Minutes of the Scientific Steering Committee Meeting of 18-19 October 2001

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

Chairman Prof.Pascal welcomed the participants of the Scientific Steering Committee. He apologised Prof.J.Bridges for both 18 and 19 October 2001. The list of participants is attached as **Annex 1**.

Declarations of interest:

No declarations of interest were made

2. Approval of the agenda

The agenda was approved without changes. It is attached as **Annex 2**.

Note: At the request of Commission Services, the SSC gave priority to the preparation of an opinion on the safety of small ruminant products should BSE in small ruminants become probable / confirmed (see Annex 4) . As a result, many of the items on the agenda were not addressed during the meeting.

3. Approval of the minutes of the meeting of 6-7 September 2001.

The minutes of the meeting of 6-7 September 2001 were adopted without changes.

4. Procedural matters:

In view of the statement in August 2001 by the UK Food Standards Agency (FSA), the SSC was invited to deliver the scientific bases for possible risk management measures in the event that new research would confirm or could not exclude that BSE was present in the UK sheep population in the early 1990's. (See item 6.2.c and Annex 4). On 18 October 2001 it appeared however that the research referred to in the FSA's statement, had not yet provided the appropriate information needed to verify the possible presence of BSE or a BSE-like agent in the UK sheep population, possibly because of problems associated with the source material.

In this context, the members of the SSC discussed matters of quality assurance, reliability and peer review of scientific data used in formulating opinions of the SSC. The SSC frequently relies on the views of scientists of international repute working in specialised areas, who may provide data from incomplete experiments prior to submission for publication or prior to peer review. The SSC reaffirmed its responsibility to question seriously all information on which it formulated opinions either directly or through its working groups in order to receive reassurance about the quality, reliability and veracity of such data.

5. Multidisciplinary matters:

a. Co-ordination: Reports of the Chairpersons of the 8 Scientific Committees

- **Activities of the Scientific Committees.** The 8 chairpersons reported on the work of their respective Scientific Committees, whilst emphasising on matters that are of a multidisciplinary nature and/or require co-ordination. Information on the activities of the various Scientific Committees is attached as **Annex 3**.

b. Harmonisation of risk assessment methods.

This item was not discussed due to a lack of time.

d. Emerging scientific issues

No progress reports were presented.

e. New questions

No new questions on non-TSE issues had been submitted to the SSC.

6. Multidisciplinary matters relating to TSE/BSE

6.1. Report on the TSE/BSE *ad-hoc* group meeting of 9 October 2001

The secretariat reported briefly on the meeting of the TSE/BSE *ad hoc* Group of 26.07.01. All items addressed at that meeting are further reported on under point 6.2. hereafter.

6.2. Reports on specific issues:

a. The origin of BSE and routes of transmission

The SSC secretariat reported on the progress made by TSE/BSE *ad hoc* Group, that discussed at its meeting of 9 October 2001 the draft report prepared by the rapporteur. It was now expected that a final draft would be available for discussion by the SSC at its meeting of November 2001.

b. TSE infectivity distribution in ruminant tissues: state of affairs, safety of ruminant heads and specified risk materials in small ruminants

The three reports on the above subjects prepared by the TSE/BSE *ad hoc* Group were discussed. The SSC considered that a number of sections needed to be updated and that some conclusions needed revision. The SSC secretariat was invited to inform the *ad hoc* Group about these comments. The SSC further recommended that the protocol of the pathogenesis studies, extensively referred to in the reports, be presented.

The TSE/BSE *ad hoc* Group was therefore invited to prepare at its next meeting updates of the 3 reports so that they could be discussed at the SSC meeting of 29-30 November 2001.

c. TSEs in small ruminants.

In view of the statement in August 2001 by the UK Food Standards Agency (FSA), the SSC was invited to deliver the scientific bases for possible risk management measures in the event that new research confirms or cannot exclude that BSE was present in the UK sheep population in the early 1990's. On 18 October 2001 it appeared however that the research referred to in the FSA's statement, had not yet provided the appropriate information needed to verify the possible presence of BSE or a BSE-like agent in the UK sheep population. The mandate of the SSC was nevertheless maintained because the risk that BSE is present in small ruminant populations can not be excluded on theoretical grounds, although there is at present no field evidence for this.

