

Final summary minutes of the Meeting of 26-27 March 1998

1. Welcome, apologies, introductory remarks.

Prof.G.Pascal, chairman, welcomed the participants and provided apologies of Prof. V.Silano and Prof.Klein. The list of participants is given as Annex 1.

In his introductory remarks he reported briefly on his meeting with the Agricultural Commission of the European Parliament, 25 February 1998. He summarised it as a very positive experience and noted that at that occasion the only topic of interest to that commission was BSE. Concerning the press reports on this event, he expressed his concern of the fact that the press release had a misleading title i.e. "Chairman of the SSC proposes a total ban of MBM" while the body text was OK. This headline created some irritation.

Members requested to receive a copy of that press release which they were promised to receive together with a copy of a report on that meeting. As a general point, the wish was underlined to receive all information on events in the Euro-political area which are relating to issues treated by the SSC as soon as possible. The Commission informed the committee that DG XXIV is currently establishing a unit with exactly that task.

2. Approval of the agenda.

The agenda was approved with some minor changes (see Annex 2).

3. Approval of the minutes of the meeting of 19-20 February 1998.

The minutes of the meeting on 19/20.02.98 were approved with some minor changes.

Concerning the harmonisation of working procedures (in particular as regards exposure assessment) a discussion took place which relates to point 8.1 of the agenda and is reported there.

4. Organisation of the Scientific Steering Committee.

4.1. Internal rules of procedure for the SSC.

The Commission briefly introduced the topic by pointing to the proposed changes of the Rules of Procedure (RoP) in comparison of the version previously distributed.

The Rules of Procedure were adopted with the following remarks:

- In the introductory paragraph a phrase should be added stating that the SSC may adapt its RoP whenever it feels the need to do so.
- Paragraph 15.1 should be modified in order to make clear that opinions are not adopted by formal voting but by the majority of the members (9) agreeing to it.
- It was proposed that members should not only complete the independence declaration by spelling out direct and indirect, financial and not-financial interests, but also provide a complete, annually updated CV.
- In six months the SSC will return to the RoP in order to verify if any modification would be needed.

The final text of the RoP is included as Annex 3.

4.2 Draft format and structure for opinions

The secretariat distributed draft guidelines for the format and structure of opinions (Annex 4) which should help to realise a way of presenting opinions which is harmonised between all scientific committees. The proposal was received without further discussion, which might be taken up at a later point in time.

4.3. TSE/BSE ad hoc group

(a) Mandate and composition of the TSE/BSE ad hoc group.

There was no discussion on the mandate of the TSE/BSE ad-hoc group. It was felt that it is sufficiently clear in the decision establishing the SSC and in the RoP.

As regards the composition of the TSE/BSE ad-hoc group, it was agreed that additional experts should be invited to become members. To this end a list of potential candidates should be established by drawing from the names known to the members of the SSC, the secretariat of the SSC and to the service in DG XII responsible for TSE/BSE related research. The TSE/BSE ad-hoc group will undertake a first screening of the proposed candidates at its next meeting and propose a shortlist to the SSC. M.Gibney, when inviting members to come up with names, proposed that the four additional experts should cover the following field of expertise: Medical sciences linked to TSE, Risk assessment incl. mathematical modelling, epidemiology, basic research related to prions and TSEs in general.

(b) Tasks and functioning of the ad-hoc group: report by the chairman of the TSE/BSE ad hoc group on the organisation and planning of its activities.

M.Gibney, chairman of the TSE/BSE ad-hoc group, introduced the topic by pointing to the considerable amount of work carried out by the group over the last 4 months.

As a possible approach to streamline the work, he proposed to group the pending questions into a number of groups which should be given to specialised working groups. This proposal was briefly discussed but no final position was taken.

To support the work of the TSE/BSE ad-hoc group, it was agreed that more external expertise should be made use of. To this end, all members were asked to communicate to the secretariat an as long as possible list of experts in the field of TSE/BSE who would be suitable members of specialised working groups of the TSE/BSE ad-hoc group. The secretariat should receive this list before 7 April 1998, blend it with the already available list of BSE-experts (secretariat and DG XII, see above; 4.2(a)) and send it back to the members of the SSC before the April meeting. At that meeting a list of the most suitable candidates shall be established.

