

Summary minutes of the meeting of 8 - 9 December 1997

1. Welcome, apologies, introductory remarks

Prof.M.Van Belle, vice-chairman, opened the meeting at 14h00 on behalf of Prof.Pascal, who could not be present until 15h30. He welcomed the participants and apologised some of the members who could not attend on 8 December 1997 due to long standing commitments. The date of the present meeting had indeed been fixed by the end of November only. The list of attendance is given as annex 1.

2. Approval of the agenda

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

3. Approval of the minutes of the meeting of 21 November 1997

The draft minutes of the meeting of 21.11.97 were adopted without changes.

4. Multidisciplinary matters - 1

From this item onwards, the meeting was chaired by Prof.Pascal.

4.1. Priority matters related to Transmissible Spongiform Encephalopathies

a) Prof.Wierup, Prof.Gibney and Prof. Vanbelle introduced the draft reports and opinions prepared by, respectively, the working groups on:

- The UK Date Based Export Scheme and the Offspring Cull proposal;
- Specified risk materials;
- The safety of tallow and of meat and bone meal.

The latest versions of the reports were distributed, and informative questions were answered by the rapporteurs. However, no in-depth discussions were held at this point. The participants were invited to study the reports in preparation of the discussions planned for the second meeting day.

For what concerns the criteria ("compliance matrix") for the evaluation of the TSE status of a country, a first draft list was distributed during the meeting. The list contains the proposed information and elements which should be included in the dossier submitted by a country as justification supporting its claim of TSE, scrapie and/or BSE freedom. This list is the result of a first analysis of the applications submitted by New Zealand, Australia and the USA which have already been scrutinised by the former Scientific Veterinary Committee. The preparation of a complete report on the matter was still in progress and the item was thus referred for further discussed during the next meeting of the SSC.

b) For what concerns the future treatment of pending TSE/BSE related questions, the following two basic decisions were taken regarding the short and medium term planning of the activities:

- 1) Apart from the previously listed questions, the next most urgent matters, which need a finalised opinion in the beginning of 1998 are :

- a) The safety of gelatine
- b) The issue of feeding of MBM to fur animals
- c) The safety of peptides and amino acids
- d) The safety of di-calcium phosphate
- e) The safety of organic fertilisers

Prof. Vanbelle was appointed chairman and rapporteur of a working group to address these questions. The following calendar was proposed: for the meeting of 22-23 January 1998, draft final reports on the safety of gelatine and of di-calcium phosphates should be ready for possible adoption. On the remaining questions (feeding of meat and bone meal to fur animals, the safety of peptides and amino-acids and the safety of organic fertilisers), draft final reports should be available for the meeting of 19-20 February 1998. The report on the safety of peptides and amino-acids would be largely based on the preparatory work already carried out by Prof.Pascal.

It was agreed that Prof.Pascal would become member of this working group. It was further agreed that the drafts of the reports on gelatine and on di-calcium phosphate would also be send to Prof.Jones, for possible comments by (an) experts from the Committee on Medicinal Products and Medical Devises. Prof.Jones would identify such expert(s). If necessary, they could join the working group.

2) The medium term planning, organisation of the TSE/BSE ad hoc group, its composition, calendar of meetings and attribution of pending questions would be further discussed during a special meeting of the TSE/BSE ad hoc group. This meeting has been set for 19 December 1997.

However, the following points were already agreed upon :

- On the size of the TSE/BSE ad hoc group it was agreed to keep it as small as possible, in practice a core team of 8-12 fixed members. This team was to be assisted on a case by case basis by a roster of experts in the various specific disciplines relevant for the different aspects of the TSE problematic. (See also item 5.1.)
- On the aspect of the safety of human blood, the ad hoc Group would not work on its own only, but would also exploit the results of the risk analysis recently initiated by the UK Spongiform Encephalopathy Advisory Committee (SEAC). The SSC Secretariat was charged to contact the SEAC Secretariat on this matter.
- It was also agreed to put the *safety of slaughter methods and practices* on the list of pending TSE/BSE issues to be studied by the ad hoc Group.

4.2. Genetically Modified Organisms :

a) State of affairs of the works related to the scientific evaluation of the dossiers on three genetically modified maize varieties and on one genetically modified winter rape seed variety.