Using a draft report prepared on 4 October by the Working Group on TSEs in sheep and on 9 October by the TSE/BSE *ad hoc* Group as the basis for its discussions, the SSC prepared and adopted the opinion attached as annex 4.

d. The six BARB cases in the UK.

This item was not discussed due to a lack of time. It will be discussed by priority at the next meeting.

e. BSE eradication: update of the SSC opinion of September 2000 and equivalence of the UK and FRG culling approaches with EC Regulation N° 999/2001.

This item was not discussed due to a lack of time. It will be discussed at the next meeting.

f. Safety of catgut from GBR I countries.

Prof Löwer asked whether it was necessary to draft an independent opinion on this subject, as the safety of ruminant materials from GBR I countries had been addressed in general in the SSC opinion of 6-7 September 2001 on « Sourcing from GBR I countries »[1]. After a short discussion the SSC decided that reference to the recently adopted opinion covers this aspect. It was agreed that the opinion of 6-7 September would be updated so as to include this clarification. Reference was also made to a previous opinion adopted by the Scientific Committee on Medicinal Products and Medical Devices[2].

The SSC also signals that the catgut is not widely used in Europe anymore by surgeons due to the fact that synthetical suture material is available.

g. Geographical BSE Risk (GBR): progress report and possible opinions.

The secretariat briefly informed the SSC of the need for an update of the GBR method so as to better take into account the "external challenge" factor which had gradually changed with the increasing number of countries where BSE was observed for the first time since the original GBR method had been developed. This larger challenge had not been taken into account in the assessments of the initial series of Member States and Third Countries assessed between January 2000 and June 2001.

The secretariat also briefly informed the SSC of a tentative schedule for assessing the GBR of a number of countries that recently submitted a dossier.

It finally recommended that the GBR Working Group would be enlarged with 2-3 experts.

It was agreed that details on the above would be provided in writing (e-mail) by the secretariat to all members and that an attempt would be made to adopt before next meeting both the revised method and the tentative planning by written procedure. Suggested names for the enlarged working group should be sent to the secretariat and would be discussed at the next SSC meeting.

h. Preliminary opinion on The risk of dissemination of brain particles when applying certain stunning methods (account of comments received so far).

The deadline for the submission of comments or contributions is 26 October 2001. The secretariat informed the SSC that no firm comments had been received so far. However several industrial associations did already express their intention to comment on the preliminary opinion or to send contributions.

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1 Opinion on Sourcing of from GBR I Countries (Sourcing of Ruminant Materials from GBR I Countries for Medical Devices) (adopted on 6-7 September 2001)

2 Opinion on the Use of Specified Risk Materials for the Manufacture of Implantable Medical Devices (adopted on 15 December 1999)

i. Progress report on pending questions:

- **BSE epidemiology (survey methods);**

  A final draft was made available to the SSC at the meeting. It was, however, not discussed partly because of a lack of time and partly because the mandate needed to be updated again so as to include surveys for TSEs and BSE in small ruminants. A final updated draft was now expected to be ready for adoption at the meeting of 29-30 November 2001.

- **The safety of human blood and human-derived products: progress report and update of the mandate.**

  Prof. Loewer, chairman and rapporteur of the Working Group informed the SSC that for reasons beyond his control, the Working Group meeting initially scheduled for 5 October 2001 had to be postponed until 31 October. No progress had therefore been made. An account of the meeting of 31 October will be provided at the next SSC meeting.

j. Pending reports on ways of disposals.

The discussion on this item was postponed to a later meeting.

k. New questions.

A request had been received inviting the SSC to recommend a protocol to investigate, by mouse bioassay or any other suitable method, whether BSE is present in the small ruminant population in the Community. The protocol should include details on

- Strain-typing to be used (if mouse bioassay is recommended, details on the protocol
- Methods for sample selection and number of samples to be analysed per Member State
- Other relevant information (for example, if each animal should be investigated individually or if pooled samples can be used).