(c) Attribution of pending questions.

There was general agreement that in addition to any organisational aspect a need exists to prioritise the topics to be tackled. This prioritisation is strongly dependent on the development with regard to the Commission Decision on SRM, and a more detailed discussion of this point shall take place at the next meeting of the SSC.

However, it is clear that the validation of the post mortem test on BSE infection will be high on the agenda for the foreseeable future (WG to be created by TSE/BSE ad-hoc group), as will be the development of quantitative procedures for the risk assessment in relation to BSE, including the geographical BSE risk (WGs to be continued). M.Gibney proposed to include also the human exposure risk into the list of top priority tasks. This was agreed (WG to be created by TSE/BSE ad-hoc group).

Concerning the follow-up of the recent developments with the commission's proposal for a new SRM-Decision, it was proposed, and generally agreed to, to continue the work in terms of clearly showing the risk related to the different risk factors. Work on the quantitative risk assessment (e.g. as regards safety of gelatine, tallow and MBM but also in relation to the geographical risk) should therefore be pressed ahead. The issue has to be well communicated and the secretariat should, in co-operation with the chairman of the TSE/BSE ad-hoc group, M.Gibney, develop a proposal for an approach.

5. SSC-Opinions

5.1. SSC- Opinions ready for possible adoption

5.1.1 Report on the comments received until 16/03.98 on the preliminary opinions on the BSE risk and the safety of tallow, meat and bone meal, and gelatine.

The secretariat reported that 24 comments on the preliminary opinions have been received. These comments have been carefully analysed by the working groups Gelatine, Tallow and MBM and the TSE/BSE ad-hoc group. An overview table was established and the appropriate modifications were integrated into the preliminary opinions. The SSC appreciated the representation of the information as very clear and informative and the process as such as very useful.

5.1.2 Presentation of the draft final opinions adopted by the TSE/BSE ad hoc group and final adoption by the SSC.

Prof. Vanbelle, rapporteur for the opinions on Gelatine, Tallow and MBM, presented the modification proposed by the working groups in response to the comments received. With some minor changes, meant to clarify the relation of the opinions to the assumed geographical risk, the opinions on the safety of gelatine, tallow, and MBM were finally adopted. Prof. Vanbelle was thanked by the committee for the work he has carried out.

As regards the opinion on MBM, the SSC discussed in detail the treatment of the minority position of two members of the working group "MBM". As no member of the SSC was willing to follow that minority opinion, and as no comment received supported that position, it was decided not to include that point of view into the final opinion. It was, however, accepted to keep the reference to the minority opinion of two of its members in the report of the working group and also to include the reference to the written contributions of these members into the literature list.

Prof. Gibney, chairman of the TSE/BSE ad-hoc group and the working group "Sourcing", presented the minor modifications required on the BSE-risk opinion, which was subsequently adopted as final.

5.2 Progress report on SSC opinions in preparation

5.2.1 Safety of semen and embryos.

Contrary to the expectation the draft opinion was not ready and the topic was not further discussed. The working group was, however, requested to come up with a useable text for the next meeting of the SSC.

5.2.2 Safety of MBM for fur animals.

The working group met under the chairmanship of Prof. Piva, who will also act as rapporteur on the subject. Progress was made and a first report is expected to become available after the next meeting, scheduled for 01.04.98.

5.2.3 Safety of organic fertilisers.

Prof. Bridges, acting as rapporteur on this subject, informed the SSC that he is currently still in the information collection phase. No concrete timing was given.

5.2.4 Quantitative assessment of the propagation, incident and human exposure risks.

Prof. Osterhaus reported on the progress made by the Working Group Sourcing in collaboration with its "modelling" sub-group. He underlined the apparent usefulness of the modelling work and informed the SSC that at its next meeting he should be able to report on a first test of the models vis-à-vis concrete data. He also hoped to be able to report a first attempt to produce a handbook for the exploitation of data sets which corresponds to the list of information needed for the assessment of the TSE/BSE status of a geographical area, as established by the SSC on 23.01.98.

6. Progress reports on ongoing activities of special interest to the SSC

6.1 Genetically Modified Organisms (Prof. Silva-Fernandes, chairman of the Scientific Committee for plants)

On four GMO-plants the SC-Plants has adopted opinions on 10.02.98.

