

Minutes of the Scientific Steering Committee Meeting of 16-17 January 2003

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

The chairman Prof. G. Pascal welcomed the participants. He apologised on behalf of Profs J. Löwer (for both 16 and 17 January), A. Hardy (for 16 January) and A. Osterhaus, I. White and K. Jones (for 17 January 2003). The list of participants is attached as **Annex 1**.

Declarations of interest: No declarations of interest were for this meeting.

Mr. B.Carsin (Health and Consumer Directorate General and Director of the Scientific Opinions Directorate since its creation in 1997) informed the SSC of his appointment as Director at the Market Directorate general. In his farewell allocation, he painted the history of the Commission's scientific advisory body composed of 9 independent scientific committees. He warmly expressed his gratitude to the SSC members for providing the Commission with excellent and independent scientific advice. The members of these committees have invested, during 3 or 6 years, considerable personal time, voluntary work and motivation in the preparation of scientific advice. This has permitted the Commission to take timely and appropriate measures on matters relating to public health, to introduce numerous legislative proposals, to take position in matters of general concern, to successfully defend cases before the Court of Justice and to be pro-active in a number of decisions that are now being considered as part of the "acquis". In his answer Chairman Prof.Pascal thanked Mr.Carsin for his contributions to this exercise, which was often conducted under high pressure and difficult conditions, and for all the services and support offered by his Directorate and its Scientific Secretariat. He elaborated on the main assets of the SSC and the other Scientific Committees, not only in the fields of the excellence and independence of their expertise and the transparency of their work, but especially of the innovations introduced in the approach towards risk assessment. These imply also a permanent concern to put specific risk assessments in a broader context covering also the environment and multiple exposure routes to a risk. He finally expressed the wish that these assets would be further nurtured by the EFSA Scientific Committee and panels that in the future will cover most of the mandate of the SSC.

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 5-6 December 2002.

The minutes of the meeting of 5-6 December 2002 were adopted with minor changes.

4. Procedural matters:

a. The establishment of the European food Safety Authority (EFSA)

Following the exchange of views at the previous SSC meeting, P.Wagstaffe (Health and Consumer Directorate General) provided additional information on the transfer of dossiers from the effected Scientific Committees, more precisely regarding:

- The procedure for the transfer of dossiers, especially for the ones still in the process of being assessed.
- The deadline for accepting new questions.
- The criteria to be used when prioritising the questions still to be addressed before the end of the mandate.

- The correspondence of the various EFSA panels with the mandates of the current Scientific Committees.

In the discussion that followed this presentation the SSC expressed its concern on the separation of advice on food and feed issues and on non-food issues already repeatedly expressed in previous meetings.

Regarding the finalisation of pending opinions (already on the SSC agenda) before the effective take-off of EFSA, the SSC considered that this should not be a target at any price. The remaining mandate of the SSC is only approx. 3 months. This may be too short for certain pending questions to prepare a balanced opinion. Speeding up the process might result in a lower quality and this should be avoided. The Commission should therefore accept that certain opinions will not be finalised before the end of the mandate and EFSA will have to continue the work. P.Wagstaffe said that the new EFSA scientific committee and panels could be given the names of the current working group members to open the possibility of using their expertise to finalise the preparatory work for certain opinions.

b. Integrating food- and non-food aspects in risk assessment.

Prof.Jones considered that the section in the minutes of the previous meeting reflecting the multidisciplinary content of the work of SSC and its constituent committees reflected the issues relevant to the environment, but was limited in its scope. He proposed an additional comment to be made about the value of wider multidisciplinary issues covered by the SSC like antimicrobial resistance, which ultimately featured in very constructive discussion at the level of Counsel of Ministers. Each of the works completed by the antimicrobial resistance group, from the first major review in 1998 to the feed additive and later Triclosan and Azole reports required discussion and views of a full multidisciplinary team which will not be available under current EFSA proposals.

Another important contribution that would not necessarily be covered by the EFSA proposals was the BSE and blood review which was commissioned by the SSC and started in the Scientific Committee on Medicinal Products and Medical Devices. This expanded considerably and performed a very useful function. He suggested that the Commission consider retaining a separate high level, multidisciplinary body independent of the EFSA that could advise on overarching scientific issues covering all disciplines.

c. The future of the GBR exercise.

