

Minutes of the Scientific Steering Committee Meeting of 6-7 March 2003

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

The chairman Prof. G. Pascal welcomed the participants. He apologised on behalf of Profs I. White and K. Jones (for both 6 and 7 March), S. Skerfving and J. Fink-Gremmels (for 6 March) and A. Osterhaus (for 7 March 2003). The list of participants is attached as **Annex 1**.

Declarations of interest: The Secretariat informed the SSC that Dr. D. Taylor had declared an interest in some of the alternative animal waste disposal processes that were currently being evaluated by the Working Group on alternative waste disposal methods. As he acted as consultant for some of the companies that had requested the evaluation of an alternative waste disposal/recycling process, he refrained from membership of this working group. Dr Taylor will also not comment on the draft reports prepared by the group.

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 16-17 January 2003.

The minutes of the meeting of 16-17 January 2003 were adopted without changes.

4. Procedural matters:

The establishment of the European food Safety Authority (EFSA)

- Mr. C. Berlingieri, Acting Director of the Scientific Opinions Directorate of the Health and Consumer Protection Directorate General, informed the SSC on the current planning of the establishment of EFSA's Scientific Committee and Scientific Panels.
- Several members signaled that the fact that the final location of the EFSA was still not known, was likely to have a negative impact on the composition and hence the quality of the future EFSA Scientific Committee and Panels. High level and heavily occupied scientists might not apply at all for membership because of the risk of additional travel time as compared to the current situation (Brussels). Others might resign once the definitive location is known. The SSC as whole shared this concern.
- Several members signaled that it was unclear whether double membership was possible of an EFSA panel and one of the 3 non-food scientific committees that will remain with the Health and Consumer Protection Directorate General. This issue will need to be addressed by both EFSA and the European Commission services.
- The SSC asked whether and how the Commission Services intended to maintain the availability of and accessibility to the archive of opinions and reports adopted since 1997 by the SSC and the 8 sectorial Scientific Committees, once EFSA would have become operational.

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**.

- The SSC explicitly expressed its gratitude to all the members of the food- and feed-related scientific committees for maintaining their willingness to actively contribute to the work of these committees in spite of the rather difficult conditions that resulted from the uncertainties accompanying the imminent end of their mandate and from the heavy burden of finalising as many opinions as possible before that end.

b. Harmonisation of risk assessment methods

Prof.s 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. A more detailed discussion was held on reports on:

- Ecological Risk Assessment of Chemicals.
- Risk Assessment for Animal Populations with emphasis on Wild Life.
- Setting Scientific Criteria for the Assessment of Quality of Life.
- Overall overview on harmonising risk assessment approaches.

The first 3 reports had already been discussed previously by the SSC and subsequently went through an internet consultation round which resulted in updates. Following the inclusion of some minor additional amendments, the SSC adopted the reports on Ecological Risk Assessment of Chemicals and on Risk Assessment for Animal Populations. They are attached as **Annexes 4 and 5**.

The SSC considered that a further exchange of ideas was necessary on the reports on Setting Scientific Criteria for the Assessment of Quality of Life and on the overview report. Their finalisation was therefore postponed until the meeting of 10-11 April 2003.

At that meeting, an opinion introducing and framing the complete set of reports resulting from the SSC's exercise on risk harmonisation would also be prepared.

c. Emerging scientific issues

No issues were reported under this agenda item.

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

An update of the Guidance, amended in the light of the SSC discussions of 16-17 January 2003 was presented by Prof. T. Hardy. This document was prepared for the Scientific Steering Committee by *The Joint Working Group on Novel Foods and GMOs* composed of members of the Scientific Committees for Plants, Food and Animal Nutrition. Prof. Hardy also introduced a daft opinion accompanying the guidance document.

The SSC made no further comments on the Guidance document. It is attached as **Annex 6**. It discussed the accompanying opinion in detail and eventually adopted the opinion attached as **annex 7**.

6. Multidisciplinary matters relating to TSE/BSE

6.1. Report on the TSE/BSE *ad-hoc* group meetings of 20 February 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. Reports and draft opinions were submitted on New Caledonia and Singapore. Following discussion the SSC concluded that both countries have a GBR level of I. It adopted the opinions attached as **Annexes 8 and 9**.

