Minutes of the Scientific Steering Committee Meeting of 8-9 February 2001

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

The chairman welcomed the participants of the Scientific Steering Committee, especially Prof.Leneindre who was elected chairperson of the Scientific Committee for Animal Health and Animal and therefore became a full member of the SSC. He apologised: Dr Ada Knaap and, for 9 February: Prof. J.Fink-Gremmels, Prof. A.Hardy, Prof. P.Puigdomenech, Prof. S.Skerfving and Dr S.Barlow (representing Dr Knaap).

Dr.E.Vanopdenbosch attended parts of the meeting as rapporteur of the working group that produced the report in preparation of the SSC's *Pre-emptive opinion on risk scenarios, should BSE in sheep be found under natural conditions. Monitoring of research results on experimental BSE in small ruminants*. (Item 6.2.a on the agenda).

Declarations of interest:

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

2. Approval of the agenda

The agenda was approved without changes. The final agenda is attached as annex 2.

3. Approval of the minutes of the meeting of 11-12 January 2001.

The minutes of the meeting of 1-12 January 2000 were amended and then adopted.

4. Procedural matters

a. Declarations of interest.

The secretariat reminded some members that they had not yet completed their annual written declaration of interest and invited to provide them to the secretariat before the next meeting.

b. Rules of procedure.

Several SSC members asked to be involved in the drafting of press releases related to its opinions. The secretariat explained that this was impossible for practical reasons and also because this was beyond the remit of the SSC.

Both the SSC and its secretariat, however, stressed the need for very concise and high quality Executive Summaries of opinions, which could then serve as the basis for the preparation of press-releases.

Some SSC members asked to receive a copy of the draft final legislative proposals based on its opinions, before they were submitted for possible final adoption to the appropriate

institution(s) such as the Council of Ministers. The secretariat informed the SSC that this was impossible because of the clear separation between scientific advice and risk management and because of the risk of interference from individual SSC members in the final risk management decision making process.

The principle was nevertheless adopted that the SSC members would receive as soon as possible a copy of the finally adopted legislative documents (e.g. decisions) and of the final versions of the Press releases.

c. Curriculum vitae.

The SSC members agreed to provide the secretariat as soon as possible with a summary of their CV to, for putting on the internet site of the Health And Consumer Protection Directorate General.

d. Membership of the TSE/BSE ad hoc Group

The SSC proposed a number of suitable possible new members for the TSE/BSE ad hoc Group. It was agreed that the secretariat would prepare a compliance matrix of required and already available thematic expertise within the TSE/BSE ad hoc Group and that on the basis of this matrix, firm proposals would be made at the meeting of 29-30 March 2001.

5. Multidisciplinary matters:

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

The multidisciplinary matters requiring co-ordination listed in the minutes of the meeting of 11-12 January 2001 were confirmed. In addition, Prof.Loewer raised the issue of the possible need for an harmonised approach at international level with regard to the risk of exposure to vCJD agent via human products. This item is further reported on in the BSE-section of the present minutes.

More detailed information on the activities of the various Scientific Committees is attached as Annex 3.

b. Harmonisation of risk assessment methods: (draft) mandate for a task force.

The composition of the task force was agreed upon. It would be composed of one member from each Committee plus several members of the SSC. Further discussions by the SSC were postponed until after the SANCO internal meeting scheduled of 28 February 2001.

c. Safety of cotton

No opinion was adopted as the rapporteur was still missing the contribution of 1 of the 3 involved Scientific Committees. Adoption is now expected for 29-30 March.

d. Emerging scientific issues (progress reports from task forces, working groups and scientific committees)

- ***Emerging viruses*** . This topic was attributed to 3 Committees: SC-VMPH, SC-AHAW, SC-MPMD.

- *Anti-microbial resistance* . The following documents and dossier had been received by the secretariat and were available at the meeting for initial consultation by the members:

1. 'Public health impact of the use of bacitracin zinc in animals' - November 2000, Alpharma, Animal Health Division;

2. 'Public health impact of the use of bacitracin zinc in animals' - November 2000, Alpharma, Animal Health Division (addendum to the dossier submitted in May 2000;

3. Expert report on the FEFANA-study 'Initial antibacterial sensitivity surveillance of bacterial isolates from farm animals in six European countries' - Flavophospholipol and Avoparcin - Prof. Dr. Jörg Hacker - 22 Sept. 2000;

4. Review of Avilamycin Microbiological Safety based on the FEFANA/EU Commission/member State - Surveillance study and supporting date - Eli Lilly and Company Ltd, Nov. 2000;

5. Review of Tylosin Microbiological Safety based on the FEFANA/EU Commission/Member State Surveillance study and supporting data - Eli Lilly Company Ltd, Nov. 2000;

6. 'Virginiamycin' Report on results of the FEFANA/EU surveillance study, and information on streptogramin resistance in *Enterococcus faecium* - Pfizer - Dec. 2000.