7. Organisational matters:

No organisational matters were discussed.

8. Info on the follow-up given to the opinions adopted at the previous SSC meeting.

This item was not addressed during the meeting.

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

No information was provided by Commission Services.

10. Any other business.

No other business were discussed

The meeting ended on Friday 19 October 2001, at 13h30

Annex 1: List of participants in the Scientific Steering Committee meeting on 18-19 October 2001.

List of presence

Members of the SSC:

- Ing. Georges Bories
- Prof. Johanna Fink-Gremmels (18 October only)
- Prof. Anthony R. Hardy
- Dr. Keith Jones
- Prof. Werner Klein
- Dr Ada Knaap
- Dr Ib Knudsen
- Dr Pierre Le Neindre
- Prof. Johannes Löwer
- Prof .Albert Osterhaus
- Prof. Gérard Pascal (Chairman)
- Prof. Pere Puigdomenech
- Prof. Vittorio Silano
- Prof. Staffan Skerfving
- Dr Ian White (18 October only)

Apologies for absence:

- Prof. James Bridges

Invited expert

Dr Emmanuel Vanopdenbosch

Participants from the Commission:

DG SANCO: B. Carsin, C. Berlingieri, P. Vossen, J. Kreysa, M. Goll, S. Abildgaard, G. Morrison, D. Jacquemin, S. Delle Chiaie, M. Walsh, M. Granero, A. Van Elst, J. Ferrière, W. De Klerck, A. Fokkema.

DG RTD: A. Boenke.

Annex 2: Agenda of the Scientific Steering Committee Meeting of 18-19 October2001

1. Welcome, apologies, introductory remarks, declaration of interest.
2. Approval of the agenda
3. Approval of the minutes of the meeting of 6-7 September 2001
4. Procedural matters (if any)
5. Multidisciplinary matters:
   a. Co-ordination: Reports of the Chairmen of the 8 Scientific Committees;
   b. Harmonisation of risk assessment methods:
      - Progress report on Task Force activities;
      - Common format for opinions and Glossary of terms.
   c. Emerging scientific issues (progress reports);
   d. Agricultural uses of azole fungicides and resistance build-up in human pathogenic fungi (for attribution).
6. Multidisciplinary matters relating to TSE/BSE

6.1. Report by the chairman of the TSE/BSE *ad-hoc* group meeting of 4 October 2001

6.2. Reports on specific multidisciplinary matters relating to TSE/BSE:

   a. The origin of BSE and routes of transmission
   b. TSE infectivity distribution in ruminant tissues:
      - state of affairs
      - safety of ruminant heads
      - specified risk materials in small ruminants
   c. TSEs in small ruminants. In view of the statement in August 2001 by the UK Food Standards Agency, in the event that new research confirms or cannot exclude that BSE was present in the UK sheep population in the early 1990's:
      1 What criteria can be used as a tool in the context of routine slaughter to ensure that meat is safe for the consumer in terms of:
         - source of the individual animal
         - age of animal, bearing in mind that it is difficult to determine the age of sheep less than one year old using physical characteristics;
         - Use of rapid testing;
         - Genotyping;
         - Removal of SRM;

         for (a) sheep and (b) goats?

      2 Is the consumption of milk and milk products derived from (a) sheep and (b) goats safe? What criteria if any can be used to ensure or maximise safety in terms of:
         - Age of animal;
         - Use of rapid testing;
         - Genotyping;
         - TSE free flocks;

         for (a) sheep and (b) goats?

      3. Is it possible to define a TSE-free sheep flock/goat herd? If so, what criteria can be used to establish such a group?
      4. What are the criteria which should be used in a widespread genotyping and breeding programme for resistance to TSEs in small ruminants?
      5. Is it possible to actualise the existing Geographical BSE Risk Analysis to small ruminants, by taking into account factors that may be unique to sheep.

d. The six BARB cases in the UK (for opinion).

e. BSE eradication: update of the SSC opinion of September 2000 and equivalence of the UK and FRG culling approaches with EC Regulation N° 999/2001 (for opinion).

f Safety of catgut (for opinion).

g. Geographical BSE Risk: progress report and possible opinions.

h. Preliminary opinion on The risk of dissemination of brain particles when applying certain stunning methods (account of comments received so far).

i. Progress report on pending questions:
   - BSE epidemiology (survey methods);
   - The safety of human blood and human-derived products: progress report and update of the mandate;

j. upcoming issues and new questions:
   - Pending reports on ways of disposals.