The SSC expressed its concern that it had not been provided so far with clear information on the strategy the Commission intends to follow with respect to the GBR exercise once the SSC will have ceased to exist. Approx. 26 countries have so far been assessed by the SSC in the second round, 18 assessments from the first round are still valid so far but will need to be re-assessed in the light of new data. And the assessment is pending for another approx. 40 countries. The latter two groups will have to be assessed in another context. The SSC considered that a lack of coherency in the methodological GBR approach should be avoided at any price because this could be detrimental to the whole exercise and have important legal and economic implications.

5. Multidisciplinary matters:

a. Reports of the Chairpersons of the 8 Scientific Committees

The 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 3**.

b. Harmonisation of risk assessment methods:

Profs.J.Bridges, W.Klein and P.Le Neindre updated the SSC on the state of advancement of the various reports under preparation in the framework of the SSC's Task Force on the Harmonisation of risk assessment methods. The planning for the finalisation of the reports and of an overarching summary opinion was presented.

A more detailed discussion was held on report on the risk assessment of food-borne bacterial pathogens. This report had already been discussed previously by the SSC and subsequently went through an internet consultation round which resulted in a significant update. Following the inclusion of some minor additional amendments, the SSC adopted the report attached as **Annex 4**.

c. Emerging scientific issues

No issues were reported under this agenda item.

d. Guidance document on the information needed for the risk assessment of genetically modified plants and derived food and feed.

A draft of the Guidance was presented by Prof.T.Hardy and by 2 leading members of the multidisciplinary working group who attended this part of the meeting: Dr H. Davies and Dr H. Kuiper.

The current draft version is the result of a multidisciplinary exercise involving the Scientific Committees on Plants, Food, Feed and Toxicity and Ecotoxicity of the Environment. It had been submitted for comments from the public via Internet, which resulted in useful additional inputs.

The SSC discussed the document in detail and made a number of suggestions especially with regard to the structure of the document. It also recommended that a covering opinion be prepared, relating the Guidance to the SSC's previous opinion of 26-27 October 2000 on genetically modified plants (GMPs) and framing this specific Guidance in the SSC's overall thinking about GMPs. It is expected that a revised draft will be available for final discussion and adoption at the SSC meeting of 6-7 March 2003. At that meeting, a short covering opinion will also be prepared.

6. Multidisciplinary matters relating to TSE/BSE

6.1. Report on the TSE/BSE *ad-hoc* group meetings of 9 January 2003

All items addressed at that meeting are further reported on under point 6.2. hereafter.

6.2. Reports on specific issues:

a. Geographical BSE Risk (GBR)

The SSC secretariat reported on the progress made by the GBR Peer Group. However, no new draft reports or opinions were sufficiently advanced for submission to the SSC at this meeting.

b. Update of the SSC opinion on the safety of phosphates from bones.

The secretariat informed the SSC that the results of the ongoing research on TSE infectivity clearance during the production of phosphates from bones had still not been received but expected to become available before the end of January 2003. The discussion of the draft opinion and report was therefore postponed once more to the SSC meeting of 6-7 March 2003.

c. Quantitative assessment of the risk of tallow, gelatine and dicalcium phosphate.

The Secretariat confirmed that no further progress had been made on this dossier.

d. BSE risk of the bovine autonomic nervous system.

The secretariat informed the SSC that a draft report and draft opinion was expected to be available for adoption by the SSC at its meeting of 6-7 March 2003.

e. Conditions under which safe burial can be achieved

Prof. Bridges, rapporteur, presented to the SSC a new draft report and opinion, amended in the light of the discussions of the TSE/BSE *ad hoc* Group at its meeting of 9 January 2003. Following discussion and amendments, the opinion was adopted. It is attached to these minutes as **Annex 5**.

f. Conditions under which safe burning can be achieved

Prof. Bridges, rapporteur, presented to the SSC a new draft report and opinion, amended in the light of the discussions of the TSE/BSE *ad hoc* Group at its meeting of 9 January 2003. Following discussion and amendments, the opinion was adopted. It is attached to these minutes as **Annex 5**.

g. Potential risks arising from the use of small incinerators

Prof. Bridges, rapporteur, presented to the SSC a new draft report and opinion, amended in the light of the discussions of the TSE/BSE *ad hoc* Group at its meeting of 9 January 2003. Following discussion and amendments, the opinion was adopted. It is attached to these minutes as **Annex 5**.

h. Chronic Wasting Disease.

