Minutes of the Scientific Steering Committee Meeting of 29-30 March 2001

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

Chairman Prof.Pascal welcomed the participants of the Scientific Steering Committee. He apologised, for 29 and 30 March: Prof.Loewer; for 29 March: Prof.Silano and Prof.Jones; for 30 March: Prof.Fink Gremmels and Prof.Hardy.

Declarations of interest:

With regard to item 7 on the Agenda, Prof.Pascal reminded his colleagues that he was chairman of the scientific council of the AFSSA. In this capacity he is co-responsible for assuring the coherence of the opinions emitted by the scientific committees of AFSSA. The AFSSA committees currently do not include the French Inter-ministerial Committee on Transmissible Sub-acute Spongiform Encephalopathies, which prepared the scientific basis for the AFSSA opinion of 14 February 2001, referred to in item 7.

The SSC members considered that Prof.Pascal's independence was not at stake and that he could chair the discussion on item 7 meeting and participate in the debate.

2. Approval of the agenda

The agenda was slightly amended and approved . It is attached as annex 2.

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

The minutes of the meeting of 8-9 February 2000 were adopted without changes.

4. Procedural matters

a. Rules of procedure.

An update of the Rules of procedure was discussed and adopted. It is attached as annex 3.

In the margin of the exchange of ideas on the Rules of procedure, the SSC discussed the general format of meeting minutes of the various Scientific Committees. It was agreed that items discussed by a given committee but that required the input of other committees would be reported on appropriately, i.e., without prejudice to the possible input or opinion of another Committee.

b. Membership of the TSE/BSE ad hoc Group

This item will be further discussed at the meeting of 10-11 May 2001.

c. Planning of activities and priorities.

Various members expressed their concern that the workload on the Committees was permanently increasing, without however additional manpower or secretarial support. The SSC's work related to the harmonisation of risk assessment methods and to emerging scientific issues contributed to this, because it requires the establishment of various working groups and task forces.

The SSC agreed to monitor this closely so as to avoid conflicting priorities and to possibly adjust its planning when needed.

5. Multidisciplinary matters:

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

- The 8 chairpersons reported on the work of their respective Scientific Committees, whilst emphasising on matters that are of a multidisciplinary nature and/or require co-ordination.

  In this context, a discussion was held on the use of animals in the safety testing of cosmetic ingredients. In his report on the activities of the Scientific Committee for Cosmetic and Non-Food Products, the Chairman of the SCCNFP informed the SSC that the 7th Amendment of the Cosmetics Directive, as proposed by the European Parliament, would introduce a complete ban on the use of animals for the additional testing of ingredients required to evaluate their safety when used in personal care products. Such a ban would cause serious problems for the work of the SCCNFP as it could lead to the lack of scientifically based safety data and it would not be possible to assess substances such as uv-filters and preservatives as required by the cosmetics directive. This provoked a wider discussion in the SSC on the possible consequences on risk assessment and consumer health in general if such a ban should be introduced

  The SSC noted the concerns of the SCCNFP and agreed to reflect on the points raised, including the need to avoid duplication of experiments and consideration of the welfare of laboratory animals.

- Other detailed information on the activities of the various Scientific Committees is attached as Annex 4.

b. Harmonisation of risk assessment methods.

Prof.Bridges reported on the First meeting of Task Force held on 12 March 2001. At this meeting, 3 Working Groups were created and respective remits were defined. The 3 Working Groups will address harmonisation of methods in the fields of (a) biological materials (b) chemical agents and (c) environmental risk assessment.

He also introduced the proposal for a format and structure of opinions that would be common for all Scientific Committees. He finally presented a draft glossary of terms related to risk analysis. It was agreed that the SSC members would sent their comments on these two items before next meeting to Prof.Bridges and the secretariat of the Task Force (Prof.J.L.Jouve), so that an updated drafts of the glossary and format can be discussed at next meeting.

