

Minutes of the Scientific Steering Committee Meeting of 10-11 May 2001

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

Chairman Prof.Pascal welcomed the participants of the Scientific Steering Committee. He apologised, for 10 and 11 May 2001: Prof.J.Fink-Gremmels and for 10 May: Prof.I.Knudsen. The list of participants is attached as Annex 1.

Declarations of interest:

At its previous meeting the SSC suggested that influenza would be used as an example when addressing the issue of Emerging viruses. Prof.Osterhaus declared that the University of Rotterdam owned a company that also conducts clinical trials on emerging infections, for example influenza. He is director of this company and on a personal basis also sometimes carries out consultations in this field.

The Secretariat reported that Prof.Piva, member of the TSE/BSE *ad hoc* Group, at the meeting of 26 April of this Group, made a declaration of possible interest in the field of safety with regard to TSE risk of ruminant-derived products. As a Professor in animal nutrition, his Faculty, its Laboratory and himself are regularly consulted by the Italian public and private sector on matters related to safety of products or requested to carry out laboratory analyses.

2. Approval of the agenda

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

3. Approval of the minutes of the meeting of 8-9 February 2001.

The minutes of the meeting of 29-30 March 2001 were adopted without changes.

4. Procedural matters

a. Rules of procedure.

Following the above declarations of interest, the SSC had a discussion on the definition of an "interest" and on the various levels of possible personal involvement in such an interest. It also briefly discussed the confidentiality of discussions in Scientific Committee or Working Group meetings. It was agreed that the secretariat would propose a set of draft guidelines on these issues, to be possibly included in the Committee's Rules of Procedure after further discussion.

b. Membership of the TSE/BSE ad hoc Group

The SSC agreed that the secretariat would contact the following scientists with the request whether they would accept to become a member of the TSE/BSE *ad hoc* Group: Dr.P.Brown, Prof.Dr.JCollinge, Dr.G.Wells, Dr.C.Ducrot, Dr.R.Somerville.

SSC was also informed of Prof.Dr.Piva's intention to resign from the TSE/BSE *ad hoc* Group, because he accepted to become membership in Italian national scientific advisory body. The Scientific Committee on Animal Nutrition was therefore invited to identify replacement for Prof.Piva as a member of the TSE/BSE *ad hoc* Group.

c. Planning of activities and priorities.

No discussion was held on this item.

5. Multidisciplinary matters:

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

- The 8 chairpersons reported on the work of their respective Scientific Committees, whilst emphasising on matters that are of a multidisciplinary nature and/or require co-ordination. Information on the activities of the various Scientific Committees is attached as Annex 4.

b. Harmonisation of risk assessment methods.

Prof.Bridges reported that a planning had been established for the 3 Working Groups on (a) biological materials (b) chemical agents and (c) environmental risk assessment. Prof.Knudsen, reported on the progress made by one of them, namely the WG on biological materials. A draft final report on this subject was expected to be submitted at the SSC meetings of either October or November 2001.

It was agreed that, before next meeting, the proposal for a common format and structure of opinions as well as the draft glossary of terms would be discussed by the various scientific committees. A final discussion and possible adoption by the SSC could then be expected at the meetings of either June or September 2001.

c. Safety of cotton

Prof.Hardy, rapporteur, informed the SSC that he had now received the missing contribution from one Committee. Discussion and possible adoption of an opinion were therefore postponed once more, this time to the meeting of 28-29 June 2001.

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

- *Emerging viruses*. Mr. C.Berlingieri (DG-SANCO) informed the SSC that the mandate being prepared by Commission Services had not yet been finalised yet. The SSC urged the Commission Services to accelerate this process because a human virus could emerge at any moment and the availability of appropriate scientific advice would then be a precious asset.
- *Anti-microbial resistance*. Prof.Jones and Prof.Bories, rapporteurs, presented the report of the discussions held on 28 March 2001 the Working Group. A detailed discussion followed and an opinion was drafted and adopted. It is attached as annex 4.

e. New questions

No new questions had been submitted to the SSC.

f. 6th Framework Programme for Research (29.03.01, 11h30)

This item was not discussed in the plenary session. However several SSC members reported on an informal meeting they had with Research Directorate General staff on 10 May 2001 during which they discussed ideas and suggestions as a contribution to the preparation of the 6th FWP.

6. Multidisciplinary matters relating to TSE/BSE

6.1. Report by the chairman of the TSE/BSE *ad-hoc* group meeting of 26 April 2001

The SSC secretariat reported briefly on the meeting of the TSE/BSE *ad hoc* Group of 26 April 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. Safety of tallow.