The secretariat informed the SSC on the state of advancement of the preparation of a report and opinion on this subject. A final draft was expected to be available for discussion and adoption by the SSC at its meeting of 6-7 March 2003.

i. BSE cases born after the reinforced feed ban in the UK (BARBs)

The secretariat informed the SSC on the state of advancement of the preparation of a report and opinion on this subject. A final draft was expected to be available for discussion and adoption by the SSC at its meeting of 6-7 March 2003.

j. BSE-related culling in cattle.

The secretariat informed the SSC on the state of advancement of the preparation of a report and opinion on this subject. It also signalled the delays in the translation of an AFSSA opinion on culling strategies into English. It was therefore not excluded that a final draft would only be available for discussion and adoption by the SSC at its meeting of 10-11 April 2003.

k. The feeding of wild fishmeal to farmed fish and recycling of fish with regard to the risk of TSE.

The secretariat informed the SSC on the state of advancement of the preparation of a report and opinion on this subject, which required an harmonisation with the work of the Scientific Committee on Animal Health and Animal Welfare which was preparing an opinion on the related field of fish waste recycling (See Minutes of 12-13 September 2003). A final draft was now expected to be available for discussion and adoption by the SSC at its meeting of 6-7 March 2003.

k. Rapid tests: Information

The Secretariat provided the SSC with an update of the current state of implementation of the BSE rapid test field evaluation programme. It also announced that a new Open call for the expression of interest to participate in a programme for the evaluation of tests for the diagnosis of TSEs in ruminants”, would be published very soon in the Official Journal of the European Communities Series C (C 15 Volume 46 22 January 2003, page 13).

It also informed the SSC that it had received a letter from one of the companies currently involved in the still ongoing rapid test evaluation programme, requesting for admission of their rapid BSE-test to the second phase of the EU validation (field trial) but also informing that in the meantime the test underwent a number of changes when compared to the test evaluated in the laboratory evaluation phase. The request and argumentation were submitted to and discussed by the TSE/BSE *ad hoc* group at its meeting of 9 January 2003. This group considered the changes introduced to be major ones. It concluded that the results of the laboratory evaluation of 2002 therefore do not describe their actual test anymore. The group recommended that the actual test should first participate in a laboratory evaluation. The SSC, who also had received a copy of the letter, supported this conclusion.

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

No information was provided under this item.

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

- Questions from DG-Research (DG-RTD) services about the Policy related research activities 1994-2002 on the ethical, legal and socio-economic aspects of agriculture, fisheries and food biotechnology.

The SSC discussed a draft reply prepared by Profs. P. Le Neindre and P. Puigdomenech. Amendments were proposed and both rapporteurs agreed to amend the draft accordingly. The reply would then be forwarded to the competent DG-RTD official via the SSC secretariat.

9. Any other business.

- The SSC asked the Secretariat to be informed about the Commission’s current strategy with regard to the introduction of resistance to TSEs in small ruminants via breeding strategies, and this in the light of current knowledge on experimental transmission of TSE to so called “resistant” sheep of the ARR/ARR genotype. The Secretariat promised a follow-up to this question for next meeting.
- Similarly, the SSC asked to be informed about the follow-up given to its *Suggested strategy to investigate the presence of BSE in small ruminants (adopted on 04-05 April 2002)*. The Secretariat promised a follow-up to this question for next meeting.

No further other businesses were discussed.

The meeting ended on Friday 17 January 2003, at 13h00

Annex 1: List of participants in the Scientific Steering Committee meeting on 16-17 January 2003.