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

The secretariat presented to the SSC the updated report and draft opinion, prepared by the TSE/BSE *ad hoc* Group at its meeting of 20 February 2003 and including the latest research results that became available in January 2003. Following discussion and amendments, an opinion was adopted. It is attached to these minutes as **Annex 10**.

c. Update of the SSC opinion on the safety of gelatine from bovine bones or hides.

The secretariat presented to the SSC the updated report and draft opinion, prepared by the TSE/BSE *ad hoc* Group at its meeting of 20 February 2003 and including the latest research results that became available in January 2003. Following discussion and amendments, an opinion was adopted. It is attached to these minutes as **Annex 11**.

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

The Secretariat confirmed that no further progress had been made on this dossier and that it was most unlikely that this exercise could still be finished before the end of the SSC's mandate.

e. BSE risk of the bovine autonomic nervous system.

The secretariat presented to the SSC the report and draft opinion, prepared by the TSE/BSE *ad hoc* Group at its meeting of 20 February 2003. Following discussion and amendments, the opinion was adopted. It is attached to these minutes as **Annex 12**.

f. Chronic Wasting Disease.

The secretariat presented to the SSC the report and draft opinion, prepared by the TSE/BSE *ad hoc* Group at its meeting of 20 February 2003. Following discussion and amendments, an opinion was adopted. It is attached to these minutes as **Annex 13**.

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

The secretariat presented to the SSC the report and draft opinion, prepared by the TSE/BSE *ad hoc* Group at its meeting of 20 February 2003. Following discussion the SSC considered that the current draft conclusions needed to be revised so as to better reflect the uncertain/unknown origin of the BARB cases in the UK and probably elsewhere in the EU. The SSC therefore invited the TSE/BSE *ad hoc* Group to red-discuss the report and draft conclusions at its meeting of 27 March 2003. Further discussion by the SSC will then take place on 10-11 April 2003.

h. BSE-related culling in cattle.

The secretariat informed the SSC that the translation of an AFSSA opinion on culling strategies into English had now become available. It expected that a final draft would be available for discussion and adoption by the SSC at its meeting of 10-11 April 2003.

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

The secretariat presented to the SSC the report and draft opinion, prepared by the TSE/BSE *ad hoc* Group at its meeting of 20 February 2003. Following discussion and amendments, an opinion was adopted. It is attached to these minutes as **Annex 14**.

j. TSEs and pigs.

The secretariat presented to the SSC the report and draft opinion, prepared by the TSE/BSE *ad hoc* Group at its meeting of 20 February 2003. Following discussion and amendments, an opinion was adopted. It is attached to these minutes as **Annex 15**.

k. Rapid tests

The SSC adopted an opinion (**Annex 16**) covering two of originally five rapid post mortem tests had now gone through the full evaluation process, which consists of an initial laboratory evaluation and an evaluation under practical conditions (field trial). The two tests have successfully completed the field trial and the opinion recommends their formal approval in the framework of Regulation (EC) No 999/2001 (the TSE Regulation). The two tests are: the Prionics-Check Luminescence Immunoassay (Prionics LIA Test) and InPro's automated Conformation Dependent Immunoassay (aCDI Test).

l. Alkaline hydrolysis: new data

The Secretariat informed that the Company WR², as a follow-up of the SSC's opinion of November 2002 on alkaline hydrolysis process, had submitted additional data and evidence related. A copy of this information was provided to the SSC members. It had also been provided to the Working Group on alternative waste disposal methods that was going to meet on 10 March 2003. This WG had been invited to evaluate the new data and to propose, if appropriate, an amendment to the report attached to the opinion of November 2002. Following further review of the data and draft amended report by the TSE/BSE *ad hoc* Group at its meeting of 27 March 2003, the SSC would then be invited on 10-11 April 2003 to update if appropriate its opinion on the WR² alkaline hydrolysis process.

m. New developments in the field of TSEs, possibly requiring further attention or to be transferred to EFSA.

