Annex 1: List of participants of the Scientific Steering Committee meeting of 24-25 September 1998

List of presence

Members of the SSC:

– Prof. Georges Bories (not present on 25 September 1998 afternoon)
– Prof. W.Bridges (not present on 25 September 1998)
– Prof. F.Garrido Abellán
– Prof. Michael J. Gibney
– Prof. Philip James (not present on 25 September 1998)
– Prof. Keith H.Jones
– Prof. Fritz H.Kemper (not present on 24 September 1998 morning)
– Prof. Werner Klein
– Prof. Ib Knudsen
– Prof. Robert Kroes (not present on 25 September 1998)
– Prof. Albert Osterhaus (not present)
– Prof. Gérard Pascal
– Prof. Vittorio Silano (not present)
– Prof. Antonio Silva Fernandes (not present on 25 September 1998 afternoon)
– Prof. Marcel Vanbelle
– Prof. Martin Wierup

Member of the TSE/BSE ad-hoc group

- Dr. Emmanuel Vanopdenbosch (present on 24 September 1998 morning)

Participants from the Commission:

DGIII: O. Rohte

DG VI P. Colombo

DGXXIV: B.Carsin, T. Daskaleros, C. Deckart, W. de Klerck, M.de Sola, C.Diez Ubierna, F. Drion, J.Kreysa, M.Lauridsen, G.Morrison, J.Moynagh, A. Sanabria, W. Schuller, E. Thevenard, A. Van Elst, R. Vanhoorde, J. Vergnettes, P.Vossen, M. Walsh, M. Zampaglione

Annex 2: Agenda of the Scientific Steering Committee Meeting of 24-25 September 1998

1. Welcome, apologies, introductory remarks
2. Approval of the agenda
3. Approval of the minutes of the meeting of 16 July 1998
4. Work plan for the SSC
   4.1. Progress on multidisciplinary matters:

a. Genetically Modified Organisms: Reflection on the possible need to broaden risk evaluation exercises so as to include factors possible potential hazards not yet recognised.
b. Harmonisation of working procedures (discussion of the reports by K.Bridges and R.Kroes and adoption of a draft mandate for a working group, including on the definitions of "reasonable" and "negligible risk")
c. Resistance to antimicrobials (progress report)

4.2. Multidisciplinary matters relating to TSE/BSE
a. General report of the work of the TSE/BSE ad-hoc group.
b. Reports on specific issues:

Production systems and products.

b.1. BSE in sheep (report and possible adoption of an opinion);
b.2. MBM for fur animals, cross contamination and organic fertilisers (progress report and possible adoption of an opinion);
b.3. Safety of hydrolysed proteins (report, possible adoption of opinion).
b.4. Fallen stock, disposal, recycling waste, and environmental aspects of disposing of potentially infected materials (progress report);

Human exposure risk.

b.5. WG-HER (progress report)
b.6. Blood, blood products, implantables, sutures (state of affairs)

Geographical risk.

b.7. Up-date on the activities related the assessment of the TSE status of countries after the recent OIE-meetings.
b.8. WG-Sourcing & Modelling (progress report; possible adoption of a handbook for the assessment of TSE-status dossiers).

Monitoring

b.9. Evaluation of diagnostic tests for TSE in bovines (progress report)

Additional questions

b.10. Additional question from the Commission on the safety of tallow.
b.11 Briefing on nvCJD infectivity of the human appendix.

6. Organisational matters

7. Co-ordination: reports of the Chairmen of the 8 Scientific Committees (for information)

a. Reports of the Chairmen of the 8 Scientific Committees
b. Briefing on the SC-TEE's activities related to Endocrine Disrupters

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

9. Any other business.
> Briefing on the consultation of the Scientific Committees.

Annex 3 : Reports from the secretariats of Scientific Committees on the major activities and milestones since the SSC meeting of 14-15 May 1998.

Scientific Committee for Food

Since last July, the SCF has hold one plenary session besides five Working Groups meetings. This last Plenary session (the 113th) took place on 16/17 September. The Committee adopted at this plenary session four opinions. The first opinion examines the applicability of the concept of the ADI (Acceptable Daily Intake), normally used when evaluating food additives, to those used in foods for infants below the age of 16 weeks. The second opinion concerns the contaminant ochratoxin A. It is an update of the previous evaluation by the SCF of 1994 and the Commission was awaiting this opinion with the aim to adopt Community-wide measures for ochratoxin A in foodstuffs. The third opinion is an additional list of 10 substances that may be used as monomers and additives for plastic materials intended to become in contact with food (packaging materials). The fourth opinion is an evaluation of the safety of the application of irradiation to 8 different categories of foodstuffs, now being carried out in one Member State.

The SCF also adopted at this 113th meeting its rules of procedure.

Scientific Committee on Animal Health and Animal Welfare

The Committee adopted an opinion on swine vesicular disease by written procedure on 10 August.

Meetings of the both the sub committee on animal health and the sub committee on animal welfare were held.

The sub committee on animal health approved a draft report on bluetongue and this will now go forward to the next plenary meeting of the Scientific Committee on Animal Health and Animal Welfare on 21 October.

Meetings of the working groups on bluetongue, gavage and BST were also held in the period.

Scientific Committee Veterinary Measures related to Public Health

1 Plenary

At its plenary of 15 July the SCVMPH adopted the *"Opinion of the SCVMPH on the 9th code of Federal Regulations Part 304, et al. Pathogen reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final rule*".