The SSC further agreed that, to avoid misunderstanding, the English term "Scientific opinion" should translate as "Avis scientifique" in French.

c. Safety of cotton

Prof.T.Hardy, rapporteur, presented the state of progress on the draft report and opinion prepared as a joint exercise of experts from the Scientific Committee for Plants, the Scientific Committee for Medicinal Products and Medical Devises, the Scientific Committee for Cosmetic and non-Food Products and the Scientific Steering Committee. However, the draft could not yet be considered as final because a contribution from one Committee was still missing. Discussion and possible adoption were therefore postponed to the meeting of 10-11 May 2001.

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

- ***Emerging viruses***. Mr. C.Berlingieri (DG-SANCO) informed the SSC that a mandate is presently being prepared by Commission Services. The SSC suggested that the Working Group would use emerging human virus diseases such as influenza as an example, but that the methodological approach should be such that it can be adapted, in a second stage, to other agents such as bacteria, fungi, pests, etc.
- ***Anti-microbial resistance***. Prof.Jones and Prof.Bories, rapporteurs, reported on the first meeting of the Working Group held on 28 March 2001. At that meeting, the mandate and background to the question were presented and a first in-depth discussion was held. The mandate and its frame are attached to these minutes as Annex N° 5. It is expected that a draft report will be available for discussion and possible adoption at the SSC meeting of either 10-11 May 2001 or 28-29 June 2001.

e. New questions

No new question on an issue other then BSE/TSE had been submitted to the SSC.

f. 6th Framework Programme for Research

Mr.B.Hansen, Director of the Directorate Life Sciences: research actions for biotechnology, agriculture and food of the Research Directorate General introduced the state of advancement of the preparation of the 6th Framework Programme for Research (6th FWP) and presented the main themes. During the exchange of ideas that followed Mr.Hansen provided further information and clarifications. Several SSC members agreed to meet each other to further discuss ideas and suggestions as a contribution to the preparation of the 6th FWP.

6. Multidisciplinary matters relating to TSE/BSE

6.1. Report by the chairman of the TSE/BSE *ad-hoc* group meeting of 4 January 2001

The SSC secretariat reported briefly on the meeting of the TSE/BSE *ad hoc* Group of 15 March 2001. All items addressed by the *ad hoc* group are further dealt with in detail under point 6.2 of these minutes.

6.2. Reports on specific issues:

a. Geographical BSE Risk: update and possible adoption of an opinion on the GBR of a number of Third Countries.

The SSC discussed and amended the reports and draft opinions prepared by the Working Group on Geographical BSE Risk Assessment (GBR) on the geographical BSE risk in Albania, the Czech Republic, Estonia, the Slovak Republic, India, Mauritius, Pakistan, Cyprus, Singapore, Colombia, Hungary, Poland and Brazil. It adopted the opinions attached as Annexes 9 - 21.

b. Safety of tallow.

The secretariat introduced the draft updated report and scientific opinion on the safety of ruminant-derived tallow, prepared by the TSE/BSE *ad hoc* Group at its meeting of 15 March 2001 on the basis of a report by a Working Group resulting from a written e-mail consultation. This written procedure had to be followed given the urgency of

the matter and the fact that most of the Working Group members were not available for a meeting before the end of March 2001.

The SSC considered that the draft report needed further discussion in the light of the following new facts and data that became available since its last meeting 2001:

a. the new question submitted on 28 February 2001 by the Commission Services to the SSC whether intestine-associated bovine discrete adipose tissues should be included in the list of specified risk materials.

b. The submission on 27 March 2001 by the European Fat Processors and Renderers Association (EFPRA) of a technical document on the TSE safety of tallow derived from tissues originated from healthy animals.). This document provides recent information on tallow production systems and standards.

An updated report and draft opinion are now being expected to be available for discussion at the SSC meetings of either 10-11 May or 28-29 June 2001.

c. Safety of collagen

The secretariat provided information on the progress made on the draft report and opinion on the safety of collagen derived ruminant hides. At its meeting of 15 March 2001 the TSE/BSE *ad hoc* Group considered that further amendments were needed and the discussions by the SSC had therefore to be postponed.

d. Treatment and disposal of animal waste by alkaline hydrolysis at 150°C for at least 3 hours

Prof.Silano introduced a draft report and scientific opinion on the Treatment and disposal of animal waste by alkaline hydrolysis at 150°C for at least 3 hours prepared by the TSE/BSE *ad hoc* Group at its meeting of 15 March 2001. According to the EU regulation in force on 1 January 2001, animals, animal waste or products derived thereof (e.g., animal meat and bone meal) potentially contaminated with TSE agent by-products shall be disposed of by incineration or co-incineration. Alternative ways may be allowed following scientific opinion.