The services of the Commission present a preliminary draft mandate, to be further finalised in an internal consultation. The final composition of the Working Group would be discussed at the meeting of 29-30 March 2001 on the basis of required expertise to be inventoried by the rapporteurs and an initial Working Group that could meet already before next meeting.

c) *High-frequency electro-magnetic fields.* The opinion from the Scientific Committee for Toxicity and Ecotoxicity of the Environment, reinforced by members of the SSC is expected for June 2001.

e. New questions

No new question on an issue other then BSE/TSE had been submitted to the SS.

6. Multidisciplinary matters relating to TSE/BSE

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

Prof. Silano reported briefly on the meeting of the TSE/BSE *ad hoc* Group of 1 February 2001. All items addressed by the *ad hoc* group are further dealt with in detail under point 6.2 of these minutes.

6.2. Reports on specific issues:

a. Pre-emptive opinion on risk scenarios, should BSE in sheep be found under natural conditions. Monitoring of research results on experimental BSE in small ruminants.

Dr.E.Vanopdenbosch, rapporteur, introduced the report of the Working Group and the draft summary and recommendations prepared by the TSE/BSE ad hoc Group at its meeting of 1 February. Following in-depth discussions, the SSC adopted the opinion attached as is attached as Annex 4.

b. Update and possible adoption of an opinion on the GBR of a number of Third Countries.

The SSC discussed and amended the reports and draft opinions prepared by the Working Group on Geographical BSE Risk Assessment (GBR) on the geographical BSE risk in Botswana, Lithuania, Namibia, Nicaragua and Swaziland. It adopted the opinions attached as Annexes 5-9.

The SSC further agreed that information on the trade of possibly BSE-contaminated material from or into a country that is not the object of a request for a scientific opinion on its geographical BSE risk, could be used as additional input information for the assessment of the risk level of another country for which such a request had been submitted. For example, data on triangular trade of possibly contaminated MBM via Greece (which is not the object of a request for a GBR assessment) could be used to assess the BSE risk of countries that imported this material from Greece and for which the GBR-assessment is ongoing.

c. Progress report on pending questions:

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

The BSE/TSE *ad hoc* Group is preparing a report and opinion on the BSE Epidemiology question submitted by Commission Services to the SSC at its meeting of 7-8 December 2000. It is currently not possible to estimate when a final draft would be available for discussion by the SSC.

- **Medical instruments.**

The Scientific Committee on Medicinal Products and Medical Devices monitors developments in the field of the safety of / possible risks related to medical instruments used for surgery and will raise the awareness of the Commission services and of the SSC should the need arise.

Reference was made to the SEAC opinion on disposable tonsil-ectomy instruments. The ongoing research at the Neuro-Pathology Unit of the University College of London funded by the UK Department of Health was also mentioned as a source of information for the SC-MPMD.

- **Origin of BSE (including possibly not yet explored ones), transmission and 3 rd route.**

The BSE/TSE *ad hoc* Group is preparing a report and opinion on the Origin of BSE (including possibly not yet explored ones), transmission and 3 rd route. However, no progress had been made so far as priority had been given to other issues such as the geographical BSE risk and the pre-emptive risk, assessment should BSE in sheep be found. It is currently not possible to estimate when a final draft would be available for discussion by the SSC. The SSC further proposed that this item could possibly form the object of a small workshop to be organised at a forthcoming meeting and to which a few selected experts would be invited.

- **Treatment and disposal of animal waste by alkaline hydrolysis at elevated temperature.**

The BSE/TSE *ad hoc* Group is preparing a report and opinion on this question. A final draft is expected to be available for discussion by the SSC at its meeting of 29-30 March 2001.

- **Safety of organic fertilisers and soil conditioners.**

The BSE/TSE *ad hoc* Group is preparing a report and opinion on the question. It is currently not possible to estimate when a final draft would be available for discussion by the SSC.

- **Alternative ways of disposal.**

Prof.Bridges presented a draft overall frame for preparing a consistent series of opinions on alternative ways of storing and/or disposing of TSE risk animals, materials and products, in addition to the ones already discussed in SSC opinions. He had prepared this at the request of 1 February 2001 of the TSE/BSE *ad hoc* Group. The SSC welcomed the draft and referred it to the TSE/BSE ad hoc Group for appropriate action.