Prof. Silva-Fernandes, chairman of the Scientific Committee Plants (SCP), reported that a working group had been installed composed of 10 members of the Scientific Committee Plants, 3 members of the Scientific Committee Animal Nutrition, 1 member of the Scientific Committee on Food and 1 member from the Scientific Committee on Toxicity, Ecotoxicity and the Environment. The SSC was of the opinion that the latter 2 Scientific Committees were underrepresented and urged the working group to increase the number of specialists in these fields. [*from the SSC Secretariat: during the SCP meeting of 22.12.97, the working group compistion has been updated. The full composition is given in the corresponding SCP meeting report.*]

Prof.Silva-Fernandes further reported that, so far, he had received only one really complete dossier, containing the reports and documentation from the applicant, the full evaluation report from the members state, additional articles and background notes, etc. The other 3 dossiers were still incomplete, sometimes only limited to a short background note. It

was agreed that, in the future, the SSC chairman or the chairman of the leading Scientific Committee would systematically and formally request the complete sets of documents and of evaluation reports related to each application.

Mr.Rogers (Forward Studies Unit) further indicated that it was necessary to evaluate whether for different dossiers, the same or different methods and criteria of evaluation were used. Prof.Pascal elaborated further on this subject and stated that such exercise, if applied from now onwards, could eventually result in an harmonisation of evaluation criteria or "harmonised compliance matrix" so that the evaluation results of all future dossiers are comparable between them. He referred in this context to related works already carried out by the Joint Research Centre, which could be exploited by the SSC and the Scientific Committees.

5. Organisation of the Scientific Steering Committee - 1

5.1. TSE/BSE *ad hoc* group:

The tasks and functioning of the group and the initial planning and handling of priority matters was already discussed as part of previous item 4.1.b).

For what concerns the membership, and following the decision made during the meeting of 21 November, Prof.Bories, Prof.Osterhaus, Prof. Garrido-Abellan and Prof. Knudsen proposed the following scientists from their respective Scientific Committees to become member: Prof. G.Piva (Scientific Committee Animal Nutrition), Prof.P.Willeberg (Scientific Committee Veterinary Measures relating to Public Health), Dr.E.Vanopdenbosch (Scientific Committee Animal Health and Animal Welfare) and Dr.S.Barlow (Scientific Committee Food). *[from the SSC Secretariat: at the time of writing these minutes, all scientists except Dr.Barlow accepted the nomination. To replace Dr.Barlow, Dr.Verger of the same Committee has been contacted and accepted the nomination]*

The discussion on the required additional expertise and the identification of potential members, as well as the establishment of a roster of high level experts in various specific fields related to TSE/BSE, will be initiated during the meeting of the ad hoc group on 19.12.97.

5.2. Dates of the next meetings and general planning (calendar) for 1998. The calendar of the meetings in 1998 as agreed upon is attached as annex 3.

6. Multidisciplinary matters - 2

6.1. Priority matters related to Transmissible Spongiform Encephalopathies.

The Scientific Steering Committee proceeded with a detailed discussion on the draft reports and opinions prepared by the working groups on:

a) The UK Date based export scheme and the UK Offspring cull proposal.

b) Specified risk materials.

Given their importance and urgency, absolute priority was given to these two items. As a result it was decided to postpone the discussion on Criteria ("compliance matrix") for the evaluation of the TSE status of a country to the next meeting and to follow a written procedure for the adoption of the draft reports and opinions on Tallow and on Meat and bone meal.

First, the draft report on the *UK proposals for a Date Based Export Scheme and the Offspring Cull* were discussed in detail. The participants introduced a number of modifications and amendments in the draft and eventually adopted the report given as annex 6.

Secondly, the draft report on *Specified risk materials* was discussed in detail. Modifications and amendments were progressively introduced in the draft. It was decided not to discuss in detail the issues related to the geographical aspects of the BSE risk, but to refer them to a working group which should report on it before the next meeting of 22-23 January 1998. It appeared indeed that more time was needed to develop a consistent and balanced text on the geographical aspects and that it was unrealistic to expect that the whole matter could adequately discussed during the meeting. The report that eventually was adopted is attached as annex 7. As suggested by Dr.Hansen (DGXII), this report also includes a section on future research needs.