Prof.Silano introduced a new the draft report and opinion on the safety of ruminant-derived tallow, updated by the TSE/BSE *ad hoc* Group at its meeting of 26 April 2001 in the light of the SSC's discussions of 29-30 March 2001 and of technical information provided by the European Fat Processors and Renderers Association (EFPRA).

Following a detailed discussion, it was agreed that the secretariat would prepare an updated draft report and opinion, to be circulated for further comments and possible approval amongst all the members of the SSC and the TSE/BSE *ad hoc* Group. Should this written consultation result in a consensus on the draft opinion and report, then they could be made public as preliminary documents for further consultation until next SSC meeting. Final adoption could then take place at the SSC meeting of 28-29 June 2001. However, in case of absence of a consensus, a further discussion would be held, first by the *ad hoc* Group and then by the SSC on 28-29 June.

b. Safety of collagen

Prof.Silano introduced a new the draft report and scientific opinion on the safety of ruminant-derived collagen. Following discussion, the attached opinion was adopted (Annex 5).

c. BSE epidemiology (survey methods)

The progress made by the BSE/TSE *ad hoc* Group was reported on. It was currently not possible to estimate when a final draft would be available.

d. Origin of BSE, transmission and 3rd route

It was still not possible to estimate when a final draft would be available for discussion by the SSC, given the number of other pending issues and priorities.

e. Safety of organic fertilisers and soil conditioners

Prof.Silano introduced a new the draft report and scientific opinion on the safety of organic fertilisers. Following discussion, the attached opinion was adopted (Annex 6).

f. Safety of gelatine

The progress made by the BSE/TSE *ad hoc* Group was reported on. It was currently not possible to estimate when a final draft would be available.

g. Safety of intestine-associated adipose tissues

The SSC discussed a draft opinion prepared by the TSE/BSE *ad hoc* Group and introduced by its chairman, Prof.Silano. The SSC considered that, before possibly adopting an opinion, it needed clarification on the following 2 issues:

- Should the question strictly be limited to fats associated with the intestine from duodenum and rectum, as in the current question, or should it be put in a broader anatomical context including the omentum;
- Should only the *bovine* intestine be covered, or should the opinion also cover small ruminants?

The SSC secretariat was invited to transmit the above questions to the appropriate Commission Service.

h. The risk of dissemination of brain particles into the blood and carcass when applying certain slaughter methods.

The SSC discussed the following question: "*On 13-14.04.01 the SSC adopted an opinion on the safety of ruminant blood. It points at the increased risk of blood becoming contaminated if certain slaughter methods are applied (e.g., captive bolt with pithing). Did meanwhile new data become available pointing at the possible distribution into the blood of brain material - hence in the carcass or for example the hart and the lungs - following slaughter by captive bolt stunning without pithing?*"

A final opinion was however not adopted because TSE/BS *ad hoc* Group members had provided additional contributions in the days just preceding the SSC meeting. A final draft document was therefore not available for adoption.

The SSC also suggested including the impact of the current rapid testing programmes in the overall risk assessment.

i. Frame for the evaluation of proposals for alternative ways of disposal;

As agreed at previous SSC meeting, Prof.Bridges had prepared a draft *Frame for the evaluation of proposals for alternative ways of disposal*. The draft was discussed and there was a consensus on its general outline and content. It finalisation would, however, require further discussion both by the SSC and by the TSE/BSE *ad hoc* Group. In order not to unnecessarily delay de liquidation of pending questions related to safe processing and/or disposal of (TSE) waste, it was agreed that the present draft Frame would be used to evaluate the pending submissions.

With respect to the pending finalisation of the evaluation of the "Treatment and disposal of animal waste by alkaline hydrolysis at 150°C for at least 3 hours" already discussed at the SSC's previous meeting, Prof.Bridges agreed to update the current draft report and scientific opinion in the light of the draft Frame and in the light of more recent information provided by the Company WR² owner of the process. This update would be discussed for adoption at the SSC meeting of 28-29 June 2001.

j. Specified Risk Materials

The progress made by the BSE/TSE *ad hoc* Group was reported on. It was currently not possible to estimate when a final draft would be available.

k. Geographical BSE Risk: 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 Costa Rica, Kenya, Slovenia and Romania. It adopted the opinions attached as Annexes 7 - 10.

1. New questions.

Since last meeting, no new questions had been submitted to the Scientific Steering Committee.

