

Minutes of the Scientific Steering Committee Meeting of 4-5 April 2002

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

Given the non-availability of Prof.G.Pascal on 4 April 2002, the meeting was chaired by Prof.A.Osterhaus, vice-chairperson of the SSC.

Prof.A.Osterhaus welcomed the participants of the Scientific Steering Committee. He apologised Profs. V.Silano, J.Bridges and J.Fink-Gremmels (for both 4 and 5 April), Prof. G.Pascal for 4 April 2002 and Profs. K.Jones and G.Bories for 5 April. The list of participants is attached as **Annex 1**.

Declarations of interest:

No declarations of interest were made for this specific 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 21-22 February 2002.

The minutes of the meeting of 21-22 February 2002 were adopted without changes.

4. Procedural matters:

The SSC briefly discussed the issue of how to deal, in written reports and opinions, with documents that were made available in scientific or commercial confidence to a Scientific Committee or to a Working Group. Mr.C.Berlingieri informed the SSC that this issue was currently also being addressed by the services of the Commission and that the SSC would be kept informed of the outcome of this exercise. The SSC signalled that the EMEA has a firmly established policy with regard to confidentiality of documents. It may contain aspects that are also applicable in a EC context and liaising with EMEA was thus recommendable.

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:

- Prof.I.Knudsen announced that the report prepared by the working group on Risk assessment of food borne bacterial pathogens had been put on internet for public consultation. Comments are awaited until June. It is expected that also the final versions of the other specific reports (e.g., chemical substances, environmental risks, quality of life, definitions and quantitative risk assessment methods) will be available around the same time. A general opinion will then be distilled from these reports, highlighting their potential to contribute to an overall harmonisation of risk assessment methods.
- The SSC had a discussion on human exposure data and considered that a correct risk assessment of any product (food, feed, medicinal, cosmetic or non-food) is impossible if no recent and appropriate human exposure data are available. These

data need to be comprehensive, i.e., not limited to averages but include ranges, exceptional exposures/intakes and corresponding probability, as well as exposures via routes of exposure uses other than the ones considered by a specific Scientific Committee (e.g., substances used in cosmetic products may also be used in food or medicinal products). Such data are very difficult to find, and often not existing at all. The SSC confirmed and broadened the recommendation it made at its meeting of 28-29 June 2001, that research and exposure data collection should receive priority and that this issue of exposure data should also receive the appropriate attention in the 6th Framework Programme for Research currently being prepared by Commission Services.

c. Emerging scientific issues

- Prof.Osterhaus briefed the SSC on the meeting on emerging infectious diseases that was held in Atlanta end March 2002 and organised by the USA's Centre for Disease Control (CDC). He commented that the EU's efforts in pro-actively cooping with emerging diseases was very minor as compared with the USA, where an approximate US \$ 2 billion were to be invested during the next 2-3 years.
- A brief tour-de-table was held, on the question whether new (re-)emerging issues needed to be signalled because they had a potential direct or indirect (e.g. via the environment or animal feed) public health impact.

An emerging issue that was signalled and that needs attention is the risks from "*non-target [unknown] properties of natural products*". A recent concrete example is the rapidly increasing use as growth promoter in animal feed of plant extracts claimed to have (phyto-)therapeutic and/or appetising and/or growth promoting and/or anti-coccidial effects. These products may, however, have toxic side-effects but for which have not been tested or for which no risk assessment has been carried out or be made available.

The Secretariat informed the SSC that it would inform the appropriate Commission Services about the above concern, as it previously did for other issues such as antimicrobial resistance, hair dyes, etc.

d. Antimicrobial resistance.

Prof.Jones reported that no further progress had been made by the Working Group since its meeting of 8 February 2002. The next meeting of the working group was scheduled for 19 April 2002.

e. Primate research facilities in Europe.

Prof.Osterhaus introduced the updated draft report on *The need for non-human primates in biomedical research*, prepared on the basis of the discussions held at the SSC's previous meeting. Following discussion and amendments, the opinion attached as **Annex 4** was adopted.

f. New questions

No new questions (apart from the ones related to TSEs listed further on) had been submitted to the SSC since last meeting.

g. The 6th Framework Programme for Research (2002-2006)

The Scientific Steering Committee had a meeting with DG RTD officials to appraise themselves of developments in the 6th Framework Programme for Research (FP6) and ERA (“European Research Area”). An update on FP6 and ERA – with emphasis on priorities 1, 5 and 8, instruments and the Expression of Interest call - was given by L. Breslin and L. Bochereau of Research Directorate General.