Since then the SC-Plants has been asked to assess three more GMO-crops. Additional information has been requested from Industry and is, in the meantime, distributed to the working groups. An opinion on these crops is expected for May '98.

In addition, the SC-Plant has been informed by DG XI that 6 other GMO-plants are forthcoming and working groups have been created accordingly. The files, however, have not yet been received by the SC-Plants.

The discussion focussed on the question in how far an opinion of the SC-Plant would justify a permission of the GMOs for the utilisation of food or the production of foodstuff and the clear answer from DG XI was that such a permission would require a special opinion of the SCF, focussing on that aspect.

6.2 Possible link between Johne's and Crohn's disease (Prof.Garrido, chairman of the Scientific Committee for Animal Health and Animal Welfare)

The working group on this subject met twice but the discussion is not yet conclusive. No timing could be given for the adoption of the opinion.

Upon request, Prof.Garrido informed the SSC that 3 members of the WG are medical doctors.

6.3 Bovine Somatotropine (Osterhaus, Scientific Committee for Veterinary Public Health)

A WG was set-up, met once and decided on a timetable and the work distribution.

6.4 Hormones in meat (DG XXIV)

H.Belveze, from the risk evaluation unit of DG XXIV, reported on the current state of affairs. The unit is currently putting together literature data, is planning additional research with the aim to close gaps in the knowledge, and tries to gather information on the scientific justification of the US-stand point.

Further activities will be undertaken in function of the results of this first phase.

6.5 Possible transmission of CJD via infected human blood and risk quantification for CJD transmission via substances of human origin

Prof.Jones, chairman of the Scientific Committee for Medicinal products and medical devices, is following this subject. He informed the SSC that the Committee on Proprietary Medicinal Products, of EMEA has just delivered an opinion on the subject (CPMP, Jan 1998). SEAC, the Spongiform Encephalopathy Advisory Committee, UK, is also currently looking into the matter and is expected to come up with an opinion in May. Prof.Jones recommended to follow that work closely and to decide, if additional work by the SSC is needed, once the SEAC opinion is also available, presumably in June 1998. This was agreed.

6.6 Report of all Chairmen with regard to subjects treated by the SCs

An Inventory of Scientific Opinions adopted by Scientific Committee since Nov.1997 is given in Annex 5

6.6.1 Scientific Committee on Food (SCF)

The SCF had its 111th Plenary Meeting on 18-19 March 1998. It adopted 4 opinions:

1. Opinion on zinc acetate as a flavour enhancer in chewing gum.
2. Opinion on an additional list of substances for food contact materials.
3. Opinion on *Aeromonas hydrophila* and *A. caviae* in natural mineral water.
4. Opinion on Beta-carotene.

A representative from DG XII, Dr.X.Goenaga informed the SCF on the fifth Framework Programme for Research and Development. He also made the SCF aware of food safety issues of relevance to the SCF addressed by European RTD and offered open collaboration between the SCF and DGXII.

The next plenary meeting of the SCF is foreseen in June.

6.6.2 Scientific Committee for Animal Nutrition (SCAN)

Plenary meeting on 13 March 1998, mainly focussing on administrative and organisationally matters. SCAN regards itself to be in a transition period, moving from an integral part of the risk management / legislative side to the risk assessment / scientific advice. Some questions in front of the Committee therefore have to be re-formulated.

One opinion was adopted, concerning a safeguard clause of Finland. SCAN did not regard the scientific justification of that clause to be convincing.

Several working groups are set up to deal with specific topics on Animal Nutrition.

6.6.3 Scientific Committee for Animals Health and Animal Welfare (SCAHAW)

A large number of meetings took place since the last SSC plenary:

- 23.2.98: Animal Welfare sub-committee, creation of two WGs.
- 24.2.98: WG "Gavage"
- 02.3.98: WG "Amendments Directive ...". One more meeting needed.
- 12.3.98: Animal Health sub-committee. Reports delivered.
- 13.3.98: WG "Foot and mouth disease".
- 18.3.98: WG "Bluetongue"
- 23.3.98: WG "Ventilation Standards during Transport" (created 23.2.98).
- 24.3.98: Plenary meeting of SC3. Rules of Procedures, Opinions on a definition of the Newcastle Disease (may become the basis of a proposal of the Commission to OIE of a standard definition).
- 25.3.98: WG Chrohn's disease (second meeting). Participation of a member of the Animal Welfare sub-committee in a WG of the SCVPH.