- The Secretariat informed the SSC that it was currently preparing the list of the emerging issues and requests for opinion received since January 2003 and for which the SSC did not have time anymore to finalise an opinion before the end of its mandate. The list contains items possibly requiring further attention or to be transferred to EFSA. The list, as existing at the end of the SSC mandate, will be provided to the EFSA management.
- The Secretariat informed that it had received a number of requests, communications and dossiers on the hypothesis of the link between BSE and the use of organo-phosphates. Prof.Klein accepted to review this information and to assess whether

they contained any additional scientifically sound evidence, data, hypotheses or other elements not covered by the SSC's two opinions on the organo-phosphates issue:

- Opinion on possible links between BSE and Organophosphates used as pesticides against ecto- and endoparasites in cattle - Report and opinion adopted at the Scientific Steering Committee meeting of 25-26 June 1998
- Opinion on hypotheses on the origin and transmission of BSE. Adopted on 29-30 November 2001.

Prof.Klein will present the result of its review to the SSC at its meeting of 10-11 April 2003.

n. Summary overview of 1997-2003 opinions and reports.

The Secretariat presented the state of progress of the preparation of the synthetic Overview of the BSE risk assessments of the EC's Scientific Steering Committee and its TSE/BSE *ad hoc* Group. A final, peer-reviewed draft was expected to be available at the SSC meeting of 10-11 April 2003.

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

Mrs; K.Hakulin, representing the Food Safety Directorate of the Health and Consumer Protection Directorate General informed the SSC about:

- the Commission's current strategy with regard to the introduction of resistance to TSEs in small ruminants via breeding strategies;
- the follow-up given to the SSC's *Suggested strategy to investigate the presence of BSE in small ruminants (adopted on 04-05 April 2002)*.

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

No information was provided under this item.

9. Any other business.

No other businesses were discussed.

The meeting ended on Friday 7 March 2003, at 16h00

Annex 1: Participants in the Scientific Steering Committee meeting of 6-7 March 2003.

List of presence

Members of the SSC:

- Ing. G. Bories
- Prof. James Bridges
- Prof. Johanna Fink-Gremmels (not present 6 March)
- Prof. Anthony R. Hardy
- Prof. Werner Klein
- Dr Ada Knaap
- Dr Ib Knudsen (not present afternoon of 7 March)
- Dr Pierre Le Neindre
- Prof. Johannes Löwer
- Prof. Albert Osterhaus (morning of 6 March only)
- Prof. Gérard Pascal
- Prof. Pere Puigdomenech (not present morning of 6 March)
- Prof. Vittorio Silano
- Prof. Staffan Skerfving (not present 6 March)

Apologies for absence:

- Dr Keith Jones
- Dr Ian White

Participants from the Commission:

DG SANCO: C. Berlingieri, P. Vossen, M. Goll, J. Ordeig Vila, G. Morrison, S. Delle Chiaie, K. Hakulin

DG ENTR: A. Gautrais

DG FISH: R. Bates

JRC: L. Bontoux, C. O'Loan, W. Philipp

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

Annex 2: Agenda of the Scientific Steering Committee Meeting of 6-7 March 2003

1. Welcome, apologies, introductory remarks, declaration of interest.
2. Approval of the agenda
3. Approval of the minutes of the meeting of 16-17 January 2003.
4. Procedural matters
 - Update on EFSA and the current transitional stage.
5. Multidisciplinary matters:
 - a. Co-ordination: Reports of the Chairmen of the 8 Scientific Committees;
 - b. Harmonisation of risk assessment methods: final discussions on the reports on:
 - Ecological Risk Assessment of Chemicals
 - Risk Assessment for Animal Populations
 - Setting Scientific Criteria for the Assessment of Quality of Life
 - c. Harmonisation of risk assessment methods: final opinion.
 - d. Emerging scientific issues.
 - e. 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 20 February 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. Safety of gelatine: update in the light of recent research results.
 - d. Quantitative assessment of the risk of tallow, gelatine and dicalcium phosphate;
 - e. BSE risk of the bovine autonomic nervous system;
 - f. Chronic Wasting Disease.
 - g. BSE cases born after the reinforced feed ban in the UK (BARBs)
 - h. BSE-related culling in cattle.
 - i. The feeding of wild fishmeal to farmed fish and recycling of fish with regard to the risk of TSE.
 - j. Rapid tests: Information
 - k. New developments in the field of TSEs, possibly requiring further attention from the SSC or to be transferred to EFSA.
 - l. Summary overview of 1997-2003 opinions and reports.
 - m. TSEs and pigs.
 - n. Alkaline hydrolysis: new data
7. Information on the follow-up given to the opinions adopted at previous SSC meetings.
 - the Commission's current strategy with regard to the introduction of resistance to TSEs in small ruminants via breeding strategies;
 - the follow-up given to the SSC's *Suggested strategy to investigate the presence of BSE in small ruminants (adopted on 04-05 April 2002)*.
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