A method for treating animal waste by alkaline hydrolysis at elevated temperature was submitted to European Commission services as a possible alternative for disposal by (co-)incineration. The Commission Services submitted the following questions for opinion to the Scientific Steering Committee (SSC):

1. Can the treatment of animal waste as described by the dossier to be considered safe in relation to TSE risk? Can the liquid residues be considered safe in relation to TSE risk?
2. Can the by-products resulting from this treatment (i.e. ash of the bones and teeth of vertebrates) be considered safe in relation to TSE risk?

The SSC considered that it is not part of its mandate to evaluate and possibly endorse production processes or equipment submitted by individual companies. It decided however to prepare a general framework of criteria against which the appropriate services can evaluate the safety with regard to BSE of new processes and/or equipment developed by the industry.

For the time being, comparing with the results of already available TSE inactivation studies but keeping in mind that a validation study of this specific process is still ongoing, the SSC considered that the alkaline hydrolysis at 150°C during 3 hours under pressure and the liquid residues and the by-products resulting from this

treatment (i.e. ash of the bones and teeth of vertebrates) appears to be a very effective infectivity reduction method. However, the quantification in terms of reduction of infectivity will depend upon a further analysis of the process by the appropriate service against the framework for evaluation to be prepared the outcome of the presently ongoing inactivation study and the composition of the residues of the process.

What precedes does not address the possible environmental impact of the technology (e.g., disposal of the effluents and of the process residues), which the SSC considers should be addressed by the appropriate scientific committee.

e. BSE epidemiology (survey methods).

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

f. Medical instruments;

The Scientific Committee on Medicinal Products and Medical Devices monitors developments in the field of the safety of / possible risks related to medical instruments used for surgery and will raise the awareness of the Commission services and of the SSC should the need arise. The SSC invited the SC-MPMD to prepare a state of the art report on the available research results and scientific evidence on the safety of surgical instruments. It should take into account the SEAC opinion on disposable tonsil-ectomy instruments and the ongoing research at the Neuro-Pathology Unit of the University College of London funded by the UK Department of Health.

g. Origin of BSE, transmission and 3rd route;

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

h. Safety of organic fertilisers and soil conditioners;

The progress made by the BSE/TSE *ad hoc* Group was reported on by the secretariat. In addition, Prof.Klein made available a copy of the recent German report on the International Expert Discussion on the *Occurrence and Behavior of BSE/TSE Prions in Soil* (Bonn, December 18, 2000) organized by the Federal Ministry for the Environment, Nature Conservation and Reactor Safety. This report provides a detailed and most recent state of affairs not only on Behavior of BSE/TSE Prions in Soil but also on a number of possible reasons for concern linked with it: safety of organic fertilizers derived from ruminant material, environmental contamination and possible transmission. It was agreed that a number of experts that contributed to this report, including Profs. Klein and Silano, would be invited to contribute to the TSE/BSE ad hoc Group's work on this question.

i. State of the art of knowledge on the safety of milk.

The BSE/TSE *ad hoc* Group prepared a state of the art report on the available research results and scientific evidence on the safety of ruminant milk. It was discussed and adopted and is attached as Annex 6.

j. Safety of gelatine

New data on TSE agent inactivation by processing have been submitted to the SSC secretariat as a result of the SSC's recommendation of 1998 for inactivation studies to be carried out not only on the various individual steps of the production process but also on the process as a whole. In addition, the gelatine industry is providing the secretariat with the results of TSE inactivation studies on alternative production processes. Finally, Commission Services also recently submitted additional questions regarding the safety of gelatine. An update of the gelatine opinion is therefore prepared by the BSE/TSE *ad hoc* Group. The progress made by the BSE/TSE *ad hoc* was reported on.