7. Organisation of the Scientific Steering Committee - 2

The main item on the agenda was a further discussion on the internal rules of procedure for the SSC introduced during the meeting of 21 November 1997. But due to a lack of time (the highest priority had been given to the discussion and adoption of the reports on the UK Date base export scheme and Offspring cull proposal and on the Specified risk materials), this item was referred to a next meeting.

The SSC secretariat informed the members that the translation into English of the summary text on the mandate of the SSC was in progress and would be attached to these minutes. (See annex 4).

8. Co-ordination matters

8.1. For the same reasons was the discussion on the internal rules of procedure for the scientific committees referred to the next meeting,

8.2. No reporting was done by the chairpersons of the 8 Scientific Committees, as none of them had a meeting since the last SSC meeting on 21.11.97.

8.3. Allocation of multidisciplinary matters which do not concern TSEs to scientific committees.

a) On Bovine Somatotropine : assessment of risk for man and animals. A short briefing note was distributed during the meeting. It is given in Annex 5. The Scientific Steering Committee decided that the Scientific Committee on Veterinary Measures relating to Public Health would act as leading Committee for this specific issue and asked that Scientific Committee to complete its working group with experts from the Scientific Committees on Animal Health and Welfare, on Food and on Animal Nutrition. If such appears useful, the Scientific Committee on Medicinal Products and Medical Devices would also be consulted. The SSC secretariat would provide the documentation on the subject presently available at the level of DGXXIV.

b) On Zoonoses : the possible links between Johne's disease and Crohn's disease. A short briefing note was distributed during the meeting. It is given in Annex 5. The Scientific Steering Committee decided that the Scientific Committee on Animal health and Animal Welfare would act as leading Committee for this specific issue and asked that Scientific Committee to complement its working group with an expert from the Scientific Committee on Veterinary Measures relating to Public Health. If such appeared necessary the working group would be further completed with experts from the Scientific Committees on Food and on Animal Nutrition. The SSC secretariat would provide the documentation on the subject presently available at the level of DGXXIV.

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

Dr.Hansen (DGXII) informed the SSC on the DGXII activities related to R&D in the field of TSEs. A call had been launched on 29th April 1997 and closed on 15 July 1997. The evaluation process was presently in its final stage with 23 projects being proposed to the Commission for funding. However most of these projects address the issue of the TSE agents, their identification and transmission, but few are the proposals related to risk assessment. DGXII is therefore planning to organise in early 1998 a workshop to which Europe's most outstanding experts in this latter field will be invited. A more "risk assessment" targeted call for proposals will then be launched in consolation with the TSE/BSE ad hoc group and with DGXXIV.

Due to a lack of time (the highest priority had been given to the discussion and adoption of the reports on the UK Date base export scheme and Offspring cull proposal and on the Specified risk materials), the presentations by the other Commission services were further referred to the next meeting.

10. Any other business : No further business had been put on the agenda.

The meeting ended at 17h30.

Annex 1 : List of participants of the Scientific Steering Committee meeting of 8 and 9 December 1998

Presence on 8 December 1997	Presence on 9 December 1997
<p>Members of the MDSC/SSC :</p> <ul style="list-style-type: none"> - Prof. Georges Bories - - Prof. Michael J. Gibney - Prof. Philip James - Prof. Keith H. Jones - - Prof. Werner Klein - Prof. Ib Knudsen - Prof. Robert Kroes - Prof. Albert Osterhaus - Prof. Gérard Pascal - - Prof. Antonio M.S. Silva-Fernandes - Prof. Marcel Vanbelle - Prof. Martin Wierup 	<p>Members of the MDSC/SSC :</p> <ul style="list-style-type: none"> - Prof. Georges Bories - Prof. W. Bridges - Prof. F. Garrido-Abellàn - Prof. Michael J. Gibney - Prof. Philip James - Prof. Keith H. Jones - Prof. Fritz H. Kemper - Prof. Werner Klein - Prof. Ib Knudsen - Prof. Robert Kroes - Prof. Albert Osterhaus, - Prof. Gérard Pascal - Prof. Vittorio Silano - Prof. Antonio M.S. Silva-Fernandes - Prof. Marcel Vanbelle - Prof. Martin Wierup
<p>Participants from the Commission:</p> <p>DGIII: O.Rohte, L.Bansil</p> <p>DGV: P.Peters, A.Berlin</p> <p>DGVI: P.Colombo</p> <p>DGXI: K.Doehler</p> <p>DGXII: B.Hansen, X.Goenaga</p>	<p>Participants from the Commission:</p> <p>DGIII: O.Rohte, L.Bansil, H.Bernard</p> <p>DGV: P.Peters, A.Berlin</p> <p>DGVI: P.Colombo</p> <p>DGXI: K.Doehler</p> <p>DGXII: B.Hansen, X.Goenaga</p>

