

Minutes of the Scientific Steering Committee Meeting of 5-6 December 2002

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

The chairman Prof.G.Pascal welcomed the participants. He apologised Profs. A. Osterhaus, I.White, J.Fink-Gremmels, G.Bories, V.Silano and J.Loewer (for both 5 and 6 December) and Profs. K.Jones and J.Bridges (for 6 December). The list of participants is attached as **Annex 1**.

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

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 7-8 November 2002.

The minutes of the meeting of 7-8 November 2002 were adopted without changes.

4. Procedural matters:

The establishment of the European food Safety Authority (EFSA)

At its previous meeting, the SSC had discussions on (1) the integration of food- and non-food issues in scientific advice related to consumer protection and (2) on the transfer of dossiers from the current Scientific Committees involved in food- and feed-related matters, to the EFSA Scientific Committee and panels. As a follow-up to these discussions, Mr.P.Wagstaffe, Head of the Commission's EFSA implementation team, provided the SSC with a detailed account of the current state of affairs and planning with regard to EFSA. As concerns timing Mr.Wagstaffe explained that it is intended to establish the EFSA Scientific Committee and Panels as soon as possible in 2003. Taking account of the time required for the call itself, for the evaluation procedure and the dates of future EFSA Board meetings, it may be possible to complete the process by early May. He stressed however the importance of the SSC and the 5 food related committees maintaining their meeting schedules in case of slippage.

He explained how the Council and European Parliament Regulation 178/2002 establishing EFSA already caters for a number of concerns expressed by SSC members, especially with regard to the flexibility of EFSA Panels to organise their own Working Groups. In particular, the Scientific Committee can establish Working Groups on multisectoral questions and matters of broader interest which draw upon the expertise of the Panels . He stressed that the high degree of flexibility in the new structure was essential to allow it to adjust to unforeseeable circumstances in a new organisation. For example, the number of Panels and their mandates as set out in the Regulation can be amended in the light of experience and the EFSA Board had recently adopted a Decision concerning the establishment and operation of the Scientific Committees and Panels (Doc MB 17.02.2002-3 available on the EFSA web site: www.efsa.eu.int) which provided for the panels to be progressively reinforced up to a maximum of 21. Mr Wagstaffe said that the strengthening of the EFSA Scientific Secretariats as compared to the current situation and the gradual build up of in-house scientific support was intended to eventually relieve Committee Members of much of the burden of detailed preparatory work that they undertook today. The provisions for reducing the number of diverging scientific opinions between EFSA and Community, national or international scientific advisory bodies, or managing them if they did occur, were also discussed. It was agreed that there were similar needs for managing divergent opinions in the non-food area.

Mr Wagstaffe said that the Health and Consumer Directorate General shared the SSC's concern to ensure integration of food- and non-food issues. Current planning relating to the management of the non-food committees included provisions for promoting this objective however, it was essential to establish some form of working agreement with the EFSA (and with other pertinent bodies) to allow effective cooperation.

Following an exchange of views, the SSC requested more detailed guidance 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 taking into account the need to minimise disruption to the provision of scientific advice, likelihood of completing an opinion before the end of the Committee's mandate and the desirability of continuing preparatory work to assist the future EFSA committee and panels.
- The possibilities of establishing a working relationship between SANCO and EFSA to manage the transfer of mandates of current questions and practical arrangements.
- The criteria to be used when prioritising the questions still to be addressed before the end of the mandate.
- The mandate of the various EFSA panels and their correspondence with the mandates of the current Scientific Committees.
- With regard to food issues, the SSC noted that the current system permits to address, within one Committee, a broad scope of issues of interest to food safety, which in the future would be handled by different EFSA panels (e.g. within the SCF, additives, contaminants, nutrition, etc.). At the level of EFSA, this will require a frequent and regular co-operation between Panels.
- The current involvement of the 4 Scientific Committees for Plants, Food, Animal Feed and Toxicity, Ecotoxicity and the Environment permits to address GMO-related issues, where necessary, in their broad multidisciplinary context of food, feed, plants and/or the environment. The Panel on GMO's extends the current practice of having a joint working group of these committees to ensure consistency in the GM component of the risk assessment.

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:

- Progress report on Task Force activities;

Prof.s J. Bridges, W. Klein and P. Le Neindre provided an update on of the current 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 various reports was presented. A more detailed discussion was held on the following documents:

- Preliminary report and opinion on Setting the scientific frame for the assessment of the quality of life as part of risk analyses;
- Risk characterisation framework;
- Weights of evidence in risk assessments.

Amendments to the above documents were proposed. The reports will be finalised by the Task Force at its meeting of 30th January 2003 and will be submitted for final discussion and adoption by the SSC at its meeting of 6-7 March 2003.