k. Correspondence matrix of BSE risk levels

At its meeting of 7-8 February 2001, the SSC suggested that an equivalency matrix be established between the geographical BSE risk levels agreed upon in its opinion on Geographical BSE Risk of 7 July 2000 and the BSE risk categories used so far in its various opinions adopted since 1998 on the safety of ruminant-derived products such tallow, gelatine, dicalcium phosphate, hydrolysed proteins, meat-and-bone meal and organic fertilisers. The SSC agreed that, rather than doing this as a separate exercise, it was preferable to establish these correspondences on a case by case basis according as those various opinions would be revised or updated. The first upcoming opinions are the revisions on the safety of tallow, gelatine and organic fertilisers and the (new) opinion on the safety of collagen.

l. Scientific background to the Austrian measures.

Following the discovery of BSE cases in Germany, Austria envisaged a number of safeguard measures and provided the Commission with a scientific justification. This justification was evaluated by the TSE/BSE *ad hoc* Group at its meeting of 15 March 2001. The SSC discussed and amended the draft report prepared by the TSE/BSE ad hoc Group. An opinion was adopted. It is attached as Annex 7.

m. Second BSE case in UK born after 1 August 1996: appreciation.

On 14 February 2001, the UK Ministry of Agriculture, Fisheries and Food informs the European Commission services, on a second BSE case confirmed in an animal born after 1 August 1996, this time in Northern Ireland. The case history and epidemiological inquiry into possible sources of infection (including maternal and feed borne transmission) were provided to the EC services and are also publicly available on the MAFF Internet site.

The Commission Services had invited the SSC to express its appreciation on this case. The issue was first discussed by the TSE/BSE *ad hoc* Group who prepared a draft report and opinion. These were discussed in detail and amended by the SSC who adopted the opinion given in annex 8.

Because of the proven higher prevalence of BSE in fallen stock and emergency slaughters and to avoid disposal-without-testing of BSE-suspects and animals claimed to be healthy, the SSC further recommended that the application of rapid *post mortem* BSE tests be generalised to all animals not intended to enter the food chain (including all emergency slaughter, suspects at slaughter and fallen stock and all animals above a given age destined for destruction).

n. New questions.

Since last meeting, a number of new questions had been submitted to the Scientific Steering Committee. They relate to: (a) the safety of gelatine; (b) the safety of blood, lungs and heart of ruminants slaughtered with captive bolt stunning but without pithing; (c) the safety of bovine adipose tissues associated with the intestine; (d) the question whether the list of ruminant specified risk materials should be extended to certain pig tissues; (e) methods for disposal of animal waste and (f) the possible public health implications of a high incidence of BSE in a region of the EU

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

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

Following the adoption of its opinion of 7-8.02.01 on BSE in sheep, the Scientific Steering Committee was invited to address the following question:

"Does the SSC consider that the arguments and scientific data provided in the AFSSA Opinion of 14 February 2001 which updates the list of specified risk materials in ovines and caprines, have not (all) been taken into account by the SSC and justify a revisit of the SSC opinion of 8-9 February 2001 which provides an assessment of the health risk should BSE be found in small ruminants under domestic conditions."

The SSC considered that the AFSSA opinion of 14 February 2001 (which updates the AFSSA list of specified risk materials in ovines and caprines), does not provide new or additional scientific data which have not been already taken into account by the SSC in its pre-emptive risk assessment of 7-8 February 2001 on should BSE in small ruminants be found under domestic conditions.

The SSC confirmed its opinion of 7-8 February 2001, which contains a number of suggestions and recommendations for preparatory actions, surveillance and data collection which would permit the European Community and Member States to be well prepared should it become probable or evident (for example on the basis of this additional data) that BSE is present in small ruminants.

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

At the meeting of 7-8 February 2001, the chairperson of the Scientific Committee for Medicinal Products and Medical Devises raised a number of questions with regard to the assessment of vCJD-risk and the harmonisation of approaches towards v-CJD risk assessment. These issues have been submitted for consideration to Directorate G - Public Health of the Commissions Health & Consumer Protection Directorate General. A feed-back from this service is expected to be available for next meeting.

