-nutritional imbalance and its direct and indirect consequences for disease;
- (natural) toxin exacerbation;
- Gene-therapy;
- Allergenicity (as yet unknown);
- Increase pressure to deliver quantitative estimates of risks involved with (unexpected) exposures to agents (chemical, biological and physical);
- New claims on supposed diseases (re cancer) due to cellular phones.
- Cardiovascular diseases, causes and prevention: role of industrial chemical and chemical pollutants from food and environment.
- Scientific illiteracy as a possible (emerging) (individual and public) health hazard.

s:

* This list is the result of an initial brainstorming and has not yet been discussed. Ranking is arbitrarily. It will gradually be amended, possibly shortened; items on the list may disappear as not relevant; other ones may be added. No firm planning exists for its discussion.

** The list has been amended at the SSC meeting of 2-3 March and the amended version will be attached to the minutes of that meeting.

Annex 4: Scientific Report and Opinion on [The Safety of gelatine](#) updated by the Scientific Steering Committee at its meeting of 20-21 January 2000 (Distributed separately, and available on Internet)

Annex 5: Opinion of the Scientific Steering Committee on [A method for assessing the Geographical BSE-Risk \(GBR\) of a country or region - Update, January 2000 \(Distributed separately, and available on Internet\)](#)

Annex 6: The possibility of an immune or autoimmune pathogenesis of BSE and TSE.

Report to the TSE/BSE *ad hoc* Group at its meeting of 13 January 2000

In a recent publication the group of Alan Ebringer have raised the possibility of an immune or autoimmune pathogenesis of BSE and TSE (Tiwana *et al*, 1999. *Infection and Immunology*, **67**: 6591-6595,).

The group's main arguments are:

- A. Spongiform-like changes similar to those that are typical of TSEs have also been observed in chronic experimental allergic encephalomyelitis (EAE).
- B. In BSE-affected cattle the authors identified immunoglobulin A autoantibodies to neurofilament and myelin and *Acinetobacter calcoaceticus*. These bacteria have protein sequences similar to neurofilaments and myelin. Antibodies against other bacteria (*E. coli* and *Agrobacterium tumefaciens*) were not found.

Autoantibodies against myelin are known to occur in EAE.

No clear concept on the etiology or pathogenesis of TSE is suggested in this publication. The authors discuss three possible explanations:

1. A mechanism similar to EAE, in which cattle would develop antibodies against *A. calcoaceticus* which then crossreact with antigens in the brain (autoimmune hypothesis).
2. Antibodies to neurofilaments and myelin develop as a consequence of severe and progressive brain damage in BSE
3. Direct infection of cattle (by *A. acinetobacter*)

Comments:

ad A: It is true that vacuolar changes similar to those found in of TSEs can be observed in a number of conditions such as neurodegenerative diseases in humans, e.g. Alzheimer's disease, and Pick's disease, copper deficiency in experimental animals (mice), hypoxia and other conditions such as EAE. On close inspection the morphology and distribution of vacuolar or spongiform-like changes observe in these conditions are different from spongiform changes that are typical of TSE. More important, lymphocytic infiltrates and perivacuolar cuffings that are typical of and pathogenetically important for EAE and similar conditions are quite atypical of TSE.

In essence the morphology of TSE is quite distinct from EAE and if anything suggests a non-autoimmune or allergic etiology of TSE.

ad B: Autoantibodies to brain antigens such as neurofilaments were indeed found in TSE a number of years ago. Indeed a number of brain-specific proteins can now be detected in the corticospinal fluid and blood of CJD patients, a fact that is certainly related to the progressive and massive nerve cell destruction in TSE. In fact it would be surprising if one did not identify antibodies to some of these antigens. Should they play a pathogenic or etiologic role one would expect to find them early on in the disease or even before the onset of clinical symptoms.

Of the three possible explanations offered by the authors, hypothesis no. 2 is compatible with our knowledge about TSE. The other two explanations put forth are not compatible with a number of known facts such as the lack of inflammatory signs in TSE, the long incubation times, the high infectious titers and others. ***Annex 7: Reports from the secretariats of Scientific Committees on the major activities and milestones since the SSC meeting of 9-10 December 1999.***

Scientific Committee for Food

Scientific Committee for Plants

No plenary session was held since the last SSC meeting

Scientific Committee on Animal Nutrition (SCAN)

The Committee updated a report on Micro-organisms used as feed additives in December 1999. The working groups continue their work.

Scientific Committee Veterinary Measures relating to Public Health

The different working groups of the SCVPH continue their work. Draft reports for possible adoption are expected for the first meeting of year 2000.

Scientific Committee on Animal Health and Animal Welfare

Scientific Committee for Toxicity, Ecotoxicity and the Environment

A. No plenary meeting of the CSTEE took place since the December 99 plenary meeting of the SSC. In terms of

progress made on the opinion requests to the CSTEE and other CSTEE initiatives the outcome was the following:

B. On the subject '*Terrestrial environment*' - '*Available scientific approaches to assess the potential effects and risks of chemicals on terrestrial ecosystems*' - Drafts on some of the different chapters of the report were produced. A WG meeting should be organised soon to take stock of developments.