7. Info on the follow-up given to the opinions adopted at the previous SSC meetings.

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

9. Any other business.

Annex 3: Reports from the chairpersons of Scientific Committees on the major activities and milestones since the SSC meeting of 6-7 September 2001.

(COMPLETE INFORMATION AT THE WEBPAGES OF THE SCIENTIFIC COMMITTEES AT THE ADDRESS HTTP://EUROPA.EU.INT/COMM/FOOD/FS/SC/SSC/INDEX_EN.HTML.)

SCIENTIFIC COMMITTEE ON FOOD (SCF)

The SCF, at its last plenary meeting on 25/26 September adopted the following opinions and statements:

- Opinion on the tolerable upper intake level of biotin
- Opinion on the tolerable upper intake level magnesium

These two are opinions in a series evaluating upper levels of all micronutrients. These opinions are to be used by the Commission in the preparation of legislation for food supplements and food fortification. This activity is now approximately midway to its completion. The Committee has evaluated so far 11 micronutrients.

- Opinion on estragole
- Opinion on methyleugenol

These two are part of a group of substances used as flavouring substances or present in flavourings or present in other food ingredients with flavouring properties regulated under the Directive 88/388 and being the object of re-evaluation by the SCF at present.

- Statement of the Scientific Committee on Food on the use of resistant short chain carbohydrates (oligofructose and oligogalactose) in infant formulae and in follow-on formulae

The Committee has concluded at this stage there is insufficient data to support the safety of preparations containing these added ingredients for infants below 4 months and has requested additional data.

The coming meeting on 12/13 December will cover probably, among other issues, the discussion and possible adoption of draft opinions on upper levels of two additional micronutrients: pantothenic acid and copper, on a number of additional flavouring substances of Annex II of Directive 88/388/EEC, the use of carbon monoxide as component of modified atmosphere packaging (food additive) for the preservation of packaged fresh meat, and additional evaluations of food contact materials. The Committee also will probably deliver an opinion on salatrim as a novel food ingredient. The Committee is likely going to be requested formally at this plenary as a new dossier to provide an update of the scientific basis of the nutritional labelling as laid down in the relevant directives.

SCIENTIFIC COMMITTEE FOR PLANTS (SCP)

The SCP met on 27 September and adopted the following opinions:

- Opinion of the Scientific Committee on Plants on specific questions from the Commission concerning the evaluation of Flufenacet in the context of Council Directive 91/414/EEC.
- Opinion of the Scientific Committee on Plants on specific questions from the Commission concerning the evaluation of Florasulam in the context of Council Directive 91/414/EEC.

SCIENTIFIC COMMITTEE VETERINARY MEASURES RELATING TO PUBLIC HEALTH

At its plenary meeting on 19-20 September the Scientific Committee on Veterinary measures relating to Public Health (SCVPH) adopted an opinion on "*Vibrio vulnificus* and *Vibrio parahaemolyticus* (in raw and undercooked seafood)".

Other draft reports have been discussed by the Committee and remarks made to the documents presented. Updated draft will be submitted for future discussion.

New questions were addressed to the Committee. The SCVPH decided to establish three new ad hoc working groups on:

- honey and microbiological hazards;

- Salmonella;

- verotoxigenic E. coli (VTEC)

The next plenary meeting is scheduled for 21-22 November.

SCIENTIFIC COMMITTEE ON ANIMAL HEALTH AND ANIMAL WELFARE (SC-AHAW)

The plenary meeting was held on 17 October and adopted a report on diagnostic tests for Contagious Bovine Pleuropneumonia (CBPP). Discussion on the Format of the reports took place.