9. Any other business.

No other business was discussed.

The meeting ended on Friday 30 March 2001, at 17h30

Annex 1: List of participants in the Scientific Steering Committee meeting on 29-30 March 2001.

List of presence

Members of the SSC:

- Ing. Georges Bories
- Prof. James W. Bridges
- Prof. Johanna Fink-Gremmels (29 March only)
- Prof. Anthony R. Hardy (29 March only)
- Dr Keith Jones (30 March only)
- Prof. Werner Klein
- Dr Ada Knaap
- Dr Ib Knudsen
- Dr Pierre Le Neindre
- Prof. Johannes Löwer (excused)
- Prof .Albert Osterhaus
- Prof. Gérard Pascal
- Prof. Pere Puigdomenech
- Prof. Vittorio Silano (30 March only)
- Prof. Staffan Skerfving
- Dr Ian White

Participants from the Commission:

DG SANCO: B. Carsin, C. Berlingieri, P. Vossen, J.Kreysa, J.L. Jouve, S. Abildgaard, I. Rollier, A. Dehove, M. Goll (FVO), G. Morrison, V. Van Haeperen, M. Walsh, G. Costa David, G. Fracchia, A. Van Elst, D. Pettauer, F. Drion, J. Maher, J-J. Rateau, A.Wilhelm. Stagiaires: C. Brochot, C. Hankin, B. Somogyi.

DG RTD: B. Hansen

DG RELEX: T. Abadia

Annex 2: Agenda of the Scientific Steering Committee Meeting of 29- 30 March 2001

1. Welcome, apologies, introductory remarks, declaration of interest.
2. Approval of the agenda
3. Approval of the minutes of the meeting of 8-9 February 2001
4. Procedural matters
   a. Rules of procedure;
   b. Membership of the TSE/BSE ad hoc Group;
   c. Planning of activities and priorities.
5. Multidisciplinary matters:
   a. Co-ordination: Reports of the Chairpersons of the 8 Scientific Committees;
   b. Harmonisation of risk assessment methods:
      - Progress report on Task Force activities;
      - Common format for opinions;
      - Glossary of terms.
   c. Safety of cotton (progress report);
   d. Emerging scientific issues (progress reports);
   e. New questions.
   f. 6th Framework Programme for Research (29.03.01, 11h30)
6. Multidisciplinary matters relating to TSE/BSE

6.1. Report by the chairman of the TSE/BSE *ad-hoc* group meeting of 15 March 2001

6.2. Reports on specific issues:
   a. Geographical BSE Risk: Update
   b. Geographical BSE Risk (GBR): possible adoption of an opinion on the GBR of a number of Third Countries.
   c. Safety of tallow
   d. Milk: state of affairs
   e. Second BSE case in UK born after 1 August 1996: appreciation.
   f. Scientific justification of certain Austrian measures.
   g. Treatment and disposal of animal waste by alkaline hydrolysis at elevated temperature;
   h. Progress report on pending questions:
      - BSE epidemiology (survey methods);
      - Medical instruments;
      - Origin of BSE, transmission and 3rd route;
      - Safety of organic fertilisers and soil conditioners;
      - Safety of collagen;

i. New questions:
   - Correspondence of BSE risk levels between "GBR-levels" and product safety opinions.
   - Determination of appropriate heat treatment of animal meal;
   - inventory of recently submitted questions.

j. Ongoing research on TSEs.

7. Info on the follow-up given to the opinions adopted at the previous SSC meeting.
   - Follow-up to the opinion of 7-8.02.01 on BSE in sheep*.

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

9. Any other business.

Annex 3:

AMENDED RULES OF PROCEDURE OF THE SCIENTIFIC STEERING COMMITTEE

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE AT ITS MEETING OF29-30 MARCH 2001-04-19

(Distributed separately)

Annex 4: Reports from the chairpersons of Scientific Committees on the major activities and milestones since the SSC meeting of 8-9 February 2001.