List of presence

Members of the SSC:

- Ing. G. Bories
- Prof. James Bridges
- Prof. Johanna Fink-Gremmels
- Prof. Anthony R. Hardy (not present 16 January)
- Dr Keith Jones (16 January only)
- Prof. Werner Klein
- Dr Ada Knaap
- Dr Ib Knudsen
- Dr Pierre Le Neindre
- Prof. Albert Osterhaus (16 January only)
- Prof. Gérard Pascal
- Prof. Pere Puigdomenech (not present morning of 16 January)
- Prof. Vittorio Silano
- Prof. Staffan Skerfving
- Dr Ian White (16 January only)

Invited experts:

- Dr H. Davies (not present 16 January)
- Dr H. Kuiper (not present 16 January)

Apologies for absence:

- Prof. Johannes Löwer

Participants from the Commission:

DG SANCO: B. Carsin, P. Wagstaffe, P. Vossen, M. Goll, J. Ordeig Vila, G. Morrison, S. Delle Chiaie, M-N. Costa, M-A. Granero Rosell, M. Marini, A. Van Elst, J. Serratos, , N. Kollmorgen (Stagiaire)

EFSA: B. Goossens, M. Hugas, S. Renckens

Annex 2: Agenda of the Scientific Steering Committee Meeting of 16-17 January 2003

1. Welcome, apologies, introductory remarks, declaration of interest.
2. Approval of the agenda
3. Approval of the minutes of the meeting of 5-6 December 2002.
4. Procedural matters (if any)
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;
 - Report on the feedback received on the public consultations;
 - c. Emerging scientific issues.
 - d. Guidance document on the information needed for the risk assessment of genetically modified plants and derived food and feed.
6. Multidisciplinary matters relating to TSE/BSE
 - 6.1. Report by the chairman of the TSE/BSE *ad-hoc* group meetings of 9 January 2003
 - 6.2. Reports on specific multidisciplinary matters relating to TSE/BSE:
 - a. Geographical BSE Risk: the GBR of certain countries.
 - b. Update of the SSC opinion on the safety of di- and tricalcium phosphate from bones;
 - c. Quantitative assessment of the risk of tallow, gelatine and dicalcium phosphate;
 - d. BSE risk of the bovine autonomic nervous system;
 - e. Potential risks arising from the use of small incinerators;
 - f. Conditions under which (1) safe burial and (2) safe burning can be achieved (progress report)
 - g. Chronic Wasting Disease.
 - h. BSE cases born after the reinforced feed ban in the UK (BARBs)
 - i. BSE-related culling in cattle.
 - j. The feeding of wild fishmeal to farmed fish and recycling of fish with regard to the risk of TSE.
 - k. Rapid tests: Information
7. Information on the follow-up given to the opinions adopted at previous SSC meetings.
8. Information by the Commission services on other 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 previous SSC meeting.

Complete information at http://europa.eu.int/comm/food/fs/sc/ssc/index_en.html.

SCIENTIFIC COMMITTEE ON FOOD (SCF)

No SCF plenary meetings were held since the last SSC plenary meeting of 5-6 December; the previous SCF meeting having taken place on 2/3/4 December 2002.

The next SCF plenary is scheduled for 3/4/5 March. A heavy agenda is expected with about 15 opinions to adopt. There are a number of working group meetings taking place in the coming weeks that will prepare the documents for discussion at this next SCF plenary meeting.

SCIENTIFIC COMMITTEE ON ANIMAL NUTRITION (SCAN)

SCAN continues its work and concentrates on finalising opinions before transfer to EFSA. New questions, unless rapidly finalisable or of political priority, are now postponed and no further working group is created.

SCIENTIFIC COMMITTEE FOR PLANTS (SCP)

Pesticides:

Three opinions were adopted on the plenary SCP of 17 December:

- Opinion on additional questions on the evaluation of fenthion (SCP/fenthion-bis/002 Final)
- Opinion on the draft document on relevant metabolites (SCP/Guide-metab-bis/002 Final)
- Opinion on the document concerning FOCUS surface water scenarios (SCP/Guide-foc-sw/002 Final).

SCIENTIFIC COMMITTEE VETERINARY MEASURES RELATING TO PUBLIC HEALTH

No plenary meeting of the SCVPH has taken place since the last SSC meeting (5-6 December). The next SCVPH plenary meeting will take place on 21-22 January.

SCIENTIFIC COMMITTEE ON ANIMAL HEALTH AND ANIMAL WELFARE (SC-AHAW)

A plenary meeting of the Scientific Committee on Animal Health and Animal Welfare took place on December 17th 2002. A draft report on the welfare of non-human primates used in research was discussed and adopted, subject to some amendments.