DGXV: A.Matton

Forward Studies Unit: M.D.Rogers

DGXXIV: B.Carsin, P.Brunko, J.Kreysa, C.Deckart, C.Diez, G.Morrison, J.Moynagh, W.Penning, P.Vossen, M.Walsh, R.Vanhoorde

DGXV: A.Matton

DGXXIV: H.Reichenbach, B.Carsin, J.Costa-David, T.Emmerling, J.Kreysa, C.Deckart, C.Diez, G.Morrison, J.Moynagh, J.J.Rateau, A.Sanabria, A.Van Elst, P.Vossen, M.Walsh, R.Vanhoorde, M.Zampaglione

For 8 December 1998, apologies were received from: Prof.Bridgens, Prof.Kemper, Prof. Silano and Prof.Garrido.

Annex 2 : Agenda of the Scientific Steering Committee meeting of 8-9.12.97

Monday 8 December 1997 (14h00 - 18h00) :

1. Welcome, apologies, introductory remarks

2. Approval of the agenda

3. Approval of the minutes of the meeting of 21 November 1997

4. Multidisciplinary matters - 1

4.1. Priority matters related to Transmissible Spongiform Encephalopathies

a) Update on progress made since last meeting by rapporteurs and discussion

- The UK proposals for a Date Based Export Scheme; and the Offspring Cull as amendment to the BSE eradication and control plan.

- Criteria ("compliance matrix") for the evaluation of the TSE status of a country.

- Specified risk materials.

- Tallow.

- Meat and bone meal.

a) Future treatment of pending questions as listed in annex.

4.2. Genetically Modified Organisms :

- Three genetically modified maize varieties and on one genetically modified winter rape seed variety: state of affairs;

- General treatment of GMO-related issues: measures taken.

5. Organisation of the Scientific Steering Committee - 1

5.1. TSE/BSE *ad hoc* group :

- tasks and functioning of the ad-hoc group;

- definition of required expertise and identification of potential members;

- initial planning and handling of priority matters.

5.2. Dates of the next meetings and general planning (calendar) for 1998.

Tuesday 9 December 1997 (9h00 - 16h30) :

6. Multidisciplinary matters - 2

6.1. Priority matters related to Transmissible Spongiform Encephalopathies, as far as possible adoption of opinions

- The UK proposals for a Date Based Export Scheme; and the Offspring Cull as amendment to the BSE eradication and control plan.

- Criteria ("compliance matrix") for the evaluation of the TSE status of a country.

- Specified risk materials.

- Tallow.

- Meat and bone meal.

7. Organisation of the Scientific Steering Committee - 2

- Internal rules of procedure for the SSC, discussion

8. Co-ordination matters

- Internal rules of procedure for the scientific committees, discussion;

- reports by the chairpersons of the 8 Scientific Committees;

- allocation of multidisciplinary matters which do not concern TSEs to scientific committees.

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

10. Any other business.

Attachment to Annex 2 :

Pending matters to be treated by the Scientific Steering Committee (as of 27/11/1997)

I. Matters of a multidisciplinary nature, but not related to BSE

a) Bovine Somatotropine:

- Assessment of risk for man and animals.

b) Zoonoses:

- Possible links between Johne's disease and Crohn's disease.

II. Matters related to Transmissible Spongiform Encephalopathies, currently not treated by the SSC :

The SSC is requested to deliver or initiate scientific advice on :

(1) Safety of products (food and non-food) derived from animal material :

a) Gelatine

b) Feeding of MBM to fur animals

c) Peptides and amino acids

d) Bi-calcium phosphate

e) Organic fertilisers

(2) Disposal of animals and animal tissues (SRM) assumed to carry a risk of being infected with BSE :

(a) plan proposed by UTG and submitted via the E.P.

