

Minutes of the Scientific Steering Committee Meeting of 27-28 May 1999

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

Prof.Dr.Pascal welcomed the participants. He apologised Prof.Dr.M.Gibney. The list of participants is attached as annex 1.

No member declared an interest in any of the point of the agenda that could conflict with his independence.

2. Approval of the agenda

The draft agenda was approved with minor changes. It is attached as annex 2. For practical reasons the chairman proposed some changes in order which were accepted.

3. Approval of the minutes of the meeting of 22-23 April 1999.

The minutes of the last meeting were approved with some minor changes.

Dr.R.Kroes apologised for not having been at the last meeting and wanted to bring to the attention of the Committee his opinion that the three new members to be nominated for the Scientific Committee for Veterinary Public Health should not exclusively be human medical doctors but preferably. The SSC agreed to this position, though it was generally understood that this competence should be strengthened in the SCVPH. However, the relevant criterion should be the experience in public health rather than a formal education in human medicine.

4. Progress on multidisciplinary matters

a. Antimicrobial resistance

The rapporteur presented the draft report which had been reviewed during the restricted drafting group meeting on 12 May and which takes into account the comments received from various SSC members.

The Committee had a long and detailed discussion on the scientific reasoning developed in the main body of the report, as well as on the executive summary and on the recommendations. Special attention was given to the coherence and overall balance of the report.

The executive summary and the full report, as amended during the plenary, were adopted and are attached as Annex 3. The Committee congratulated the chairman of the WG Dr.K.Jones, the two co-chairmen, Prof.M.Vanbelle and Prof.M.Wierup, and the secretary of the WG, R.Vanhoorde, the rapporteur and the members of the working group on the quality of the work.

The SSC recommended the Commission to ensure a close monitoring of the effects of the moratorium of the utilisation of 4 AMGPs. This should be seen as a golden opportunity to deepen the understanding of this issue.. O.Rohte, DG III, immediately proposed to present this project to the scientific co-operation network. The SSC appreciated this proposal.

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

The SSC was updated on the progress made. Two discussion documents are currently looked at by the WG. Both are focussing on the use of genetically modified organisms (plants) in food and the WG decided to concentrate on this issue.

c. Harmonisation of risk assessment procedures (progress report)

No progress made since the last meeting of the SSC.

5. Multidisciplinary matters relating to TSE/BSE

5.1. General report of the work of the TSE/BSE ad-hoc group.

Prof.A.Osterhaus, member of the TSE/BSE ad-hoc group, provided a summary report on the recent activities of the ad-hoc group. Most of the details are given under the subsequent points of the minutes.

A.Osterhaus reported in addition to the points discussed in detail below also on a discussion of the ad-hoc group on the terminology to be applied in the TSE-context as regards LD₅₀ or ID₅₀. The report of a WG on this issue is currently under revision.

He also reported on the decision taken to closely link the work of the WG-HER (approaching conclusion) and the recently established WG-HELL (Human Exposure Limit Line). Once the latter has come to a conclusion as to the relative importance of different Human Exposure Levels, the WG-HER should return to its position and complement its position with a discussion on the infection risk resulting from different exposure levels.

5.2. Reports on specific issues

a. "Fallen stock": The risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials.

Following the discussion at the last meeting and in light of the comments received on the preliminary opinion a draft final opinion was prepared and discussed at the TSE/BSE ad-hoc group. The SSC took notice of this draft and had a first discussion on it. It requested the WG-"fallen-stock" to take account of this draft final opinion and to verify its consistency with the final version of the working-group report.

A final opinion shall be adopted at the next plenary meeting of the SSC.

b. Overall view on the various "products" opinions (gelatine, MBM, tallow, etc.)

An overview of the different opinions was prepared by the secretariat and distributed. Members were asked to verify this overview in view of a detailed discussion at the next meeting.

c. Intra-species recycling of animal waste (progress report).

It is expected that a draft will be available for discussion by the SSC at its meeting of 24-25 June 1999.

d. Breeding of scrapie-resistant sheep

The Working Group held its first meeting on 11 May 1999. E.Vanopdenbosch, chairman of the group, reported on the meeting and informed the SSC that a draft report is already circulating among the WG-members. A draft opinion should be ready for adoption at the next SSC plenary meeting.

e. BSE in sheep

Following the conclusions reached at the previous meeting of the SSC, the TSE/BSE ad hoc Group further addressed the issue: "Surveillance of TSEs in sheep and goat in relation to the risk of infection with bovine spongiform encephalopathy agent and related actions to be taken at EU-level:

Actions to be taken on the basis of (1) the September 1998 SSC Opinion on the Risk of infection of sheep and goats with the BSE agent and (2) the April 1999 SEAC Subgroup report on Research and surveillance for TSEs in sheep."