The SSC had already had a discussion on what they saw as important priorities and will indeed forward these to DG RTD as a position paper in the near future. This position paper is expected to be more focussed than the list of items that emerged in the discussion (see below). A drafting group, consisting of members of the SSC will meet first on 23 April.

The following is a resume of the principal items they raised - these items are relevant to Priorities 1, 5, 6 and 8:

- Science of Risk Assessment – exposure, integrated assessment covering positive and negative aspects of food intake, microbiological and chemical risks, environmental risks - linked to food, international dimension of risk assessment.
- Needs of Population groups: ageing and genomics, children.
- Status of the human immune system, food consumption, links to prevention of diseases/disorders, e.g. cancers, allergies, osteoporosis.
- Infectious diseases and food - zoonoses, other animal Spp., infectious diseases and wildlife – not linked to food, emerging infectious diseases – possibly not linked to food.
- Human well being – move from an approach “reducing risk” to “maximising health”.
- Properties (side effects) of preparations from natural products.
- Global change and effects on emerging phytosanitary issues and infectious diseases.
- Epidemiological studies as a source of reliable assessment data – not just linked to food.
- Genomic tools for food safety, gene-environment interactions, genomic aspects of infectious diseases not linked to food.
- Assessment of novel foods, GMOs, novel ingredients.
- Re-cycling of materials, e.g. packaging and safety in the food chain; by products – in animal feed and food safety.
- Environmental interactions – health – food safety, agents in the environment.

The concept of the new instruments (LIPs and NoEs) was presented and was well received. The acting chairman of the SSC welcomed the new approach stressed that the SSC were very interested in FP6 and ERA and that it should be obligatory for these large projects to adopt a professional approach to communication of results and public acceptability and new technologies.

6. Multidisciplinary matters relating to TSE/BSE

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

The secretariat, on behalf of Prof.Silano, chairman of the TSE/BSE *ad hoc* Group, reported briefly on the meeting of the TSE/BSE *ad hoc* Group of 21 march 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

The Secretariat reported on the progress made by the GBR working group, which is currently not only evaluating new country submissions but also reassessing the GBR level of a number of already assessed EU Member States. In total, 89 country-dossiers are currently being (re-)assessed. The earlier announced opinions for Austria, Finland, Sweden and Greece are now expected to be ready for adoption at the meeting of 16-17 May 2002.

b. The bovine vertebral column as a specified risk material;

At its meeting of 21 March 2002 the TSE/BSE *ad hoc* Group discussed a preliminary draft report. A draft opinion is expected to be available for possible adoption by the SSC at its meeting of 16-17 May 2002.

c. Animal waste disposal

The secretariat confirmed that the date of finalisation of the pending opinion on the alkaline treatment for waste reduction, depends on the date of availability of the final results of the currently ongoing inactivation experiments. They are now expected to be available by early May 2002, which would mean that the adoption of an opinion becomes possible for the meeting of 16-17 May 2002.

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

The secretariat reported that the Working Group “Quantitative Risk Assessment – QRA” had its first meeting on 28 February. A draft report presenting the basic input parameters and assumptions was currently being circulated for comments. Once these are adopted, calculations of the risk levels corresponding with various scenarios (e.g., with and without removal of SRMs) and assumptions (e.g., regarding the species barrier) will be made. A draft opinion is expected to be available for possible adoption by the SSC at its meeting of June 2002 at the earliest.

e. Safety of rennet derived from ruminants.

The TSE/BSE *ad hoc* Group is currently preparing a detailed report on the subject. It will, however, not be finalised in the immediate future because it requires the inputs from several other opinions which are still pending. These include the opinions on *Safe sourcing of small ruminant materials* (addressing, amongst others, the safety of the small ruminant stomachs) and the *Quantitative risk assessment of tallow and fats* (assessing, amongst others, the possible residual risk in milk replacers fed to calves).