(b) environmental impact of several possible methods of disposal

(c) the use of BSE infected cattle waste as combustible in power stations

(3) Maternal transmission

(a) Routes of infection

(b) Risk assessment for these routes

(c) Options to mitigate the risk from these routes

(4) Animal-derived rennet

(a) Need for carrying out a risk assessment and transmission studies

(5) Scrapie infectivity of peripheral nerves of sheep: implications in a BSE context

(6) Transmission of nv-CJD via infected human blood

III. Issues which might lead to questions in the near future

(1) Risk to spread BSE infectivity through cross contamination of different tissues by using (pneumatic) stunners during the slaughtering process of cattle.

Annex 3 : Calendar of the Scientific Steering Committee meetings in 1998

Third meeting of the SSC : 22 and 23 January

Fourth meeting of the SSC : 19 and 20 February

Fifth meeting of the SSC : 26 and 27 March

Sixth meeting of the SSC : 16 and 17 April

Seventh meeting of the SSC : 14 and 15 May

Eighth meeting of the SSC : 25 and 26 June

Ninth meeting of the SSC : 16 and 17 July

Tenth meeting of the SSC : 24 and 25 September

11th meeting of the SSC : 22 and 23 October

12th meeting of the SSC : 12 and 13 November

13th meeting of the SSC : 10 and 11 December

The timing of the meetings is as follows :

First day: from 11h00 to 18h00

Second day: from 9h00 - 16h30

Annex 4 : Mandate of the Scientific Steering Committee. Presentation by B.Carsin, DGXXIV-B at the first meeting of the SSC, 21 November 1997.

The SSC has a major role to play in helping the Commission design a consumer health protection policy. This role was not initially foreseen, i.e. before the decision setting up the SSC on 10 June 1997, and had been defined by the Commission in its communication of 30 April 1997.

What is this role?

- 1) Co-ordinate the work of the Scientific Committees that have been set up;
- 2) Deliver scientific opinions;
- 3) Help the Commission by alerting it and via monitoring.

Co-ordination

1. Evaluation,

follow up,

harmonise, if necessary, the working methods of the scientific committees.

First exercise in this field: the rules proposed for the functioning of the various committees will be submitted to the SSC.

2. **Identify** the committees involved when a question requires that several committees be consulted (in other words orchestrate the committees' work when a question is of a multidisciplinary nature).

Examine the opinions delivered (when several opinions are delivered).

(If necessary) **ensure** a coherent, overall view (i.e. if the opinions diverge considerably, see to it that a consistent synthesis is prepared).

One exercise in this field now before the SSC concerns GMOs.

3. **Evaluate**, at the Commission's request, the need for a scientific opinion at Community level and select the committee to provide it, whenever Community measures are based on assessments made by scientists belonging to Member State organisations.

Example : pesticide authorisation system based on national assessments : peer review procedures at Community level will be organised under the authority of the SSC.

Delivery of opinions

1. Delivery of scientific opinions, at the Commission's request, only on questions which do not come within the terms of

reference of a specific scientific committee.

Delivery of scientific opinions on multidisciplinary aspects of TSE and notably BSE. To this end, the SSC creates an **ad hoc group** chaired by one of its members.

Assistance, alerts, monitoring

This is largely a matter for the Committee's own initiative.

1. **Identification** of areas in which mandatory consultation of the Committees must be provided for. Example: do
GMOs

merit such consultation?

2. **Alert** the Commission on all emerging questions relating to consumer health.

3. **Monitor** the review of procedures for assessing existing risks and **propose**, if necessary, the development of new risk
assessment procedures in such fields as food-related illnesses, transmissibility of animal diseases to man, etc.

Certain aspects of this mandate must be highlighted.

1. The SSC will be the main source of scientific opinions on TSE/BSE.

This field is highly multidisciplinary, in that most of the problems concern expertise relating to several scientific
committees.

The BSE/TSE sub-committee will be a permanent SSC structure and, as the list of the questions to be addressed shows,
a very active one.

This sub-committee will not deliver opinions, since only the SSC is entitled to do this. This sub-committee will however
prepare these opinions.