- **Safety of collagen.**

The BSE/TSE *ad hoc* Group is preparing a report and opinion on the safety of collagen. A final draft is expected to be available for discussion by the SSC at its meeting of 29-30 March 2001.

- **Literature survey on milk.**

The BSE/TSE *ad hoc* Group is preparing a state of the art report on the available research results and scientific evidence on the safety of ruminant milk. A final draft may be available for discussion by the SSC at its meeting of 29-30 March 2001, but delays are not to be excluded as the rapporteur is also involved in a number of other pending questions.

- **Scientific background to the Austrian measures.**

Following the discovery of BSE cases in Germany, Austria envisaged a number of safeguard measures and provided the Commission with a scientific justification.

d. New questions: safety of tallow.

The secretariat informed the SSC of a new question on the safety of tallow with respect to BSE/TSE risk. More precisely, the SSC was invited to specify, in the light of new and not yet published scientific evidence, the process conditions for the application of an additional heat/pressure treatment as recommended in its opinion of 12 January.

e. Other issues

- Safety of human-derived products

Prof.Loewer raised the issue the emerging need to provide guidance for assessing the risk that vCJD occurs in function of the geographic location. This need emerges from the different approaches of risk managers throughout the world, e.g. concerning the safe sourcing of blood. More precisely, he raised the question whether it would be desirable to develop a methodology for the evaluation of the "geographical vCJD risk" of countries and / or to establish a compliance matrix between GBR-risk levels and risk levels for exposure to vCJD infectivity via human-derived products. The SSC considered that such an exercise "Geographical vCJD risk" is almost not feasible because the required data most likely would simply not be available or retrievable. The example was given of how difficult it had been to find a minimum of real data in the framework of the preparation of the SSC's opinions on Human Exposure Risk and on feeding practices of sheep.

However, it was recognised that a contribution to the harmonisation at EU level of approaches with regard to the use of human-derived products would be most welcome. Such enhanced harmonisation would reduce the occurrence of contradictions / inconsistencies between risk assessments made by national authorities and the resulting risk management measures. Presently a lack of harmonisation exists regarding, for example, blood donorship of persons who themselves have been blood recipients; the critical national vCJD incidence level to exclude people from becoming donors; the length of stay of a person in a vCJD country before considering him/her for exclusion from blood donorship; etc.

It was agreed that the secretariat would submit the above issue on behalf of the SSC to the appropriate Services of the Commission.

- Compliance between the GBR risk levels and the risk scale used in the product safety opinions (gelatine, tallow, etc.)

Prof. Jones signalled that the SSC needed to establish a compliance matrix between the "risk levels" in the SSC opinions on product safety (e.g. gelatine) and the GBR risk levels, especially concerning the use of some of these products in a human medicinal product safety context. This issue would be further discussed at a next meeting, for example at the occasion of the adoption of future opinion on the safety of a product or on the basis of a proposal from the secretariat.

7. Organisational matters.

No other organisational matters were discussed.

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

This point was not addressed.

9. Any other business.

No other business was discussed.

The meeting ended on Friday 9 February 2001, at 17h30

***Annex 1*: List of participants in the Scientific Steering Committee meeting on 8-9 February 2001.**

***Members of the SSC*:**

Ing. Georges Bories, Prof. James W. Bridges, Prof. Johanna Fink-Gremmels (8 February only), Prof. Anthony R. Hardy (8 February only), Dr Keith Jones, Prof. Werner Klein, Dr Ada Knaap (excused), Dr Ib Knudsen, Dr Pierre Le Neindre, Prof. Johannes Löwer, Prof .Albert Osterhaus, Prof. Gérard Pascal, Prof. Pere Puigdomenech (8 February only), Prof. Vittorio Silano, Prof. Staffan Skerfving (8 February only), Dr Ian White, Dr Susan Barlow [representing Dr Knaap] (8 February only)

Invited Expert:

- Dr Emmanuel Vanopdenbosch (not present 8 February morning)

***Participants from the Commission*:**

DG SANCO: B. Carsin, C. Berlingieri, P. Vossen, J.Kreysa, J.L. Jouve, S. Abildgaard, I. Rollier, A. Dehove, G. Morrison, V. Van Haeperen, M. Walsh, G. Costa David, D. Pettauer A. Van Elst, E. Poudelet, A. Fokkema, I. Demade.