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

SCIENTIFIC COMMITTEE ON FOOD (SCF)

There are two remaining plenary meetings of the SCF planned before it is expected to stop its activities: on 3/4/5 March and on 2/3/4 April. As to the next SCF plenary, there is a heavy agenda with about 17 opinions and statements to be adopted. There are still a few working group meetings taking place in the next coming weeks to finalise documents for discussion at this plenary meeting or at SCF's last plenary meeting scheduled in April.

SCIENTIFIC COMMITTEE ON ANIMAL NUTRITION (SCAN)

The Scientific Committee on Animal Nutrition continues to achieve opinions. During the January-February period, it completed opinions on a colouring agent, two enzymes, a micro-organism, fumaric acid, bioprotein, copper, a feed colouring matter and mycotoxins.

Another opinion, covering another trace element, zinc, is about to be adopted.

New questions except those that can be completed before end of April and those with high political priority, are therefore postponed to later, when EFSA takes over.

SCIENTIFIC COMMITTEE FOR PLANTS (SCP)

The SCP held its 37th Plenary Meeting on 30 January 2003 and adopted the following opinions:

1. Opinion on the Guidance Document on Environmental Risk Assessment of Active Substances used on Rice;
2. Opinion on the herbicide Atrazine;
3. Opinion on the herbicide Simazine;
4. Opinion on the herbicide Isoxaflutole;
5. Opinion on the draft Annex VI B (Uniform Principles) to Council Directive 91/414/EEC on the placing of plant protection products on the market, concerning micro-organisms.

This was the last Plenary Meeting of the SCP as the Committee had responded to all questions submitted to it. The Committee will be replaced by the new EFSA scientific panel on "Plant Health, Plant Protection Products and their Residues".

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 21-22 January 2003.

The Committee adopted an opinion on "Verotoxigenic *E. coli* (VTEC) in foodstuffs". Other draft reports in preparation were discussed by the Committee and in the light of the comments received these documents will be updated for future discussion.

A new urgent question on "The evaluation of antimicrobial treatments for poultry carcasses" was submitted to the Committee. The Committee agreed to the request and set up an *ad hoc* working group for the question and meeting dates have been arranged.

The next SCVPH plenary meeting is organised for 26-27 March.

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 February 26th 2003.

A draft report on the use of fish by-products in aquaculture was discussed and adopted by the Committee, subject to some agreed amendments. This report was developed in parallel with a draft opinion of the TSE/BSE *ad hoc* group of the Scientific Steering Committee on the feeding of wild fishmeal to farmed fish and recycling of fish with regard to the risk of TSE.

Progress is ongoing in a number of other working groups and the next plenary meeting of the Committee is scheduled to take place on April 24th and 25th.

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

Since the last SSC plenary meeting of 16-17 January 2003, 10 Working Group meetings of the Scientific Committee on Cosmetic Products and Non-Food Products have taken place.

Although no particular items of a multi-disciplinary nature have been discussed, a series (20) of draft opinions on hair dyes, preservatives, UV Filters and ad hoc substances have been approved and addressed to the plenary meeting of 18 March 2003 for adoption.

However, the genotoxicity/mutagenicity data were found unsatisfactory in general and this is of concern.

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

Several opinions were adopted at the last plenary meeting of the Scientific Committee on Toxicity, Ecotoxicity and the Environment, which took place on 6 February 2003.

- In the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances, the opinions on the results of the Risk Assessment of Benzene (environmental part), Phenol (environmental part) and a few chromates (Chromium trioxide, Sodium Chromate, Sodium Dichromate, Ammonium Dichromate and Potassium Dichromate) were adopted.
- Furthermore the CSTEE adopted an opinion on the Potential health risks associated with the use of lead containing candle-wicks, whereby the CSTEE concluded that frequent indoor burning of candles with lead wick cores may result in a high additional exposure to lead and represents a health hazard especially in sensitive groups (children), for whom PTWI may already be reached by exposure to lead in diet and in dust.