(COMPLETE INFORMATION AT THE WEBPAGES OF THE SCIENTIFIC COMMITTEES AT THE ADDRESS HTTP://EUROPA.EU.INT/COMM/FOOD/FS/SC/SSC/INDEX_EN.HTML.)

SCIENTIFIC COMMITTEE ON FOOD (SCF)

The SCF in its last plenary meeting has concluded on the assessment of 10 substances used in food packaging materials. For its next meeting a number of draft opinions on a wider range of issues are scheduled for possible adoption. Among them there will be evaluations of further food contact material compounds, and the evaluation of the upper levels of vitamins B1, D and possibly biotin and magnesium. The Committee is also likely to consider updated guidelines on food additives, and the residues of n-vinyl pirrolidone in the polymers authorised as food additives and some other food additives. The Committee will embark on the updating of the essential requirements of infant formulae. Regarding food contaminants, the SCF is likely to finalise its evaluation of the mycotoxin T2-HT2 and the update of its previous opinion on 3-monochloropropane-diol (3-MCPD) on the basis of new information.

SCIENTIFIC COMMITTEE FOR PLANTS

The SCP met on 7 March. At this meeting the following 5 opinions have been adopted by the Committee (4 on the evaluation of PPPs and 1 dealing with the issue of adventitious presence of GMs in conventional seeds):

- Opinion regarding the evaluation of benomyl, carbendazim and thiophanate-methyl in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Opinion expressed by the Scientific Committee on Plants on 7 March 2001).
- Opinion regarding the evaluation of cyhalofop-butyl in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Opinion expressed by the Scientific Committee on Plants on 7 March 2001).
- Opinion regarding the evaluation of iprovalicarb in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Opinion expressed by the Scientific Committee on Plants on 7 March 2001).
- Opinion regarding the evaluation of pyraflufen-ethyl in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Opinion expressed by the Scientific Committee on Plants on 7 March 2001).
- Opinion of the Scientific Committee on Plants concerning the adventitious presence of GM seeds in conventional seeds (Opinion expressed by the Scientific Committee on Plants on 7 March 2001).

On 7 March, the Committee also decided that there were no specific issues that it wished to raised on the 2 dossiers referred without specific questions (on acibenzolar-S-methyl and glyphosate/glyphosate trimesium).

SCIENTIFIC COMMITTEE ON ANIMAL NUTRITION (SCAN)

SCAN met on 21 and 22 March. It discussed the outcome of several Working Group which met in the period February-March 2001. Some reports were adopted on 21 and 22 March.

New questions have been addressed to the Committee. A wide question on undesirable substances in feed, connected to the ongoing review of the Council Directive 1999/29/EC, has just been put the SCAN agenda. The Committee is reflecting on how to address these questions, and on the identification of the most suitable and experienced experts to work on them.

Some questions involve cooperation with other Committees, such as:

- one which includes a GM aspect, and will consequently be addressed in connection with the GMOs Joint WG, which includes SCAN, SCP and SCF experts.
- one which covers trace elements such as Copper or Zinc, and will therefore involve experts from the SCTEE.

The next SCAN meeting is foreseen on 16 and 17 May.

SCIENTIFIC COMMITTEE VETERINARY MEASURES RELATING TO PUBLIC HEALTH

Last plenary meeting of the Scientific Committee on Veterinary Measures relating to Public Health took place on 14-15 February. An opinion on "Ovine gas de-pelting" has been adopted by the Committee subjects to editorial changes agreed at the plenary meeting.

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

Two new draft mandates were presented and accepted by the Committee.

Several Working Groups meetings are planned to be organised in the meanwhile.

The next plenary is organised for 2-3 May, the discussion will be focused on:

(i) reports for possible adoption;

(ii) draft opinions will be presented for possible discussion;

(iii) new possible mandate.

SCIENTIFIC COMMITTEE FOR TOXICITY, ECOTOXICITY AND THE ENVIRONMENT

A. Opinions/position papers were adopted on the following:

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

a) *Acrylonitrile;* b) *Anisidine;* c) *Methyl methacrylate;* d**)** *Acrylamide*;

Risk assessment reports on Human health effects of:

Nonylphenol and nonylphenol (branched).