6.6.4 Scientific Committee for Veterinary Public Health (SCVPH)

Meetings of Working Groups:

18.2.98 Working Group on the use of antimicrobial treatments of poultry carcasses, the various methods of carcass

rinsing including trisodium monophosphates (TSP), organic acids and hyperchlorinated water.

18.2.98 Working Group addressing the 9th code of Federal Regulations Part 304, et al. Pathogen reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final rule.

24.3.98 Working Group on cooling of carcasses during transport;

25.3.98 Working Group on the safety of Bovine Somatotropin;

25.3.98 Working Group on possible links between Crohn's disease and paratuberculosis in animals;

Draft opinions for adoption at the plenary of April

- equivalence of two protocols for the detection of trichinella larvae in horse meat and in pork with the methods approved in accordance with Council Directive 77/96/EEC;

- modification of the methods approved in accordance with Council Directive 77/96/EEC for the detection of trichinella larvae in horse meat;

- allergic reactions to ingested anisakis simplex antigens and evaluation of the possible risk to human health

Working Group meetings planned

31.3.98 evaluation of microbiological criteria and temperatures for storage and transport of products of animal origin intended for human consumption:

- microbiological criteria;

- temperatures for storage and transport;

11.5.98 revision of ante- and post- mortem inspection procedures for an alternative inspection system for the slaughter of pigs;

26/28.5.98 Decontamination and US Megareg (Cf. above)

6.6.5 Scientific Committee for Plants (SCP)

No plenary meeting since last SSC-plenary.

WG created on carcinogenicity of new compounds.

Links to SCTEE established.

6.6.6 Scientific Committee for Cosmetology and Non-food Consumer Products (SCCNFCP)

No plenary meeting since last SSC-plenary.

Work is generally carried out in specific WGs, the most important being the WG "Alternatives", which held three meetings since.

6.6.7 Scientific Committee for Medicinal Products and Medical Devices (SCMPMD)

No plenary meeting since last SSC-plenary.

Five WG busy working, including one on GMP (good management practices) and one on blood and blood products. On the latter topic the SCMPMD is waiting for input from SEAC where the issue is just debated (see above).

6.6.8 Scientific Committee for Toxicology, Ecotoxicology and the Environment (SCTEE)

The SCTEE has not met in plenary since the last SSC meeting.

Currently there are four active working groups, covering the following issues:

- Phthalates in toys: Since the last SSC meeting there has been one further meeting of the WG at which representatives from SCF and SCCNFCP participated. Some revisions have been made to the interim opinion because of the decision to change the extraction time and child body weight assumptions. The final opinion is expected at the next plenary meeting of the SCTEE, scheduled for 24 April 1998.
- Tin, arsenic and cadmium: The first meeting of that WG has been held and an initial opinion is being drafted. The final opinion is expected for the June plenary meeting of the SCTEE.
- Water framework directive: One meeting of the WG has been held and a second will take place very shortly. Final opinion is expected at the April plenary meeting of the SCTEE.
- Pentachlorophenol: First meeting of the WG will be in week 14 (30.3.-3.4.). Final opinion possibly at the June meeting of the SCTEE.

There are also three additional issues presently in front of the SCTEE with a less certain time frame:

- Chrysotile. Additional data are requested from DG III.
- Creosate. A WG is set-up and has to meet.
- Proposal of a member of the SCTEE to establish a risk assessment framework for terrestrial animals.