A report and draft opinion prepared by the TSE/BSE ad hoc Group were discussed in detail by the SSC, amended and adopted (see annex 4).

f. Update on the state of the validation of BSE-post-mortem tests.

Due to a lack of time, this item was not discussed and postponed until the SSC meeting of 24-25 June 1999. For that time a report on (preliminary) results is expected.

g. The discussion on the report of the Working Group "Human Exposure Risk", that was distributed for discussion at the previous meeting, was postponed to 24/25 June. Members were invited to provide written comments before the meeting.

h. Update and outlook on the assessment of the geographical BSE-risk.

So far, applications have been received from 27 countries (14 Member States and 13 Third Countries) for evaluation of their epidemiological status with regard to TSEs.

The SSC secretariat reported on the presently May exercise on the assessment of the geographical BSE-risk in cattle, in EU Member States and in Third Countries, an essential element of the evaluation of the epidemiological status with regard to TSEs. 5 third countries and two Member States were assessed for the first time, 10 Member States were re-assessed, following comments received from the countries on the first assessment reports prepared in March. The reports are currently undergoing revision as a new structure was developed during the assessment session. This structure better clarifies the basic logic of the assessment, i.e.: Stability of the BSE/cattle system + Challenges to the system = Risk that BSE is/was propagated and is present in the domestic cattle herd, Risk that BSE-infected animals are entering processing for food and/or feed. The geographical BSE-risk is then derived by combining these two risks.

The next assessment exercise is scheduled for the last week of June (28 June to 3 July). Re-assessment of all countries already assessed once is foreseen as well as a first assessment of one Member State (GR), which has not yet delivered a dossier, and up to 8 Third Countries, the final number depending on timely delivery of sufficiently complete dossiers. As before, results will be sent for comments and complementary information to each country individually. These will then be taken into account during the final review of all assessed countries, which is scheduled for the week 28 September to 02 October. A final opinion on the geographical BSE risk of these countries could then be delivered by the SSC in December 1999.

i. BSE-status categories

The SSC secretariat reported on the 67th General Session of the Office International des Epizooties (OIE), which was held in Paris from 17-21 May 1999. A revised version of Chapter 3.2.13 *Bovine Spongiform Encephalopathy* of the Code was adopted at that meeting but a list of open question, still to be clarified, too. The secretariat pointed at

the main differences between the adopted version and the draft version, which had been the object of detailed comments by the SSC (see SSC meeting of 10-11 December 1998). The new Code will be carefully analysed in the framework of the ongoing discussion on “a method for the definition of a BSE status of countries or geographical regions”.

Prof Garrido also explained the OIE-approach underlining that it is based on the expected BSE-prevalence in the cattle population. In relation to other diseases the OIE status “free” indicates that the agent is not present on the territory in question and that all measures are taken to avoid introduction. Accordingly “provisionally free” indicates that the agent is apparently not present but final confirmation is lacking.

A basic approach for defining a scientifically based BSE-status under a consumer-protection perspective was presented, discussed and in principle agreed by the committee. The TSE/BSE ad-hoc group was asked to continue along these lines.

j Monitoring of the evolution of the BSE epidemic in the UK

The Commission asked the SSC to address a number of issues related to the recent evolution of the BSE epidemic in Great Britain. The TSE/BSE *ad hoc* Group had therefore prepared a report and draft opinion. These documents were, discussed and adopted as *Report and Opinion on Monitoring Some Important Aspects of the Evolution of the Epidemic of BSE in Great-Britain (Status, April 1999)*” (see annex 5).

Some parts of the original mandate had to remain open and will be covered at a later stage.

6. Organisational matters.

No organisational matters were discussed.

7. Co-ordination:

Reports of the Chairmen of the 8 Scientific Committees.

The chairmen of Scientific Committees provided a written report on the activities of their committees since the last SSC meeting (23-25 May 1999). A summary of their reports is given in annex 6.

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

DG XII informed the SSC on the current openings in the FP5 for research and development actions related to antimicrobial resistance and to TSEs and invited the SSC to contribute to the ongoing revision of the work programme for the year 2000.