All the above produced under the so-called Existing substances Regulation (793/93).

2. *Carcinogenic and non-carcinogenic effects of Nickel in ambient air*

3. *The availability of substitutes for soft PVC containing phthalates in certain toys and childcare articles* – RPA final report ETD/99/502498

4. E*xposure data in risk assessment of organic chemicals* **(multidisciplinary**). Note: to be put soon on the DG SANCO website for public comments. Also to be forwarded to the European Chemicals Bureau for input into the Technical Guidance Document (in support of Regulation 793/93) revision.

5. *Margins of safety* (**multidisciplinary**).

Note: some of the above are still pending editorial corrections at the time of writing this brief and as such all are not yet available in DG SANCO website.

B. The CSTEE is also pursuing its activities on the following opinion requests:

i) *Evaluation of sludge treatments for pathogen reduction* (**multidisciplinary issue** – involves participation of SCCNFPC member).

ii) *Carcinogenic and non-carcinogenic effects of Cadmium and Arsenic in ambient air and*

iii) *Derivation of limit values for PAH in ambient air.*

iv) *Health effects of Radio Frequency and Electromagnetic fields* **(emerging issue).**

v) *Assessment of the risks to human health posed by azo colorants in toys, writing inks and paper products, and analysis of the advantages and drawbacks of restrictions on their marketing and use* – LGC report ETD/99/502495

vi) Evaluation of the following Regulation 793/93 Risk Assessment Reports:

Risk assessment reports on Human health & Environmental effects of:

a) *Dibutyl phthalate ; b) Methyl oxirane (propylene oxide)*; c) *Toluene*; d) 1,2,4-*Trichlorobenzene;* e) *Acrylic acid;* f) *Methyl-tert-Butyl Ether*.

vii) *Proposed standards for a revised bathing water directive* (**multidisciplinary issue**).

viii) Review of a *draft CPMP discussion paper on Environmental Risk assessment of medicinal products*.

SCIENTIFIC COMMITTEE FOR COSMETICS AND NON-FOOD PRODUCTS

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

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

Again, the SCCNFP expressed its concern about the proposed 7th Amendment of the cosmetics Directive and the draft report of the European Parliament on the 7th Amendment. If a total ban, after a specified date, of all animals tests, including those for which no alternative/non-animal test method has been validated at that time, is maintained, the SCCNFP will not longer be in a position to execute its responsible advisory function because of the lack of scientifically based safety data.

SCIENTIFIC COMMITTEE FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

A Plenary Meeting of the SCMPMD was held on 26 February 2001, and subjects discussed included progress on "Blood & vCJD" and on "Xenotransplantation".

The Working Groups on "TissueEngineering", "Xenotransplantation" and "Blood & vCJD" met on 5th, 6th and 8th March respectively in order to prepare a State of the Art Paper on the two first subjects and an update of the Opinion given by the Committee on "Blood & vCJD".

These groups will meet again in May.

<u>Annex N° 5</u>: Mandate and background of the SSC Working Group on anti-microbial resistance.

MANDATE:

The services of the European Commission asked the Scientific Steering Committee (SSC) to address the following question:

"Do the results of the collaborative surveillance programme of the five antimicrobial feed additives withdrawn respectively in January 1997 (avoparcin) and in December 1998 (tylosin, spiramycin, virginiamycin and zinc bacitracin) plus two other still used antibiotics (avilamycin and flavophospholipol), and the recently published data especially on antibiotic resistance gene transfer, bring new information which would legitimate a reconsideration of the applicability of the SSC opinion of 28 May 1999 regarding the use of antimicrobial growth promoters which are or may be used also as antibiotics in animal and human therapy?"

BACKGROUND:

1 The glycopeptide antibiotic avoparcin authorised as feed additive has been banned through the adoption of Commission Directive 97/6/EC of 30 January 1997. The authorisations of four other antibiotics, namely tylosin, spiramycin, virginiamycin and zinc bacitracin, were withdrawn through the adoption of Council Regulation n° 2821/98 of 17 December 1998.