Regarding the Risk assessment of food-borne bacterial pathogens, it was agreed that it would be discussed for final adoption at the SSC meeting of 16-17 January 2003.

c. Emerging scientific issues

No issues were reported under this agenda item.

d. Draft WHO/FAO Document on “Diet, nutrition and prevention of chronic diseases” (for information).

The SSC Secretariat informed the SSC of the draft document “Diet, nutrition and the prevention of chronic diseases”, which is currently being prepared by WHO and FAO. A sample copy was available at the meeting and the web-address where the document can be found, was provided.

e. Ethical, legal and socio-economic aspects of agriculture, fisheries and food biotechnology.

Ms. E.Sanchez of the Research Directorate General presented the report on the above subject which had recently been finalised by the Biotechnology, Agriculture and Food Directorate. She invited the SSC members to send in comments on the report and suggestions how to further explore it, for example by organising a Workshop. The document was well received and several SSC members announced that they would provide comments. These will be collected and edited by Dr.P.Le Neindre.

6. Multidisciplinary matters relating to TSE/BSE

6.1. Report on the TSE/BSE *ad-hoc* group meetings of 21 November 2002

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 adopted an opinion on the geographical BSE risk (GBR) of Greece and one on the GBR of Andorra. (**Annexes 4 and 5**). Both countries are considered as “GBR III” countries, meaning that presence of one or more cattle clinically or pre-clinically infected with the BSE agent is likely but not confirmed or confirmed, at a lower level.

b. Update of the SSC opinion 12-13 September 2002 on the safety of gelatine.

Following comments and a request from Gelatin Manufactures Europe (GME), the SSC discussed and adopted a number of clarifications to its updated opinion on the

safety of gelatin adopted on 12-3 September 2002. The revised text is attached as Annex 6.

c. 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 December 2002. The discussion of the draft opinion and report was therefore postponed to the SSC meeting of 16-17 January 2003.

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

The Secretariat confirmed that the Health and Consumer Directorate General had now launched the administrative procedure for contracting out the calculations on the basis of the method and ranges of input data provided in the Report of the TSE/BSE ad hoc Group finalised in July 2002.

e. BSE risk of the bovine autonomic nervous system.

The secretariat informed the SSC that a draft report had been discussed a first time by the TSE/BSE ad hoc Group at its meeting of 21 November. The report is now being amended and will be discussed again on 9 January 2003. A draft opinion may then be available for adoption by the SSC at its meeting of 16-17 January 2003.

f. Potential risks arising from the use of small incinerators

Prof. Bridges, rapporteur, the Secretariat presented to the SSC a first draft report and opinion. A brief introductory discussion followed. The document was then referred to the TSE/BSE ad hoc Group for in-depth discussion at its meeting of 9 January 2003.

g. Conditions under which (1) safe burial and (2) safe burning can be achieved

Prof. Bridges, rapporteur, the Secretariat presented to the SSC two draft reports and opinions. A brief introductory discussion followed. The documents were then referred to the TSE/BSE ad hoc Group for in-depth discussion at its meeting of 9 January 2003.

h. Chronic Wasting Disease.

The secretariat presented to the SSC the updated draft report prepared following the TSE/BSE *ad hoc* Group meeting of 21 November. It informed the SSC that an additional working group meeting is planned for 8 January 2002, to be followed by a second discussion by the TSE/BSE ad hoc Group on and 9 January 2003. A submission to the SSC is now expected for 16-17 January 2003.

i. 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.

j. Criteria for considering a production process effective in terms of TSE clearance.

Following a suggestion of Dr.R.Somerville, member of the TSE/BSE *ad hoc* Group, the issue of the level of TSE infectivity clearance by processing/physical treatment that would result in acceptable risk reduction was briefly discussed. The level of required clearance is dependent on the intended fate of the residual material. If the material is proposed to be utilised for various purposes, a larger risk reduction must be assured than is the case where the residue will only be further processed as part of its final

waste disposal. In the design of any study the potential fate of the residues must be borne in mind.

This item was referred to the TSE/BSE ad hoc Group for possible further discussion.

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

The secretariat informed the SSC that Commission Services submitted a new question on the above subject. The SSC referred the question to the TSE/BSE *ad hoc* Group, with the request to update its opinion on the BARB cases in the UK in the light of the question of the Commission Services and the information attached to the request.

l. BSE-related culling in cattle.

The secretariat informed the SSC that Commission Services submitted a new question on the above subject. The SSC referred the question to the TSE/BSE *ad hoc* Group, with the request to update its opinion on culling in the light of the question of the Commission Services and the reports on culling from France, Denmark and Belgium attached to the request.

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.

No information was provided by Commission Services.