The Animal Welfare sub committee met on 24-25 September and discussed a draft on the Welfare of animals kept for fur production.

The Animal Health sub committee met on 25 September, discussed and approved a draft report on diagnostic tests for Contagious Bovine Pleuropneumonia (CBPP).

Other working groups are engaged in drafting reports on topics such as welfare of animals during transport and welfare of non-human primates in experiments, and on health matters such as Chlamidiosis (psitaccosis), Fish waste and rabies.

The next plenary meeting is scheduled for 12 December and eventually the 13 (still to be confirmed) and should consider draft reports on the Welfare of animals kept for fur production and welfare of animals during transport.

SCIENTIFIC COMMITTEE FOR COSMETICS AND NON-FOOD PRODUCTS (SC-CNFP)

Since the last SSC plenary meeting of 6-7 September 2001, 6 Working Party meetings and 1 plenary meeting of the Scientific Committee on Cosmetic Products and Non-Food Products have taken place.

Although no particular items of a multi-disciplinary nature have been discussed, the committee adopted opinions on the following items :

* Preliminary discussion paper on an inventory of detergent ingredients. The paper will be sent to industry for comments. Additionally, they will be asked to submit information required to complete the inventory.
* Opinion on an initial list of perfumery materials which must not form part of cosmetic products except subject to the restrictions and conditions laid down.
* Opinion concerning chemical ingredients in cosmetic products classified as carcinogenic, mutagenic or toxic to reproduction according to the chemicals directive 67/548/EEC. The committee was asked whether such substances pose a significant threat to the health of the consumer when used in cosmetic products.

* Opinion on the use of alpha-Tocopherol acetate.

* Opinion on the amendment to entry n° 419 of Annex II to Directive 76/768/EEC on cosmetic products. The opinion is an further update of previous opinions because of new scientific evidence regarding the use of specified risk material presenting a risk as regards TSE.

SCIENTIFIC COMMITTEE FOR ON TOCITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)

A. Opinions adopted at the 25th CSTEE plenary (20 July 2001) and 26th CSTEE plenary (11 September 2001)]:

1. Risk assessment reports produced under the so-called Existing substances Regulation (793/93):

i) Human health and the environment: **a)** *1,2,4-Trichlorobenzene;* **b)** Hydrogen peroxide;

ii) Environmental part only: **c)** *Styrene*; **d)** *1-vynil-2-pirrolidone.*

2. JRC report on Validation of methodologies for the release of diisononylphthalate (DINP) in saliva simulant from toys.

3. *Assessment of the risks to human health posed by azo colorants in toys, writing inks and paper products, and analysis of the advantages and drawbacks of restrictions on their marketing and use* – LGC report ETD/99/502495.

4. Exposure data in risk assessment of organic chemicals (CSTEE own initiative report).

B. The CSTEE is also pursuing its activities on the following opinion requests:

1. *Ecotoxicological properties of Creosote* (Submission to the EC under article 95 of the Treaty). Note: this follows the adoption by the CSTEE of an interim position when all the data was not yet available for the committee.

2. *Health effects of Radio Frequency and Electromagnetic fields* (emerging issue).

3. Evaluation of the following Regulation 793/93 Risk Assessment Reports:

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

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

5. Revision of the 'Technical Guidance Document' in support, among other legislative pieces, of Regulation 793/93, which includes: a) *'Environmental exposure';* b) *'Marine risk assessment';* c) *'Environmental effects assessment';* d) *Human health exposure assessment';* e) *'Human Health effects assessment'***.**

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

7. *'Incineration of animal waste'* (Terms of reference not yet submitted).

Annex 4

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C1 - Follow-up and dissemination of scientific opinions

TSEs IN SMALL RUMINANTS

OPINION ON THE SAFETY OF SMALL RUMINANT PRODUCTS SHOULD BSE IN SMALL RUMINANTS BECOME PROBABLE / CONFIRMED.

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE AT ITS MEETING OF 18-19 OCTOBER 2001

(DISTRIBUTED SEPARATELY.)