Given the urgency of an opinion on the safety of calf rennet used for the production of lactose in medicinal products, the SSC prepared, discussed and adopted a short statement addressing only the issue of calf rennet (**Annex 5**). It is based on the already exploitable parts of the above draft TSE/BSE *ad hoc* Group report and on Report on the Risk and regulatory assessment of lactose prepared using calf rennet adopted by EMEA’s¹ Biotechnology Working party at its meeting of 11-13 February 2002. It should be noted that the statement might need to be updated once the full report on the safety of rennet has become available.

¹ EMEA (European Agency for the Evaluation of Medicinal Products), 2002. Risk and regulatory assessment of lactose prepared using calf rennet. Report from Biotechnology Working Party of the EMEA, London, 12 February 2002. Doc. Ref: EMEA/CPMP/BWP/337/02/Final.

f. Prions in muscle: evaluation of the Bosque *et al* (2002) paper.

Investigations published on 19 March 2002 in the Proceedings of the [USA] National Academy of Sciences (PNAS) by Stanley Prusiner's group indicate that skeletal muscles of scrapie-infected mice contain and may amplify the agent (Bosque *et al*, 2002). In this study, infectivity was found in hind-limb muscles of wild-type mice inoculated i.c. and i.p. with two mouse-adapted scrapie strains.

As a follow-up to this paper, the Commissioner for Health and Consumer Protection asked the Scientific Steering Committee to evaluate Prusiner's paper and to judge whether it provided scientific grounds justifying revising or amending previous SSC opinions related to TSE risks.

Using a detailed evaluation prepared by the TSE/BSE *ad hoc* Group at its meeting of 21 March 2002, the SSC discussed and adopted the statement attached as **Annex 6**. This statement takes also into account the tests carried out after 19 March 2002 by the French Food Safety Agency (AFSSA).

g. New questions.

- BSE risk of the bovine autonomic nervous system;

Following a request from the German Federal Authorities, Commission Services invited the SSC to prepare an opinion on the question whether the evaluation of the safety of the bovine autonomic system carried out by a number of scientists contained elements and scientific data justifying a revising of previous SSC opinions related to bovine specified risk materials. The Secretariat informed the SSC that the TSE/BSE *ad hoc* Group at its meeting of 21 March 2002 appointed a rapporteur and that it would submit as soon as possible a report to the SSC

- Safety of bovine embryos;

Commission Services invited the SSC to prepare an opinion on the question whether the results of the UK embryo transfer research that became available in early 2002, contained elements and scientific data justifying a revising of previous SSC opinions related to maternal risk enhancement and to the safety of bovine embryos. The Secretariat informed the SSC that the TSE/BSE *ad hoc* Group at its meeting of 21 March 2002 appointed a rapporteur and that it would submit as soon as possible a report to the SSC

h. Safe sourcing of small ruminant materials should BSE in small ruminants become probable: genotype, breeding, rapid TSE testing, flock certification and Specified Risk Materials.

Using the detailed and revised Working Group report finalised by the TSE/BSE *ad hoc* Group at its meeting of 21 March 2002, the SSC discussed and adopted the opinion attached as **Annex 7**.

i. Approach to investigate the possible presence of BSE in sheep.

Using a detailed report prepared by a special working group and finalised by the TSE/BSE *ad hoc* Group at its meeting of 21 March 2002, the SSC discussed and adopted the approach attached as **Annex 8**.

j. Actualisation of the existing Geographical BSE Risk methodology to small ruminants, by taking into account factors that may be unique to sheep.

The secretariat reported that the newly created Working Group had its first meeting on 19 March 2002. A report was currently being prepared.

k. Evaluation of rapid BSE tests (progress report)

The SSC suggested that the Commission would present the procedure to be used for the approval of new BSE tests (in vivo, post mortem, scrapie/BSE differential, lymphoid tissues, CNS).

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

No information on this subject was provided.

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

Apart from the 6th Framework Programme for research-related issues, no information was provided by other Commission Services.

9. Any other business.

No other business were discussed.

The meeting ended on Friday 5 April 2002, at 11h30.

Annex 1: Participants in the Scientific Steering Committee meeting of 4-5 April 2002.