9. Any other business.

The SSC had an exchange of ideas on two pieces of information that recently became available in the field of BSE. The first information is the paper from Asante *et al* (2002) on BSE prions propagating as either variant CJD-like or sporadic CJD-like prion strains in transgenic mice expressing human prion protein. The second information is the interview recently given by Dr.S.Prusiner to press in the UK, warning that eating meat could still pose a serious health risk and that regular meat from cattle and sheep may harbour deadly levels of prions that cause CJD, that many UK citizens might be harbouring BSE agent and that this would need verification by massive testing. In the interview S.Prusiner also claims that a test developed by his team is 10.000 times more sensitive than systems currently in use in Europe and the USA.

The SSC recommended that the BSE/TSE *ad hoc* Group consider the Asante *et al* paper on its possible implications for the prevalence of CJD and vCJD in human populations and for BSE risk assessments.

Regarding the declarations made by Dr.Prusiner in the media, and provided he was correctly quoted, the SSC considered that there was currently no new scientific evidence to support either the warning on meat safety or the claim of test sensitivity. The SSC further referred to the currently ongoing programme of field evaluation of rapid *post mortem* BSE tests, which is expected to yield a first series of results (including their sensitivity) in early 2003.

The meeting ended on Friday 6 December 2002, at 12h30

Annex 1: List of participants in the SSC meeting on 5-6 December 2002.

List of presence

Members of the SSC:

- Prof. James Bridges (5 December only)
- Prof. Anthony R. Hardy
- Dr Keith Jones (5 December only)
- Prof. Werner Klein
- Dr Ada Knaap
- Dr Ib Knudsen
- Dr Pierre Le Neindre
- Prof. Gérard Pascal
- Prof. Pere Puigdomenech (not present morning of 5 December)
- Prof. Staffan Skerfving

Apologies for absence:

- Ing. Georges Bories
- Prof. Johanna Fink-Gremmels
- Prof. Johannes Löwer
- Prof. Albert Osterhaus
- Prof. Vittorio Silano
- Dr Ian White

Participants from the Commission:

DG SANCO: B. Carsin, C. Berlingieri, P. Wagstaffe, P. Vossen, M. Goll, B. Goossens, J. Ordeig Vila,
G. Morrison, S Delle Chiaie, M-N. Costa, M. Marini, J. Serratosa, V. Rolland, G. Fontanesi,
N. Kollmorgen (Stagiaire)

DG RTD: E. Sachez.

Annex 2: Agenda of the Scientific Steering Committee Meeting of 5-6 December 2002

1. Welcome, apologies, introductory remarks, declaration of interest.
2. Approval of the agenda
3. Approval of the minutes of the meeting of 7-8 November 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. Food and non-food aspects of risk assessments.
 - e. Draft WHO/FAO Document on "Diet, nutrition and prevention of chronic diseases" (for information).
6. Multidisciplinary matters relating to TSE/BSE
 - 6.1. Report by the chairman of the TSE/BSE *ad-hoc* group meetings of 21 November 2002
 - 6.2. Reports on specific multidisciplinary matters relating to TSE/BSE:
 - a. Geographical BSE Risk: the GBR of certain countries.
 - b. Safety of gelatine: update.
 - c. Update of the SSC opinion on the safety of di- and tricalcium phosphate from bones;
 - d. Quantitative assessment of the risk of tallow, gelatine and dicalcium phosphate;
 - e. BSE risk of the bovine autonomic nervous system;
 - f. Potential risks arising from the use of small incinerators;
 - g. Conditions under which (1) safe burial and (2) safe burning can be achieved (progress report)
 - h. Chronic Wasting Disease.
Rapid tests:
 - i. Information
- For discussion
 - j. Criteria for considering a production process effective in terms of TSE clearance.
New questions:
 - k. BSE cases born after the reinforced feed ban in the UK (BARBs)
 - l. BSE-related culling in cattle.
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)

This note reports the activities of the SCF in the last 135th plenary session taking place on 2/3/4 December 2002. The Committee adopted 11 opinions and statements. The most important ones are:

- Opinion polycyclic aromatic hydrocarbons (PAHs) as contaminants.
- One additional upper levels of a micronutrient: Vitamin D. The Committee has established 16 out of 29 initially foreseen when this work started. Many of the most important of the 29 micronutrients have already been evaluated by the Committee.
- The Committee re-evaluated the sweetener aspartame.
- The Committee evaluated the safety of 3 particular impurities in 3 food additive Community specifications.
- The Committee evaluated a tropical fruit juice (tahitian noni juice) as a novel food.
- The Committee evaluated two additional flavourings: thujone and furfural. It also evaluated two Groups of chemically defined flavouring substances listed in the Community Register of flavouring substances used in or on foodstuffs.
- As regards plastic food contact materials, the Committee adopted an opinion about the introduction of a Food Consumption Factor in the assessment of plastic food contact, a factor to take into account more realistic fat intakes rather than the prevailing assumptions used both by the SCF and the Commission in the safety assessment and in the regulations respectively.
- The Committee adopted a statement about the status of Bisphenol A diglycidyl ether (BADGE) in food contact materials.