These measures were taken considering:

a. the scientific reports of Denmark and Germany supporting the safeguard clause (Article 11 of Directive 70/524/EC) taken against avoparcin (Denmark on 20.05.95 and Germany on 19.01.96), of Finland supporting the safeguard clause taken against tylosin and spiramycin (on 1.01.98) and of Denmark supporting the safeguard clause taken against virginiamycin (on 15.01.98);

b. the reports and opinions of the Scientific Committee of Animal Nutrition (SCAN) consecutive to the critical analysis of the above mentioned reports:

- Report of the SCAN on the possible risk for humans of the use of avoparcin as feed additive (21 May 1996)
- Report of the SCAN on the efficacy and risk for users of the therapeutic macrolides antibiotics tylosin and spiramycin used as feed additives, (05 February 1998);
- Opinion of the SCAN on the immediate and long-term risk to the value of streptogramins in human medicine posed by the use of virginiamycin as an animal growth promoter, (10 July 1998);

The stated reasons were the potential risk of transfer of antimicrobial resistance from micro-organisms from livestock origin to human pathogens.

2. Commission Directive 97/6 EC and Council Regulation n° 2821/98 state that the Commission would re-examine the adopted measures in the light of the new investigations concerning the induction of resistance by the use of the antibiotics concerned and of the results of the collaborative surveillance programme carried out by the applicant companies.

The surveillance programme was launched in 1997 and was conducted over a 2-year period. The experimental design was discussed and approved by the National authorities responsible for feedingstuffs.

The study surveyed the susceptibility of *Enterococcus faecium* isolates obtained from healthy animals at slaughter to six antibiotics (the four above-mentioned, plus avilamycin and flavophospholipol which are still in use). Isolates were taken from pigs and broiler chickens in six countries (DK, S, NL, UK, F and E). The collection of samples from slaughterhouses and the isolation of the selected bacteria were performed by National microbiology laboratories. The Minimum Inhibitory Concentration (MIC) testing was conducted at the Elphinson Research Centre Laboratories of Inveresk Research (Scotland).

3. Because of great concern over the implication for the human health of the rapidly increasing rate of development of resistance the Commission asked, end 1998, the Scientific Steering Committee (SSC) to review the scientific information available on this issue. The mandate was to scientifically evaluate the current position regarding the prevalence and development of antimicrobial resistance, examine its implications for human and animal health, particularly with regard to the development and management of infections. It was asked to advise on the means of monitoring the out come of the measures which it might recommend and consider the implications of its advise.

In its opinion of 28 May 1999 the SSC recommended, regarding the use of antimicrobials as growth promoting agents, that the use of substances from classes which are or may be used in human or veterinary medicine (i.e. where there is a risk of selecting for cross resistance to drugs used to treat bacterial infections) should be phased out as soon as possible and finally abolished.

Annex 6

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

SAFETY OF MILK WITH REGARD TO TSE:

STATE OF AFFAIRS

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE
AT ITS MEETING OF

29-30 MARCH 2001

(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

THE SCIENTIFIC BASIS FOR IMPORT BANS PROPOSED BY AUSTRIA WITH REGARD TO BSE RISKS IN GERMANY AND FRANCE.

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE AT ITS MEETING OF 29-30 MARCH 2001

(Distributed separately)

Annex 8

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

OPINION ON

BOVINE SPONGIFORM ENCEPHALOPATHY IN A SECOND UK ANIMAL BORN AFTER 1 AUGUST 1996 (CASE CONFIRMED IN NORTHERN IRELAND)

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE AT ITS MEETING OF 29-30 MARCH 2001

(Distributed separately)

Annexes 9 - 21

Opinions of the

Scientific Steering Committee

on the

GEOGRAPHICAL RISK OF

BOVINE SPONGIFORM ENCEPHALOPATHY (GBR) IN

ALBANIA, THE CZECH REPUBLIC, ESTONIA, THE SLOVAK REPUBLIC, INDIA, MAURITIUS, PAKISTAN, CYPRUS, SINGAPORE, COLOMBIA, HUNGARY, POLAND AND BRAZIL.

ADOPTED ON 29-30 MARCH 2001

(Distributed separately)