CABINET: B. Montague

***Annex 2*:** Agenda of the Scientific Steering Committee Meeting of 8-9 February 2001

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

2. Approval of the agenda

3. Approval of the minutes of the meeting of 11-12 January 2001

4. Procedural matters

a. Declarations of interest;

b. Rules of procedure;

c. Curriculum vitae;

d. Membership of the TSE/BSE ad hoc Group

5. Multidisciplinary matters:

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

b. Harmonisation of risk assessment methods (draft mandate and membership of a task force);

c. Safety of cotton (progress report);

d. Emerging scientific issues (progress reports from task forces, working groups and scientific committees; report from the secretariats);

e. New questions.

6. Multidisciplinary matters relating to TSE/BSE

6.1. Report by the chairman of the TSE/BSE *ad-hoc* group meeting of 1 February 2001

6.2. Reports on specific issues:

a. Pre-emptive opinion on risk scenarios, should BSE in sheep be found under natural conditions. Monitoring of research results on experimental BSE in small ruminants.

b. Update and possible adoption of an opinion on the GBR of a number of Third Countries.

c. Progress report on pending questions:

- BSE epidemiology (survey methods);
- Medical instruments;
- Origin of BSE (including possibly not yet explored ones), transmission and 3 rd route;
- Treatment and disposal of animal waste by alkaline hydrolysis at elevated temperature;
- Safety of organic fertilisers and soil conditioners;
- Alternative ways of disposal (including adoption of an outline for progressing the storage/disposal issue).
- Safety of collagen;
- Literature survey on milk.
- Scientific background to the Austrian measures.

d. New questions: safety of tallow.

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

8. Information by the Commission services on 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 11-12 January 2001.**

(Complete information at the webpages of the Scientific Committees)

Scientific Committee on Food (SCF)

The SCF has not met since the last SSC meeting on 11/12 January 2001. In the meantime, work has continued in meetings of the SCF Working Groups on Food Microbiology and Hygiene, Additives, Flavourings, Contaminants (finalisation of the discussion on Fusarium toxins, including 5 individual toxins and a group evaluation) and Novel Foods. The meeting of the latter was held jointly with the SCP working group on GMOs, a practice that will be maintained for the future meetings.

Scientific Committee for Plants

The SCP met on 26 January. At this meeting the following 3 opinions have been adopted by the Committee:

- Opinion regarding the evaluation of pymetrozine in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Opinion expressed by the Scientific Committee on Plants on 26 January 2001).
- Opinion regarding the evaluation of flurtamone in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Opinion expressed by the Scientific Committee on Plants on 26 January 2001).
- Opinion regarding the evaluation of carfentrazone-ethyl in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Opinion expressed by the Scientific Committee on Plants on 26 January 2001).

On 1 February, the newly established joint "GMO/Novel food" working group held its first meeting.

The special ad hoc working group on contamination of conventional seeds by GM plants is preparing a draft opinion which is expected to be ready for adoption by the Committee at the next plenary meeting of 7 March.

(Note: identification of specific horizontal issues to be eventually reported to the SSC is in SCP chairman hands.)

Scientific Committee on Animal Nutrition (SCAN)

The Committee adopted in January 2001 revisions of reports on the safety of enzymes and of micro-organisms. Other questions were discussed but no document adopted. New questions were submitted by the Commission and ad hoc working groups were created. For one of these, involving a genetically modified micro-organisms, the GM aspect will be addressed in the cross-sectorial (SCP, SCF & SCAN) Working Group.

The Chairman introduced the work of the SSC, in particular the needs for participants in various SSC working groups.

SCAN identified members who will attend them.

Scientific Committee Veterinary Measures relating to Public Health

No meeting was held since the last SSC meeting

Scientific Committee on Animal Health and Animal Welfare

The Scientific Committee on Animal Health and Animal Welfare met on 19 January 2001

1. Election of Officers

The committee elected the following officers:

Chairman Dr Pierre Le Neindre

First Vice Chair Dr Reinhard Ahl

Second Vice Chair Prof. Per Jensen

The Committee has two statutory sub committees. Dr Ahl was elected chair of the sub committee on Animal Health and Prof. Jensen was elected chair of the sub committee on animal welfare.

2. Review of ongoing work

Fish waste

This group is examining the possible transmission of disease agents through fish feed and the treatments or other methods required to deal with the risks. Some species of fish (eg turbot) which have recently begun to be farmed require untreated feed, especially early in life. A working group was established and it has met once.

Diagnostic tests for CBPP

A working group selected

Brucella melitensis

This is an important zoonosis which is found in Mediterranean countries. A working group has met on several occasions and document reviewed at previous subcommittee meeting. Considerable editing is needed but nearing finalisation.

Welfare of fur animals

A working group established and met on several occasions, most recently on 1 February. The report is nearing finalisation.

Welfare of animals kept for beef production

A working group was established and met on several occasions. Also this report is nearing finalisation.