Progress is ongoing in a number of other working groups and the next plenary meeting of the Committee is scheduled to take place on February 26th.

SCIENTIFIC COMMITTEE FOR COSMETICS AND NON-FOOD PRODUCTS (SC-CNFP)

Since the last SSC plenary meeting of 5-6 December 2002, one plenary meeting of the Scientific Committee on Cosmetic Products and Non-Food Products has taken place (17 December 2002).

Opinions were adopted on :

- Updated Basic Requirements for Toxicological Dossiers to be Evaluated by the SCCNFP

- Assessment Strategies on Hair Dyes
- Determination of certain formaldehyde releasers in cosmetic products
- Clarification on the formaldehyde and para-formaldehyde entry in Directive 76/768/EEC on cosmetic products
- P74 - 2,4-Dichlorobenzyl alcohol
- P81 - Zinc pyrithione (to be adopted by written procedure)
- Amendment to Entry n° 419 of Annex II to Directive 76/768/EEC on cosmetic products

Apart from the above-mentioned opinions, adopted within the framework of the adaptation to technical progress of the annexes to Directive 76/768/EEC on cosmetic products, no particular items of a multi-disciplinary nature have been discussed.

SCIENTIFIC COMMITTEE FOR ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)

The last plenary meeting of the Scientific Committee on Toxicity, Ecotoxicity and the Environment took place on 17 December 2002. Several opinions were adopted at this meeting :

- In the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances, three opinions were adopted on the results of the Risk Assessment of Chlorinated Alkanes, Short-Chain Chlorinated Paraffins and n-Pentane.

- Following the adoption of the CSTEE opinion on the effects of electromagnetic fields on health on 24 September 2002, and further to the acknowledgement of a number of critical gaps in knowledge in this area, the CSTEE identified priorities for research in this field, and adopted them as an appendix to the opinion of 24 September 2002.

- The CSTEE adopted an opinion on Risk to human health from chrysotile asbestos and organic substitutes, whereby they reiterate (1) evidence for a harmful potential stronger for chrysotile than for its organic substitutes (2) recommendation for a continuing environmental control of workplaces, where substitute fibers are produced and used (3) recommendation for expanded research in toxicology and epidemiology of substitutes fibers and in the development of new less respirable fibers.

Work is ongoing on the scientific evaluation of reports provided to the CSTEE on (1) the safety and quality of drinking water in selected European cities, (2) the risks to health and the environment related to the use of lead in products, and (3) the impact on the environment that would result from substituting phosphates in household detergents.

In addition the CSTEE has been consulted on the assessment of the risks to health and the environment posed by the use of organostannic compounds. A working group will convene and liaise with the SCF working group addressing health risks to consumers associated with exposure to organotin in food.

Furthermore, new requests relating to the results of the risk assessment of benzene, phenol, and some chromates in the framework of Council Regulation (EEC) 793/93 have been received and will be answered by the CSTEE.

SCIENTIFIC COMMITTEE FOR ON MEDICINAL PRODUCTS AND MEDICAL DEVICES (SC-MPMD)

No meeting was held.

Annex 4



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

**RISK ASSESSMENT OF FOOD BORNE BACTERIAL
PATHOGENS: QUANTITATIVE METHODOLOGY RELEVANT
FOR HUMAN EXPOSURE ASSESSMENT.
REPORT**

**ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE
AT ITS MEETING OF 16-17 JANUARY 2003**

(DISTRIBUTED SEPARATELY)

Annex 5

**OPINION ON
THE USE OF BURIAL FOR DEALING WITH ANIMAL
CARCASSES AND OTHER ANIMAL MATERIALS THAT
MIGHT CONTAIN BSE/TSE**

**ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE
AT ITS MEETING OF 16-17 JANUARY 2003**

(DISTRIBUTED SEPARATELY)

Annex 6

**OPINION ON
OPEN BURNING OF POTENTIALLY TSE-INFECTED ANIMAL
MATERIALS**

**ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE
AT ITS MEETING OF 16-17 JANUARY 2003**

(DISTRIBUTED SEPARATELY)

Annex 6

**OPINION ON
THE USE OF SMALL INCINERATORS FOR
BSE RISK REDUCTION**

**ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE
AT ITS MEETING OF 16-17 JANUARY 2003**

(DISTRIBUTED SEPARATELY)