C. '*The use of measured exposure data in risk assessment*' - No major progress on this activity given the short time span since the November 99 CSTEE plenary meeting.

D. Regarding the opinion request on a *report from a study on Technical specifications for classification and presentation of ecological status of surface waters and a report from a study on technical specifications for monitoring of ecological status of surface waters*, the prospect of having the two outstanding studies on classification and monitoring of ecological status for the Water Framework Directive available from DG Environment for the first CSTEE plenary meeting in 2000 have so far not been confirmed.

E. On the subject of the text of a **draft Commission Decision Adopting measures prohibiting the placing on the market of toys and childcare articles intended to be placed in the mouth by children under three years of age made of soft PVC containing one or more of the substances Di-iso-nonyl phthalate (DINP), Di(2-ethylhexyl) phthalate (DEHP), Dibutyl phthalate (DBP), Di-iso-decyl phthalate (DIDP), Di-n-octyl phthalate (DNOP), and Butylbenzyl phthalate (BBP)**, and following the developments explained in the minutes of the previous SSC plenary meeting, the Commission proposed to M. States and these adopted unanimously a proposal with corrections made to the previous draft, in conformity with the suggestions made by the CSTEE.

F. **Evaluation of Technical s for Guidance (TNsG) in support of Directive 98/8/EC concerning the placing of biocidal products on the market** - A working group meeting is taking place on the 21st of January 2000 to finalise the draft opinion for submission to the next CSTEE plenary. The version of December 99 of the Technical s for Guidance has in the meantime been made available and it is this version that will be scrutinised.

G. On the subject '*Construction products in contact with drinking water*' no progress has been made as this activity is now dependent upon the developments within the M.S. group; the definition of questions to be submitted to the CSTEE are possible later but no time schedule for this can be anticipated at this stage.

H. Regarding the two opinion requests on '**lead**' [(i) a notification of the Danish authorities informing Commission services of their intention to ban lead in a significant number of applications and (ii) a general opinion request on hazards and risks posed by lead and its compounds to human health and the environment] no major progress other than the submission of contributions took place since the date of the previous SSC plenary meeting. Another WG meeting will probably take place soon.

I. The opinion request mentioned in the previous briefing (four chemicals, with others to come, which have been risk assessed under Regulation 793/93 on existing substances: Nonylphenol (straight and branched chain) CAS 84852-15-3, 25154-52-3, Pentabromodiphenyl ether CAS No.32534-81-9, Octabromodiphenyl ether CAS No.32536-52-0 and Decabromodiphenyl ether CAS No.1163-19-5) have in the meantime been received by the CSTEE secretariat. A working group meeting took place on the 16th of December 99 where the activities of the CSTEE as regards its "peer-review" role have been clarified. Given the relative complexity and daunting nature of the exercise it was agreed to submit the agreed scheme to a trial period of six months. Draft opinions on the environmental risk assessments of Nonylphenol and Pentabromodiphenyl ether are already being elaborated by the appointed CSTEE rapporteurs.

J. The next CSTEE plenary meeting is taking place on the 4th of February 2000.

Scientific Committee for Cosmetics and Non-Food Products

One Working Party took place since the last meeting of the SSC and concerned the update of the Inventory of ingredients employed in cosmetic products. A draft document has been presented which includes existing ingredients as well as new ingredients to be used. This means that, without taking into account the fragrance ingredients, the

information of about 7000 ingredients has to be checked.

The SCCNFP is presently discussing other topics such as:

- The use of human volunteers in the testing of potentially sensitising cosmetic ingredients. The SCCNFP has already adopted some specific guidelines on the use of human volunteers in the testing of cosmetic ingredients and products, which has been deemed as necessary since such guidelines do not exist at the Community or national level.
- Consumer exposure levels for the various types of cosmetic products.
- The risk evaluation of amino acids from human hair hydrolysates with regard to transmission of Creutzfeldt-Jakob Disease and viral diseases.
- The safety evaluation of 2,4-DPO with the question of a possible pharmacological activity when used in cosmetic products at levels currently proposed.
- The safety evaluation of α - and β -Hydroxyacids
- The use of Coal-Tar in cosmetic products when refined by bi-distillation.
- The safety evaluation of Titanium dioxide as UV filter. The various types of coatings have to be considered as well.

Scientific Committee for Medicinal Products and Medical Devices

¹ Shepherd, A., 1999. Validation of the Manufacturing Process for gelatine to show Reduction of the Scrapie Agent. Inveresk report N° 16032 sponsored by Leiner Davis Gelatine (International) (Botany, Australia). Tranent (Scotland), 29 pp. (Confidential)