List of presence

Members of the SSC:

- Ing. Georges Bories (4 April only)
- Prof. Anthony R. Hardy
- Dr Keith Jones (4 April only)
- Prof. Werner Klein
- Dr Ada Knaap
- Dr Ib Knudsen
- Dr Pierre Le Neindre
- Prof. Johannes Löwer
- Prof. Albert Osterhaus (Chairman)
- Prof. Gérard Pascal (not present on 4 April)
- Prof. Pere Puigdomenech (not present 4 April morning)
- Prof. Staffan Skerfving
- Dr Ian White (not present 4 April afternoon)

Invited experts:

- Dr Emmanuel Vanopdenbosch (4 April only)
- Prof. Gerald Wells (4 April only)

Apologies for absence:

- Prof. James Bridges
- Prof. Johanna Fink-Gremmels
- Prof. Vittorio Silano

Participants from the Commission:

DG SANCO: B. Carsin, C. Berlingieri, P. Vossen, J. Kreysa, M. Goll, G. Morrison, D. Jacquemin, M. Granero, R. Morgan, A. Van Elst, J. Connell, A. Meesters (stagiaire), M. Bregu (stagiaire), S. Iñigo (stagiaire).

DG RTD: L. Breslin, L. Bochereau, E. Schez

Annex 2: Agenda

1. Welcome, apologies, introductory remarks, declaration of interest.
 2. Approval of the agenda
 3. Approval of the minutes of the meeting of 21-22 February 2001
 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;
 - Risk assessment of food borne bacterial pathogens (for comments)
 - c. Emerging scientific issues (reports, if any);
 - d. Antimicrobial resistance (progress report on azole and on Triclosan resistance)
 - e. Primate research facilities in Europe (Statement, for adoption)
 6. Multidisciplinary matters relating to TSE/BSE
 - 6.1. Report by the chairman of the TSE/BSE *ad-hoc* group meeting of 21 March 2002
 - 6.2. Reports on specific multidisciplinary matters relating to TSE/BSE:
 - a. Geographical BSE Risk: the GBR of certain countries (progress report).
 - b. The bovine vertebral column as a specified risk material (progress report);
 - c. Animal waste disposal (progress report)
 - d. Quantitative assessment of the risk of tallow and gelatine (progress report)
 - e. Safety of rennet derived from ruminants (for adoption).
 - f. New questions: is there a need to revise/amend existing SSC opinions?
 - TSE infectivity in muscle tissue: Evaluation of the Bosque *et al* (2002) paper
 - BSE risk of the bovine autonomic nervous system;
 - Safety of bovine embryos;
- TSEs in small ruminants:
- g. Safe sourcing of small ruminant materials should BSE in small ruminants become probable: genotype, breeding, rapid TSE testing, flock certification and Specified Risk Materials (for opinion).
 - h. Protocol to investigate the possible presence of BSE in sheep (for opinion).
 - i. Actualisation of the existing Geographical BSE Risk methodology to small ruminants, by taking into account factors that may be unique to sheep (progress report)
- Rapid tests:
- j. Evaluation of rapid BSE tests (progress report)
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 SSC meeting of 29-30 November 2001, as provided by the secretariats of these Committees.

(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 had its 131st plenary on 25/26/27 February, just after the last SSC meeting.

The SCF adopted at this plenary session opinions on the following subjects: capsaicin in flavourings, the group evaluation of *Fusarium* toxins (as contaminants in food), the foods derived from genetically modified maize line GA21 as novel food, an additional list of monomers and additives in food contact materials, certain chemical and microbiological parameters of the Commission's specification on gelatine, and a report on the risk profile of the food borne pathogens for fruit and vegetables eaten raw.

The next, 132nd, SCF plenary takes place just after this SSC plenary, on 15/16/17 April. During this period there has also been several meetings of SCF Working Groups: Additives, Contaminants, the Task Force on Polycyclic aromatic hydrocarbons, the Task Force on Upper Levels of vitamins and minerals. The WG Nutrition meets shortly.

The SCF will likely discuss and possibly adopt opinions at this next plenary on the following issues: tolerable upper intake levels of niacin and pantothenic acid, reference nutritional values for nutrients used in the Directive on nutrition labelling, requirements for dietetic foods for persons suffering from diabetes, the safety assessment of the genetically modified sweet maize line Bt 11 as novel food, an additional list of monomers and additives for contact materials and also Bisphenol A in food contact materials, impurities of ethylene oxide in food additives specifications, clarifications of the recent SCF opinions on the food additive carnauba wax and on N-vinyl-pyrrolidone residues in the food additives PVP and PVPP. The Committee also will evaluate a number of flavouring substances at this meeting.