7. Organisational matters: No other organisational matters were discussed.

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

The secretariat informed the SSC that Commission is currently preparing a draft proposal for a Decision on improved TSE surveillance in small ruminants. This proposal addresses several of the SSC's recommendations made in its pre-emptive risk assessment of 8-9 February 2001 should BSE in sheep be found in small ruminants under domestic conditions. Issues covered by the proposal are, for example, TSE testing of samples of fallen stock and animals offered for human consumption and strain-typing of animals found positive. The SSC asked that it would further be kept informed about the actions taken by the Commission in this context.

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

No information was provided by Commission Services.

10. Any other business.

- a. The SSC asked its secretariat to officially contact the UK authorities with the request to provide an update on the currently ongoing studies on the pathogenesis of BSE in cattle and in small ruminants including the research protocols and their state of current advancement, so that the importance of the findings and the need for a possible updating of the lists of SRMs in cattle and in small ruminants could be adequately assessed.
- b. Referring to its repeated recommendations on the urgent development of differential tests for scrapie and BSE in small ruminants, the SSC invited the Research Directorate General to consider proposals in this field as a priority when evaluating the outcome of their forthcoming call for proposals on TSEs.
- c. The SSC expressed its concern of the fact that apparently no data base existed providing data on BSE in Europe in an harmonised way and according to a standard format. Elements to be reported on would be (non exhaustive list): age, sex and breed; intended use (dairy, meat, breeding, ...), date of suspicion, date of confirmation, type surveillance system in place, method(s) leading to confirmation (clinical, laboratory, tests, ...). Such data base would be an invaluable tool for research, epidemiological monitoring and risk management. The SSC strongly recommended that such data base be designed and established at European Scale.

The meeting ended on Friday 11 May 2001, at 15h30

**Annex 1: List of participants in the Scientific Steering Committee meeting on
10-11 May 2001.**

List of presence

Members of the SSC:

- Ing. Georges Bories
- Prof. James W. Bridges (not present afternoon of 11 May)
- Prof. Anthony R. Hardy (not present afternoon of 11 May)
- Dr Keith Jones (not present afternoon of 11 May)
- Prof. Werner Klein
- Dr Ada Knaap
- Dr Ib Knudsen (not present 10 May)
- Dr Pierre Le Neindre
- Prof. Johannes Löwer
- Prof. Albert Osterhaus
- Prof. Gérard Pascal
- Prof. Pere Puigdomenech
- Prof. Vittorio Silano
- Prof. Staffan Skerfving
- Dr Ian White

Apologies for absence:

- Prof. Johanna Fink-Gremmels

Participants from the Commission:

DG SANCO: B. Carsin, C. Berlingieri, P. Vossen, J.Kreysa, J.L. Jouve, S. Abildgaard,
A. Dehove, G. Morrison, V. Van Haeperen, G. Fracchia, A. Van Elst, W. Penning,
A. Chamas

Annex 2: Agenda of the Scientific Steering Committee Meeting of 10-11 May 2001

1. Welcome, apologies, introductory remarks, declaration of interest.
2. Approval of the agenda
3. Approval of the minutes of the meeting of 29-30 March 2001
4. Procedural matters
 - a. Membership of the TSE/BSE ad hoc Group;
 - b. Planning of activities and priorities.
5. Multidisciplinary matters:
 - a. Co-ordination: Reports of the Chairmen of the 8 Scientific Committees;
 - b. Harmonisation of risk assessment methods:
 - Progress report on Task Force activities;
 - Common format for opinions;
 - Glossary of terms.
 - c. Safety of cotton (draft opinion);
 - d. Emerging scientific issues (progress reports);
 - e. New questions (if any).
 - f. 6th Framework Programme for Research
6. Multidisciplinary matters relating to TSE/BSE
 - 6.1. Report by the chairman of the TSE/BSE *ad-hoc* group meeting of 26 April 2001
 - 6.2. Reports on specific issues:
 - a. Safety of collagen (for opinion)
 - b. Safety of intestine-associated adipose tissues (for opinion);
 - c. The risk of dissemination of brain particles into the blood and carcass when applying certain slaughter methods (for opinion)
 - d. Safety of organic fertilisers and soil conditioners (for opinion)
 - e. Safety of tallow (for discussion)
 - f. Geographical BSE of a number of Third Countries (for opinion).
 - g. Progress report on pending questions:
 - BSE epidemiology (survey methods)
 - Origin of BSE, transmission and 3rd route
 - Frame for the evaluation of proposals for alternative ways of disposal;
 - Safety of gelatine
 - SRMs
 - h. New questions:
 - New questions related to the safety of human-derived products and medical devices, with regard to TSEs;
 - Other new questions submitted by Commission Services.
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 8-9 February 2001.