There were also other issues in the agenda that were discussed and on which the Committee decided to consider them at the next meeting as they needed further consideration by the Working groups.

SCIENTIFIC COMMITTEE ON ANIMAL NUTRITION (SCAN)

The SCAN continues its work and concentrates on finalizing as many opinions as possible in order to limit the carry over to EFSA.

The SCAN met at the beginning of the week and discussed several opinions for possible adoption among which a number were considered satisfactory and consequently adopted.

SCIENTIFIC COMMITTEE FOR PLANTS (SCP)

As the last SCP Plenary took place on 23 October 2003, there is nothing new to report from the SCP.

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 27-28 November.

Two new questions on “Tuberculosis in bovine animals: risks for human health and control strategies” and on “West Nile virus” were presented. The Committee agreed to the requests and gave mandate to set up an ad hoc working group for each question.

Other draft reports were discussed by the Committee, and remarks made to the documents presented, to be updated for future discussion.

The next SCVPH plenary is organised for 21-22 January 2003.

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

A meeting of the Sub-Committee on Animal Health took place on the 20th November, where a draft report on the use of fish by-products in aquaculture was discussed and commented upon. The document will be re-tabled at the next Sub-Committee meeting in January.

A draft opinion on the feeding of wild fishmeal to farmed fish and recycling of fish with regard to the risk of TSE, prepared by the TSE/BSE ad hoc group of the Scientific Steering Committee, was also presented to the members. It was agreed that there should be co-ordination and cross-referencing between both the SSC and the SCAHAW papers.

Progress is ongoing in a number of other working groups and the next plenary meeting of the Committee is scheduled to take place on December 17th.

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

Since the last SSC plenary meeting of 7-8 November 2002, the following 5 Working Group meetings of the Scientific Committee on Cosmetic Products and Non-Food Products have taken place:

12 November WG on Hair Dyes

13 November WG on Alternatives

20 November WG on Inventory

2 December WG on Preservatives

3 December WG on UV Filters

At the WG on Hair Dyes, *ad hoc* groups were formed to work towards finalising the risk assessment of 21 substances being evaluated.

At the Inventory WG it was explained that, according to Directive 76/768/EEC the Commission shall update the Inventory of Cosmetic Ingredients. As the SCCNFP has no legal mandate for the Inventory, DG ENTR has now taken over full responsibility for the Inventory. DG ENTR will organize a meeting with all concerned parties (DG ENTR, JRC, DG SANCO and other stakeholders) in order to establish an appropriate strategy and timing for the second update.

On 11th October 2002 the SCCNFP received a mandate from DG ENTR concerning the safety assessment of Fluorine compounds in oral hygiene products for young children. The mandate was openly discussed at the SCC meeting on the 8 November. It was agreed that experts previously involved on the risk assessment on Fluoride from other areas could be proposed in order to avoid inconsistencies. The Scientific Committees involved were Food, Tox & Ecotox and Medical Devices. In order to organise an *ad hoc* WG on Fluoride & Young Children we wish to receive from these Committees the names of any recommended experts. The names will be presented at the SCCNFP Plenary 17th December with the aim of organising a first WG meeting in January 2003.

Through the process of Conciliation, a 7th Amendment of the Cosmetics Directive has been formulated that includes prohibition of safety evaluation using animals, labelling of certain

fragrance allergens identified by the SCCNFP and the prohibition of CMR category 1 and 2 and restrictions on CMR 3 substances in cosmetic products.

No other particular items of a multi-disciplinary nature have been discussed.

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

No meetings of the SC-TEE were held since the last plenary meeting of the SSC. The next SC-TEE Plenary meeting will take place on 17th December 2002.

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

No meetings of the SC-MPMD were held since the last plenary meeting of the SSC.

Annex 4



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

OPINION ON
THE GEOGRAPHICAL RISK OF BOVINE SPONGIFORM
ENCEPHALOPATHY (GBR) IN GREECE
ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE
AT ITS MEETING OF 5-6 DECEMBER 2002

(DISTRIBUTED SEPARATELY)

Annex 5

OPINION ON
THE GEOGRAPHICAL RISK OF BOVINE SPONGIFORM
ENCEPHALOPATHY (GBR) IN ANDORRA
ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE
AT ITS MEETING OF 5-6 DECEMBER 2002

(DISTRIBUTED SEPARATELY)

Annex 6

UPDATED OPINION ON
THE SAFETY WITH REGARD TO TSE RISKS OF GELATINE
DERIVED FROM RUMINANT BONES OR HIDES
ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE
AT ITS MEETING OF 5-6 DECEMBER 2002

(DISTRIBUTED SEPARATELY)