SCIENTIFIC COMMITTEE ON ANIMAL NUTRITION (SCAN)

Several SCAN working groups have met since the last SSC meeting, but no plenary session has been organized since then. Consequently there is progress made with the preparation of opinions, but no final ones have been adopted recently.

SCIENTIFIC COMMITTEE FOR PLANTS (SCP)

No SCP Plenary meeting took place since the last SSC Plenary of 21-22 Feb.

SCIENTIFIC COMMITTEE VETERINARY MEASURES RELATING TO PUBLIC HEALTH

No SCP Plenary meeting took place since the last SSC Plenary of 21-22 Feb.

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

A plenary meeting was held on the 5th of February and next one is planned on 16 April.

An opinion on the Welfare of animals during transport was adopted on 11 March by using a written procedure as decided in the last plenary meeting.

Last 20 March took place a subcommittee meeting on Animal Health and was approved a report on Avian Chlamydiosis under the chairmanship of Dennis Alexander, this report will be proposed for discussion and possible adoption during the next plenary meeting on the 16th of April.

DG research requested a document on research priorities for the Sixth Framework research programme on animal health and animal welfare areas. The document was prepared and has been circulated between the members to rank the priorities. It has been sent to DG Research.

Other working groups are engaged in drafting reports on topics such as Fish waste (17 April), rabies (7 March), welfare of non-human primates (27 March) and Stunning (first meeting not yet decided) .

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

Since the last SSC plenary meeting of 21-22 February 2002, 1 Plenary meeting and 3 Working Party meetings of the Scientific Committee on Cosmetic Products and Non-Food Products have taken place.

The following issues of particular interest have been discussed :

Alternatives : a draft work programme for a complete revision of the Notes of Guidance has been presented, indicating the chapters to be updated, re-written or re-arranged.

Detergents, Household & Similar Products : as mentioned in the previous progress report, the Committee has adopted a Position Statement on the need for the complete labelling of ingredients in such products (similar to cosmetic products and for the same reasons) and on the role of the SCCNFP regarding the safety review of substances used in these. Assessment of risk requires information on consumer exposure and this is not presently provided for.

Hair Dyes : Also, and referring to the previous report, the Committee adopted a discussion paper on "Assessment strategy on hair dyes" during its 19th Plenary meeting of 27 February 2002. Because of the considerable implications of the items discussed in the document, interested external parties have been invited to send their comments before 6 May 2002.

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

No report was made available to the SSC secretariat.

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

No SCP Plenary meeting took place since the last SSC Plenary of 21-22 Feb.

Annex 4



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

THE NEED FOR NON-HUMAN PRIMATES IN BIOMEDICAL RESEARCH

**STATEMENT OF THE SCIENTIFIC STEERING COMMITTEE
ADOPTED AT ITS MEETING OF 4-5 APRIL 2002**

(DISTRIBUTED SEPARATELY)

Annex 5



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

**PROVISIONAL STATEMENT ON THE SAFETY OF
CALF-DERIVED RENNET FOR THE MANUFACTURE OF
PHARMACEUTICAL LACTOSE.**

**ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE
AT ITS MEETING OF 4-5 APRIL 2002.**

(DISTRIBUTED SEPARATELY)

Annex 6



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

PRIONS IN MUSCLE

**STATEMENT ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE
AT ITS MEETING OF 4-5 APRIL 2002**

(DISTRIBUTED SEPARATELY)

Annex 7



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

OPINION ON:

SAFE SOURCING OF SMALL RUMINANT MATERIALS

**(SAFE SOURCING OF SMALL RUMINANT MATERIALS SHOULD BSE IN
SMALL RUMINANTS BECOME PROBABLE: GENOTYPE, BREEDING,
RAPID TSE TESTING, FLOCKS CERTIFICATION AND SPECIFIED RISK
MATERIALS)**

**ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE AT ITS
MEETING OF 4-5 APRIL 2002**

(DISTRIBUTED SEPARATELY)

Annex 8



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

**STRATEGY TO INVESTIGATE
THE POSSIBLE PRESENCE OF BSE IN SHEEP**

**OPINION ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE
AT ITS MEETING OF 4-5 APRIL 2002**

(DISTRIBUTED SEPARATELY)