It is therefore of the essence that this sub-committee include the most appropriate members and experts.

2. The SSC not only has the right to inform and to alert the Commission on major emerging issues of relevance to
consumer health, but it must also act both as a watchdog and guarantor of the most reliable scientific methods in regard
to

risk assessment.

To this end it must be in touch with the scientific literature and on-going developments in the field of consumer health
protection and food safety; it must know the implications for policy makers of the most recent research findings.

3. The SSC has a function which clearly relates to risk assessment.

Its job is not to provide opinions in regard to risk management. However, the distinction is not always cut and dried.

While the practice of scientific expertise is an autonomous and independent procedure (the very rationale for this initial
meeting today is to address to this essential concern) it is nonetheless inseparable from political, social and legal
realities.

In other words scientific expertise is not a purely intellectual exercise which scorns real problems and blithely ignores
the implications of the opinions it delivers.

That said, there is no question of coalescing two procedures which, may I repeat, are autonomous and different.

But autonomy is not the same as ignorance. It is not a question of lining up science against politics but of conciliating or indeed reconciling the two domains. It is a matter of ensuring mutual compatibility, i.e. while maintaining their distinctive characteristics and specific features, we have to reinforce their interdependence.

Without wishing to sound grandiloquent, I think this in a way is the challenge facing us.

The task is no easy one and the SSC will have a vital part to play. Its work, which is new, will be widely analysed, dissected and criticised.

Annex 5 : Short briefing notes on item 4.1.b) - Matters of a multidisciplinary nature, but not related to BSE.

a) Zoonoses: Possible links between Johne's disease and Crohn's disease.

1. Referring to recent questions on the possible link between Johne's Disease of cattle and sheep (caused by *Mycobacterium paratuberculosis*) and Crohn's Disease in Humans, the Directorate General VI-Agriculture requests the opinion of the competent Scientific Committees, on the following preliminary question :

*There has been speculation and claims recently that both Johne's and Crohn's disease are caused by the same organism, *Mycobacterium intercellulare* var *paratuberculosis* (formerly *M. paratuberculosis*). Please examine the evidence for and against a link and comment.*

2. A preliminary discussion was held on 17 November 1997, by the Scientific Committee Animal Health and Animal Welfare. A rapporteur (Professor Badiola) has been designated to further analyse the issue and to identify the expertise and members required for a working group on the subject.

3. It is proposed that the Scientific Steering Committee confirms the Scientific Committee Animal Health and Animal Welfare as the leading Committee (chef de file) on this subject.

4. Depending on the outcome of the examination, it may be necessary to ask further questions of the Scientific Committees.

b) Bovine Somatotropine: Assessment of risk for man and animals.

Recombinant Bovine Somatotropine (rBST) is a growth hormone obtained via biotechnology and genetic engineering. It can also be used in dairying for a non-therapeutic applications, i.e. milk yield enhancement.

In the European Union, there exists, until 31.12.99, a moratorium on the placing on the market and administration of rBST.

With a view to a definitive decision to be taken on this matter at the end of the moratorium, the Council has instructed the Commission to "*entrust a Working Party of independent scientists with the task of assessing the effects of using BST, in particular as regards the impact of the use of this product on the incidence of mastitis*".

However, according to some scientists, the possible risks linked to the use of BST might not be limited to an animal health issue, but risks may also exist for human health (cancer, abnormal growth, ...), animal welfare and human food quality (milk, meat). The issues to be addressed by the working part are thus of a multidisciplinary nature.

The establishment of the Working Party is under the competence of DGXXIV. As the Commission should submit to the Council, before 1.07.98, a report on the situation, the establishment of the Working Party is urgent.

Annex 6 to the minutes of the Scientific Steering Committee of 8-9 December 1997.

Report on The UK Date Based Export Scheme and the UK proposal on Compulsory Slaughter of the Offspring of BSE Cases

Opinion adopted by the Scientific Steering Committee during its Second Plenary Session of 8-9 December 1997

(Distributed separately)

Annex 7 to the minutes of the Scientific Steering Committee of 8-9 December 1997.

Listing of Specified Risk Materials: a scheme for assessing relative risks to man

Opinion of the Scientific Steering Committee adopted on 9 December 1997

(Distributed separately)