7. Up-date and attribution of pending questions not relating to TSE/BSE

- Resistance against antibiotics: The SSC discussed the issue at length and it became clear that this is a very multidisciplinary problem, requiring input from many SCs. As the human issue is the critical aspect, Prof. Jones, chairman of SCMPMD, was asked to start working on a draft mandate for a working group on the subject. He will try to have a first draft of a working document as basis for an in-depth discussion at the next SSC plenary meeting. However, he is dependent of inputs from other SSC-members, in particular the chairmen of the other SCs. These should provide Prof. Jones with a list of potential experts for an eventual WG on the subject and information on issues related to it which have already been tackled or are foreseen to be tackled by the SCs. A formal mandate shall be adopted by the SSC at a later stage.
- Non-conventional medicines: The SSC found the current question too global and requested more specification of it. The secretariat should clarify the terms of reference and report on it at the next meeting of the SSC.
- Treatment of fallen stock and specified risk material: The SSC agreed that the issue should be treated by SCAHAW and SCVPH and asked the Commission to define the lead committee as appropriate.

8. Co-ordination matters

8.1. Working methods of the various Scientific Committees

8.1.a) Report of the Chairmen of the 8 Scientific Committees.

Each chairman was requested to provide the secretariat with a short summary of the working methods of "his" committee and the secretariat should put together an overview table on this.

8.1.b) Discussion on harmonisation needs.

The subject was first tackled in relation to the minutes of the previous meeting, homing in on the need to come forward with a certain harmonisation of risk assessment methods, in particular as regards to exposure assessment, applied by the different Scientific Committees.

It was felt necessary to first establish an inventory of the currently risk assessment issues currently pending before the different Scientific Committees and the methods applied and main problems encountered.

The Chairmen of the 8 Scientific Committees should provide Prof. Bridges (and in parallel the secretariat of the SSC) with that information on their committee before 7 April. Guidelines for this input are attached as Annex 4.

Prof. Bridges would then put together a working document as basis for a further discussion. This working document should focus on common elements on which a common approach could be based upon. Common problems should be identified which merits a discussion by the SSC.

8.1.c) Decision on follow-up.

See point 8.1.b)

8.2. The role of the Scientific Committees and the SSC in relation to risk assessment and risk management

This topic was not further discussed but H. Belveze informed the SSC on the role and functioning of the "risk evaluation unit" inside DG XXIV. Underlining that the exact role is still developing, he explained four main lines of activity:

- The technical monitoring of emerging risks, potential problems.
- The provision of urgently needed advice to risk managers in cases where consultation of scientific committees is not possible.
- The contribution of inputs to the development of risk assessment procedures and techniques.
- The support to risk assessments.

The SSC briefly discussed on this issue and underlined its desire that the risk evaluation unit would be complementary and not competitive to its own work.

8.3. Definition of "acceptable" or "negligible" risk level

This point of the agenda was referred to the next meeting of the SSC.

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

DG XI informed the SSC on the follow-up given to the opinions of the SC-Plants on four GMOs (see 6.1). The Regulatory Committee established under the Directive 90/220/EEC gave on 18 March 98 a favourable opinion on four draft measures proposed by the Commission, aiming at allowing the placement on the market of 3 genetically modified maize and one genetically modified rapeseed. The scientific bases for these proposals were the opinions of the SCP, adopted on 10.2.98.

DG XII reported on its recently published targeted call for proposals in the field of risk assessment in relation to TSE/BSE and invited the SSC members to identify experts in that field as candidates for the evaluation of proposals. It also asked the members to inform any suitable contact of that call.

10. Any other business

A draft press release, reporting on the meeting up until Friday lunchtime was distributed, thoroughly discussed and finally approved.

The SSC was informed on the follow-up to its SRM opinion and in particular the fate of the Commission's proposal on SRMs. Coming from the Standing Veterinary Committee, M.Rateau reported that even the slightly modified proposal of the Commission failed to receive a majority. It will probably now be put to the agricultural ministers, who meet on 31.3.98.

Members asked for a copy of the Commission's proposal as of February 1998, which was promised.

Members expressed their concern about the accumulating delays with the reimbursement of travel and subsistence cost. Some of the SSC members, and also in the other Scientific Committees, have advanced several thousands of ECU. As the situation becomes unacceptable, the Committee stated its intention to stop working if the situation is not improved at its May meeting. The chairman was asked to send a letter to Commissioner Bonino, explaining the situation.

Acknowledging the situation, Mr.Carsin, Director of DG XXIV-B, informed the SSC that until the moment of significant improvement, a pre-paid ticket system would be in force, allowing the members to avoid advancing this important part of the cost. Unfortunately he could not offer any immediate improvement as regards to the subsistence cost.