The SSC appreciated the information provided and agreed to include a paragraph on the relevant FP5-openings into the report on antimicrobials (see annex 3) and in the opinion on TSEs in sheep (see annex 4).

8. Any other business:

No other business were discussed

The meeting ended on Friday 28 May 1999, at 17h00.

The next meeting will be held in Brussels, on 24-25 June 1999.

Annex 1: List of participants of the Scientific Steering Committee meeting of 27-28 May 1999

List of presence

Members of the SSC:

- Prof. Georges Bories
- Prof. James W. Bridges
- Prof. Fulgencio Garrido Abellán
- Prof. Anthony R. Hardy
- Prof. Philip T. James
- Prof. Keith H. Jones (not present morning of 27 May)
- Prof. Fritz H. Kemper (not present in the afternoon of 28 May)
- Prof. Werner Klein
- Prof. Ib Knudsen
- Prof. Robert Kroes
- Prof. Albert Osterhaus (not present morning of 28 May)
- Prof. Gérard Pascal
- Prof. Vittorio Silano
- Prof. Marcel Vanbelle
- Prof. Martin Wierup

Invited expert:

- Prof. Emmanuel Vanopdenbosch (27 May only)

Apologies: Prof. Michael Gibney

Participants from the Commission:

DG III: O. Rohte

DG V H. Martin

DG VI D. André, T. Chalus, C. Michmacher, J. Perez-Lansac, I. Peutz

DG XI V. Matzeit

DG XII A. Fabre, B. Hansen

DG XXIV: B. Carsin, C. Cox, M. de Solà, F. Drion, C. Diez, M. Granero Rossel, J. Kreysa, M. Lauridsen, G. Morrison, J.J. Rateau, A. Sanabria, J. Savio, K. Sbirrazzuoli, A. Somogyi, E. Thevenard, J. Vergnettes, R. Vanhooorde, P. Vossen

Stagiaires: J. Dratwa, N. Howell

Annex 2:

Agenda of the Scientific Steering Committee Meeting of 27-28 May 1999

1. Welcome, apologies, introductory remarks, declarations of interest
 2. Approval of the agenda
 3. Approval of the minutes of the meeting of 22-23 April 1999.
 4. Progress on multidisciplinary matters:
 - a. Discussion and possible adoption of the report on antimicrobial resistance
 - b. "Considerations for the evolution of scientific advice to address emerging health issues" (progress report)
 - c. Harmonisation of risk assessment procedures (progress report)
 5. Multidisciplinary matters relating to TSE/BSE
 - 5.1. Report by the chairman of the TSE/BSE ad-hoc group, including progress reports of the various working groups
 - 5.2. Reports on specific issues:
 - Production systems and products.
 - a. "Fallen stock": possible adoption of a final opinion, following the integration of the comments resulting from the public consultation.
 - b. Intra-species recycling of animal waste (progress report).
 - c. Overall view on the various "products" opinions (gelatine, meat-and-bone meal, tallow, etc.) – first discussion
 - d. Breeding of scrapie-resistant sheep (progress report)
 - e. BSE in sheep: actions that need to be taken (urgently) with respect to the possible risks resulting from BSE having been introduced in EU sheep populations (for opinion).
 - f. BSE tests (update)
 - Human exposure risk.
 - g. Discussion of the draft report.
 - Geographical risk.
 - h. Assessment of the geographical BSE risk: progress report on risk assessment exercise of Member States and Third Countries.
 - i. BSE-status categories (progress report, discussion)
 - j. Monitoring of the evolution of the BSE epidemic in the UK (report, for opinion)
 6. Organisational matters.
 7. Co-ordination:
 - reports of the Chairmen of the 8 Scientific Committees.
 8. Information by the Commission services on matters related to consumer health.
 9. Any other business.
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Annex 3:



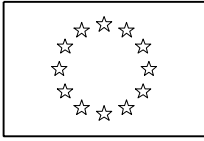
EUROPEAN COMMISSION
DIRECTORATE-GENERAL XXIV
CONSUMER POLICY AND CONSUMER HEALTH PROTECTION
Directorate B - Scientific Health Opinions

**OPINION OF THE
SCIENTIFIC STEERING COMMITTEE
ON
ANTIMICROBIAL RESISTANCE**

**ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE AT ITS MEETING OF 27-28
MAY 1999.**

(Distributed separately)

Annex 4:



**SURVEILLANCE OF TSEs IN SHEEP AND GOAT
IN RELATION TO THE RISK OF INFECTION WITH
BOVINE SPONGIFORM ENCEPHALOPATHY AGENT
AND RELATED ACTIONS TO BE TAKEN AT EU LEVEL**

OPINION ON:

**ACTIONS TO BE TAKEN ON THE BASIS OF (1) THE SEPTEMBER 1998 SSC
OPINION ON THE RISK OF INFECTION OF SHEEP AND GOATS WITH THE BSE
AGENT AND (2) THE APRIL 1999 SEAC SUBGROUP REPORT ON RESEARCH AND
SURVEILLANCE FOR TSEs IN SHEEP**

**ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE AT ITS MEETING
OF 27-28 MAY 1999.**

(Distributed separately)

Annex 5:



OPINION ON

**MONITORING SOME IMPORTANT ASPECTS OF THE
EVOLUTION OF THE EPIDEMIC OF BSE
IN GREAT-BRITAIN (STATUS, APRIL 1999)**

**ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE
AT ITS MEETING OF 27-28 MAY 1999**

(The table in annex was amended on 3 June 1999)

Text subject to possible further editorial changes

(Distributed separately)

Annex 6: Reports from the secretariats of Scientific Committees on the major activities and milestones since the SSC meeting of 18-19 March 1999.

Scientific Committee Veterinary Measures relating to Public Health

The Committee adopted the opinion on the *Assessment of potential risks to human health from hormone residues in bovine meat and meat products*.

The Committee had a long and detailed discussion on the scientific reasoning developed in the main body of the report, as well as on the executive summary and on "the questions to the answers in the mandate". The discussion covered both general considerations, as well as characteristics of the individual compounds under consideration.

The report (including its executive summary and the "answers to the questions in the mandate"), as amended during the plenary, was adopted by unanimity.

Scientific Committee on Animal Health and Animal Welfare

The Sub-Committee on Animal Health met on 26 April 1999. The following is a summary report:

- The Sub Committee discussed and approved a report on Classical Swine Fever in Wild Boar (Rapporteur: Prof. Moenning)
- The Sub Committee discussed a preliminary working paper on the inactivation of viruses in blood (Rapporteur: Prof. Van Oirschot)
- The report on the Revision of the annexes to Council Directive 64/432/EEC was not the object of discussion, because some aspects have still to be worked out.
- Dr. Alexander was asked to deal with the request for an opinion by the SCAHAW on Testing for Crimean Congo Haemorrhagic Fever Virus Infections in Ratites.

Scientific Committee for Cosmetics and Non-food Products

This report will be included in the minutes of the meeting of 24-25 June 1999.

Scientific Committee for Toxicity, Ecotoxicity and the Environment

- A. Since the April 99 SSC plenary meeting the CSTEE had its 9th plenary on the 7th of May 1999. No opinions were adopted formally at the plenary. However the progress made on the request on '*Tropospheric ozone*' allowed for an opinion to be adopted shortly after by written procedure (21st of May 1999).
- B. Activities on the opinion request '*Terrestrial environment*' - '*Available scientific approaches to assess the potential effects and risks of chemicals on terrestrial ecosystems*' continued. A working group meeting had been foreseen for the 1st of June 1999. This had to be cancelled though given the unexpected budgetary difficulties of the Commission.
- C. A discussion on the opinion request '*Selection of a Community wide mineral oil marking system – Safety of the preferred product*' took place at the May CSTEE plenary. The CSTEE requested further documentation on the intrinsic properties of the substances in question, in principle obtainable from BASF. The requester service will try and provide them to the CSTEE.
- D. A presentation was made by one CSTEE member on 'The use of measured exposure data in risk assessment'. In principle this is to be the starter of another CSTEE own initiative

report. The creation of a Working Group was agreed, the composition of which still remains to be settled.

- E.** Another opinion request submitted by DG XI was presented to the CSTE. It concerns the '**Water framework directive**' and the CSTE opinion is generally being requested on the general quality of the following:
 - A.
 - I) Report from a study on *Technical specifications for classification and presentation of ecological status of surface waters*, March 1999 and
 - II) Report from a study on *Technical specifications for monitoring of ecological status of surface waters*, March 1999.
 - B. Revised proposal for a list of priority substances in the context of the Water Framework Directive (COMMPS procedure) and Draft Final Report on the Assessment of options of the statistical treatment and evaluation of monitoring data within the COMMPS procedure.
- F.** The **next CSTE plenary** is confirmed for the 1st of July 1999 in Oslo, Norway.