(COMPLETE INFORMATION AT THE WEBPAGES OF THE SCIENTIFIC COMMITTEES AT THE ADDRESS [HTTP://EUROPA.EU.INT/COMM/FOOD/FS/SC/SSC/INDEX_EN.HTML.](http://europa.eu.int/comm/food/fs/sc/ssc/index_en.html))

SCIENTIFIC COMMITTEE ON FOOD (SCF)

The SCF has not met in plenary since the last SSC meeting, but the work continued in numerous meetings of SCF working groups. At its next plenary meeting on 29/30 May the SCF will discuss an update of its opinion on dioxins on the basis of new scientific information. Other items for possible adoption are opinions on contaminants, food additives, flavourings, upper levels for vitamins and minerals, food contact materials and novel foods. Also, nine new requests will be presented to the SCF, including requests for opinion on the risk assessment of polyaromatic hydrocarbons and organotin compounds in food, and others.

SCIENTIFIC COMMITTEE FOR PLANTS

The SCP met on 25 April. At this meeting the following 3 opinions have been adopted by the Committee:

- Opinion regarding the evaluation of 2,4-D 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 25 April 2001).
- Opinion regarding the evaluation of imazosulfuron 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 25 April 2001).
- Opinion regarding the evaluation of flumioxazin 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 25 April 2001).

On 25 April, the Committee also decided that there were no specific issues that it wished to raise on the dossier concerning ferric phosphate referred without specific questions.

SCIENTIFIC COMMITTEE ON ANIMAL NUTRITION (SCAN)

The SCAN working groups started or continued their work.

SCIENTIFIC COMMITTEE VETERINARY MEASURES RELATING TO PUBLIC HEALTH

The last plenary meeting of the Scientific Committee on Veterinary Measures relating to Public Health took place on 2- 3 May.

Draft reports have been discussed by the Committee and remarks made to the documents presented, to be updated for future discussion.

One new draft mandate was accepted by the Committee on “Criteria for evaluation of methods of Salmonella detection”.

A draft document on “Harmonisation of Risk Assessment Procedure” was presented by a member of the Committee, member of the ad hoc SSC - WG. The Committee commented on the document presented.

SCIENTIFIC COMMITTEE ON ANIMAL HEALTH AND ANIMAL WELFARE

The Scientific Committee on Animal Welfare and Animal Health met on 25 April 2001.

Two draft reports were on the agenda for discussion and possible adoption.

1. Report on *Brucella melitensis*

This draft had been approved by the subcommittee on Animal Health at its meeting on 27 March 2001. *Brucella melitensis* is a serious zoonosis causing Malta fever in man. This disease is found in the Mediterranean region in sheep and goats. Considerable resources are being expended to eradicate it but there are several difficulties. Firstly the diagnostic tests are not optimal. Secondly the use of vaccine is necessary to reduce the incidence of clinical disease and the reduce the shedding of the organism and consequent human infection. However the use of vaccine interferes with the already sub optimal tests further decreasing their effectiveness. However past experience has shown that a reduction in the use of vaccination can result in an upsurge of disease and increase in human cases.

Because of time constraints, the committee approved the document in principle and agreed to put it into written procedure for adoption when a number of modifications were made.

2. Report on the welfare of cattle kept for beef production.

This draft report had been approved by the subcommittee on Animal Welfare at its meeting on 3 April.

Beef cattle are kept for fattening in all member states though the farming systems vary enormously depending on factors such as climatic conditions, diet and bedding availability. The report makes several recommendations covering the housing and management of the animals. These include for example, space allowances for the animals, use of mutilations (castration ,dehorning etc), genetics,

The draft report was adopted unanimously by the Committee, subject to certain editorial changes being made.

3. Foot and Mouth Disease

The committee also spent some time discussing the Foot and Mouth outbreaks in various Member States. In particular, members drew attention to two reports of the Committee

- The killing of animals for disease control purposes, adopted in September 1997 and
- Strategy for Emergency Vaccination against Foot and Mouth Disease, adopted in March 1999.

While the actual management of the outbreak and the eradication of the disease is a matter for the risk manager, it is important that we learn from the present outbreaks and take steps to avoid a repeat. These include reinforcements to avoid reintroduction of the virus and additional research on vaccines and tests. Considerations should also include the effects of measures on the welfare of the animals involved.

A statement bring this to the attention of the Commission is being circulated with a view to obtaining the agreement of the members of the Committee.

SCIENTIFIC COMMITTEE FOR TOXICITY, ECOTOXICITY AND THE ENVIRONMENT

Since the last briefing on CSTEE's activities the following is of note:

A. Opinions were adopted on the following:

1. Risk assessment reports (Human health and the environment) of:

a) *Dibutyl phthalate* and b) *Methyl-tert-Butyl Ether*, both produced under the so-called Existing substances Regulation (793/93).