Progress 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, (3) the impact on the environment that would result from substituting phosphates in household detergents, and (4) the risks to health and the environment posed by the use of organostannic compounds.

Furthermore, new working groups will be set up to review the current knowledge on the impact of indoor air quality on health and future trends, and to identify important gaps in knowledge, as well as possible options to effectively improve indoor air quality and health.

In addition, new requests have been received to peer-review a study on Heavy metals and organic compounds from wastes used as organic fertilisers, a risk assessment report carried out by a Member State on the Use of copper containing anti-fouling on pleasure craft, and the results of the risk assessment of Sodium perborate within Council Regulation (EEC) 793/93.

SCIENTIFIC COMMITTEE FOR ON MEDICINAL PRODUCTS AND MEDICAL DEVICES

No opinions were adopted by the SC-MPMD.

Annex 4

**FINAL REPORT ON THE ECOLOGICAL RISK ASSESSMENT OF CHEMICALS
(DISTRIBUTED SEPARATELY)**

Annex 5

**FINAL REPORT ON THE RISK ASSESSMENT FOR ANIMAL POPULATIONS WITH
EMPHASIS ON WILD LIFE.
(DISTRIBUTED SEPARATELY)**

Annex 6

**OPINION ACCOMPANYING THE GUIDANCE DOCUMENT FOR THE RISK
ASSESSMENT OF GENETICALLY MODIFIED PLANTS AND DERIVED FOOD AND FEED.
(DISTRIBUTED SEPARATELY)**

Annex 7

**GUIDANCE DOCUMENT FOR THE RISK ASSESSMENT OF GENETICALLY MODIFIED
PLANTS AND DERIVED FOOD AND FEED
PREPARED FOR THE SCIENTIFIC STEERING COMMITTEE BY
THE JOINT WORKING GROUP ON NOVEL FOODS AND GMOs COMPOSED OF
MEMBERS OF THE SCIENTIFIC COMMITTEES FOR PLANTS, FOOD AND ANIMAL
NUTRITION.
(DISTRIBUTED SEPARATELY)**

Annex 8

**OPINION AND REPORT ON THE GEOGRAPHICAL RISK OF BOVINE SPONGIFORM
ENCEPHALOPATHY (GBR) IN NEW CALEDONIA
(DISTRIBUTED SEPARATELY)**

Annex 9

**OPINION AND REPORT ON THE GEOGRAPHICAL RISK OF
BOVINE SPONGIFORM ENCEPHALOPATHY (GBR) IN SINGAPORE
(DISTRIBUTED SEPARATELY)**

Annex 10

**UPDATED OPINION AND REPORT ON THE SAFETY OF DICALCIUM PHOSPHATE (DCP) AND TRICALCIUM PHOSPHATE (TCP) FROM BOVINE BONES, USED AS AN ANIMAL FEED ADDITIVE OR AS FERTILISER
(DISTRIBUTED SEPARATELY)**

Annex 11

**UPDATED OPINION ON THE SAFETY WITH REGARD TO TSE RISKS OF GELATINE DERIVED FROM RUMINANT BONES OR HIDES
(DISTRIBUTED SEPARATELY)**

Annex 12

**OPINION ON BSE RISK OF THE BOVINE AUTONOMIC NERVOUS SYSTEM
(DISTRIBUTED SEPARATELY)**

Annex 13

**OPINION ON
CHRONIC WASTING DISEASE
(DISTRIBUTED SEPARATELY)**

Annex 14

**OPINION ON THE FEEDING OF WILD FISHMEAL TO FARMED FISH AND RECYCLING OF FISH WITH REGARD TO THE RISK OF TSE
(DISTRIBUTED SEPARATELY)**

Annex 15

**OPINION ON THE POTENTIAL REQUIREMENT FOR DESIGNATION OF SPECIFIED RISK MATERIALS IN PIGS.
(DISTRIBUTED SEPARATELY)**

Annex 16

**OPINION ON THE FIELD TRIAL EVALUATION OF TWO NEW RAPID BSE POST MORTEM TESTS.
(DISTRIBUTED SEPARATELY)**