Welfare aspects of animal transport

The question was discussed in general terms at the last subcommittee meeting. This will be a major review which is planned to complete by the end of the year 2001.

3. New questions for the Committee

Two new questions were put to the Committee:

Review of policy on Psittacosis

Community legislation requires tests for psittacosis on parrots on importation into the EU and for measures if positives are detected. There are no legislative provisions relating to this condition in any other circumstances. The committee is asked to review this condition and especially the zoonotic aspects to assist in future policy making.

Bovine Wasting disease

The Committee is asked to review epidemiological information concerning the existence of this condition as a possible emerging condition.

4. Relations with the Scientific Steering Committee

TSE ad hoc Committee

The Committee nominated a representative in the TSE ad-hoc committee. The committee also suggested that other members would also be useful in this area and could contribute on specific questions.

Emerging issues

The Committee is extremely interested in this issue as most emerging viruses are zoonotic conditions. It was decided to await the exact question and the decision of the SSC about handing this question before nominating experts.

Antimicrobial resistance

The Committee drew attention to a very recent review by Prof. Radositis (World Buiatrics Congress) covering this area.

Harmonisation of Risk Assessment Procedures

Two members were appointed who will continue to liaise in this task.

Scientific Committee for Toxicity, Ecotoxicity and the Environment

A. Opinions/position papers were adopted on the following:

1. Risk assessment reports of: a) Acrylonitrile; b) Anisidine; c) Methyl methacrylate; [all these produced under the so-called Existing substances Regulation (793/93)].

2. Opinion on **i)** *Technical Specifications for Classification and Presentation of Ecological Status of Surface Waters*; **ii)** *Technical Specifications for Monitoring of Ecological Status of Surface Waters*; **iii)** *Development of a Specification for the Intercalibration of Biological Monitoring Methods*.

3. *The use of exposure data in risk assessments*.

4. *Margins of safety*.

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

i) *Evaluation of sludge treatments for pathogen reduction*

ii) *Carcinogenic and non-carcinogenic effects of Cadmium, Nickel and Arsenic in ambient air*

iii) *Derivation of limit values for PAH in ambient air.*

iv) *Health effects of Radio Frequency and Electromagnetic fields* **.**

v) *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

vi) *The availability of substitutes for soft PVC containing phthalates in certain toys and childcare articles* - RPA final report ETD/99/502498

vii) Evaluation of the following Regulation 793/93 Risk Assessment Reports:

On Risk assessment reports on Human health & Environmental effects:

a) *Acrylamide*; b) *Dibutyl phthalate*

On Risk assessment reports on Environmental effects:

Methyl-tert-Butyl Ether.

On Risk assessment reports on Human health effects:

Nonylphenol and nonylphenol (branched).

viii) *Proposed standards for a revised bathing water directive*.

Scientific Committee for Cosmetics and Non-Food Products

Since the last SSC plenary meeting, 3 Working Party meetings of the Scientific Committee on Cosmetic Products and Non-Food Products have taken place. No items of a multi-disciplinary nature have been discussed.

However it has to be underlined that the SCCNFP is confronted with increased difficulties in implementing its tasks of risk assessment of ingredients used in cosmetic products because of the planned ban of animal testing. For example, Member States regularly request updating of toxicological data when the proposed studies are too old and do not comply with the present standards (cf. Risk assessment of hair dyes) and blame Industry and the SCCNFP when these animal studies are requested.

Presently, the proposed 7 th Amendment of the "Cosmetics" Directive is being discussed at the European Parliament (EP). In the Draft Amendment a testing ban in the European Union is proposed with a deadline for all animal tests in about 5 years; the rapporteur to the EP is in favour of a marketing ban of cosmetic products containing ingredients tested on animals after a specific date added to a testing ban. In these conditions the SCCNFP will not be able to exercise an appropriate advisory function.

Scientific Committee for Medicinal Products and Medical Devices

No meeting was held since the last SSC meeting

Annex 4

OPINION

PRE-EMPTIVE RISK ASSESSMENT SHOULD BSE IN SMALL RUMINANTS BE FOUND UNDER DOMESTIC CONDITIONS.

Adopted by the Scientific Steering Committee

At its meeting of

8-9 February 2001

(Distributed separately)

Annexes 5 - 9

Opinions of the
Scientific Steering Committee
on the

GEOGRAPHICAL RISK OF
BOVINE SPONGIFORM ENCEPHALOPATHY (GBR) in
Botswana, Lithuania, Namibia, Nicaragua and Swaziland

Adopted on 8-9/02/2001

(Distributed separately)