2. *Evaluation of sludge treatments for pathogen reduction.*
3. *Proposed standards for a revised bathing water directive.*

B. The report *Exposure data in risk assessment of organic chemicals* was put on the DG SANCO website for public comments on 9 May 2001 (comments can be sent till 8 June 2001 to : Jorge.costa-david@cec.eu.int or patricia.decamps@cec.eu.int). On the basis of comments received the CSTE E may revise the text.

C. The CSTE E is also pursuing its activities on the following opinion requests:

- i) *Carcinogenic and non-carcinogenic effects of Cadmium and Arsenic in ambient air and:*
- ii) *Derivation of limit values for PAH in ambient air.*
- iii) *Health effects of Radio Frequency and Electromagnetic fields (emerging issue).*
- iv) *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.*
- v) Evaluation of the following Regulation 793/93 Risk Assessment Reports:
Risk assessment reports on Human health & Environmental effects of: a) *Methyl oxirane (Propylene oxide)*; b) *Toluene*; c) *1,2,4-Trichlorobenzene*; d) *Acrylic acid*; e) *Hydrogen Peroxide*; f) *Di(isononyl)phthalate (DINP)*; g) *Di(isodecyl)phthalate (DIDP)*.
- vi) *JRC report on results of the validation of methodologies for determining the release of DINP from toys and childcare articles.*
- vii) Review of a draft CPMP discussion paper on *Environmental Risk assessment of medicinal products.*
- viii) *Ecotoxicological properties of Creosote* (Submission to the EC under article 95 of the Treaty).
- ix) Participation of the CSTE E in activities/working groups of other scientific committees of the Commission: *Toxicity of minerals such as Cu and Zn in animal feed regarding the possible environmental impact of these minerals – activity of the SCAN.*

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 particular items of a multi-disciplinary nature have been discussed. However, the attention of the Committee has been drawn to the following two emerging events:

1. At the end of April, an article appeared concerning the *in vitro* and *in vivo* oestrogenicity of UV filters. An *ad-hoc* Working Party of the SCCNFP was convened on 27 April 2001 and made an analysis of the study concerned.

A preliminary statement was issued saying that, at present, the biological relevance of positive results obtained has not yet been established.

Because of the importance of the above, the SCCNFP Working Party 'UV-filters' will be convened on 29 May 2001 at which time it is intended to review the original and relevant available data to be submitted by Industry and possibly by other parties.

2. A publication in the International Journal of Cancer concerning a population-based case-control study which involved incident cases of bladder cancer and an equal number of age-, sex-, and ethnicity-matched controls. The study implicates long-term use of permanent hair dyes as a risk factor in bladder-cancer development.

At a first stage, the WP concluded that the potential risk for the development of bladder cancer in users of permanent hair dyes is of concern and therefore would request a full quantitative inventory of all dye intermediates currently used in permanent hair dye formulations in the EU.

The WP would also recommend that the European Commission provides the resources for the urgent review of the information and performs further epidemiological studies to evaluate the possible association between bladder cancer and the use of permanent hair dyes in the EU.

SCIENTIFIC COMMITTEE FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

The Scientific Committee for Medicinal Products and Medical Devices held its Working Group meeting on "Xenotransplantation" on 3 May and its Working Group meeting on "Tissue engineering" on 4 May. Progresses were made in both groups.

Annex 4:



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

SCIENTIFIC STEERING COMMITTEE

2ND OPINION ON ANTI-MICROBIAL RESISTANCE

ADOPTED ON 10-11 MAY 2001

(Distributed separately)

Annex 5



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate C - Scientific Opinions
C1 - Follow-up and dissemination of scientific opinions

OPINION AND REPORT ON

**SAFETY WITH RESPECT TO TSE RISKS OF COLLAGEN
PRODUCED FROM RUMINANT HIDES**

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE

AT ITS MEETING OF 10-11 MAY 2001

(Distributed separately)

Annex 6



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate C - Scientific Opinions
C1 - Follow-up and dissemination of scientific opinions

UPDATED OPINION ON:

THE SAFETY OF ORGANIC FERTILISERS DERIVED FROM RUMINANT ANIMALS

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE

AT ITS MEETING OF 10-11 MAY 2001

(Distributed separately)

Opinions of the
Scientific Steering Committee
on the
GEOGRAPHICAL RISK OF
BOVINE SPONGIFORM ENCEPHALOPATHY (GBR) IN:
COSTA RICA, KENYA, SLOVENIA AND ROMANIA

ADOPTED ON 10-11 MAY 2001

(Distributed separately)