The Committee also discussed the comprehensive draft opinion concerning the use of antimicrobial treatments of poultry carcasses, the various methods of carcass rinsing including trisodium monophosphates (TSP), organic acids and hyperchlorinated water.

2. Working group meetings

2.1 BST

The next meeting of the Working Group concentrating on the public health aspects of this issue is scheduled for 02 October.

2.2 Simplification

The next meeting of the Working Group is scheduled for 29 September.

2.3 Cooling of carcasses during transport

Substantial progress has recently been made on this since long outstanding question. A final Working Group meeting should take place on 09 October.

2.4 Cysticercosis

The Committee established a Working Group to examine this question.

2.5 Revision of ante- and post-mortem inspection procedures for an alternative inspection system for the slaughter of pigs.

A draft report is being circulated amongst the members of the Working group.

Scientific Committee for Plants (SCP)

No meeting of SCP was held since the previous SSC meeting on 16 July. The next plenary session is scheduled for 2 October 1998.

Scientific Committee Cosmetic and non-Food Products

Since the SSC meeting of 16-17 July 1998 one plenary and five working party meetings of the SCCNFP took place. The points dealt with are:

a) Alternatives to animal testing & Dossier. The issues dealt with are :

- the revision of Annex VII of the Notes of Guidance on Microbiological Quality of the Finished Product was finalised and sent to the plenary meeting for adoption.
- the Discussion on human testing and the ethical considerations will be linked to the discussion on the clinical testing of finished products to assess their skin compatibility.
- Rapporteurs have been appointed to report on the validation study on photo-toxicity and on skin corrosivity.
- a report on the current status of the alternative method for skin irritation.
- preliminary discussion of the local lymph node assay as a possible alternative method for acute or chronic toxicity testing.

b) Inventory.The work done in the framework of the 1st up-dating of the inventory and common nomenclature of ingredients used in cosmetic formulations since the previous SCC meeting of 16-17 July 1998 concerned discussion with the cosmetic industry on :

- the problem of the ambiguity of the INCI names ‘octyl’ and ‘octanoate’-compounds;
- the issue of the ampho-derivatives, proposed differentiation between the imidazole- and acyclic –type;
- corrections proposed by the JRC on inconsistencies or incompleteness of data;
- involvement in and invitation to the International Naming Committee (INC) in Washington - convention proposals concerning INCI names of ingredients derived from plants (botanicals);
- the first draft on the revision of Section II of the inventory on fragrances.

c) Preservatives, colorants and fragrances:

- acrylamide : new data were received from the industry concerned, but not yet incorporated in the draft opinion due to their late receipt. A final draft will be presented to the next meeting on 3.11.98.
- carbamide peroxide : a first impression of the data received was given. A draft opinion is to be presented to the next meeting on 3.11.98.
- labelling of fragrances : the rapporteur was asked to include in her outline document more details of the clinical significance of fragrance ingredient allergy.
- Strontium nitrate, lactate and polycarboxilate : these are the last so called Angelopharm-substances for with the SCCNFP had not yet adopted a final opinion. A draft was prepared and sent to the plenary for adoption.

d) UV filters. The organisation of the "expert panel workshop" on 'sun protection' was further discussed and a meeting is fixed on 9.12.98 to finalise this work.

e) Plenary meeting. Opinions were adopted on :

- the revision of Annex VII of the Notes of Guidance on the microbiological Quality of the finished product;
- the report on the revision of the inventory concerning the botanicals;
- boric acid, borates and tetraborates;
- strontium lactate, nitrate and polycarboxylate;
- the foreseeable use of hair dyes;
- revision and adaptation of the opinion of 24 June 1997 on tallow derivatives

The plenary meeting also adopted their rules of procedure.

Human testing, ethical considerations : the results of the discussion in the WP meeting were presented to the plenary. Seen the complexity of the issue, there was a proposal to discuss with or to ask comments from the industry and consumer representatives. The Chairman was asked to present the issue to the SSC meeting and to ask for their views.

Scientific Committee for Medicinal Products and Medical Devices

At their last plenary meeting the SCMPMD adopted an opinion and approved a report on "*The equivalency of alternative products to intestines of animal origin for use as surgical sutures*".

The reports on the following subjects were further discussed:

- "Colouring agents for use in medicinal products".
- The concept of "Similarity" in Orphan Drugs..

After introduction of the comments received, the Committee will submit these reports at its next meeting for possible approval.

The issue of "Risk quantification for CJD transmission via substances of human origin" will be further discussed by the W.G. before the final draft report will be discussed by the plenary.

Regarding the subjects "Clinical superiority" and "Starting materials", it is expected that progress will be made in the next months.

Scientific Committee for Toxicity, Ecotoxicity and the Environment

The Committee adopted the following opinions at the plenary session held 14/15 September 1998:

i) Chrysotile asbestos
The CSTEE agreed that there is sufficient evidence that chrysotile asbestos is both an established experimental carcinogen in experimental animals and a human carcinogen. There is insufficient data to identify whether there is a threshold dose for the carcinogenic effects in man.

Three possible substitutes were also considered: Cellulose, PVA and P-aramid fibres. On the basis of the data provided the CSTEE's opinion was that the ability of these substitute fibres to induce cancer or fibrosis of the lung in man is likely to be lower than that of chrysotile. The CSTEE emphasised that there were substantial gaps in the toxicology database for all three substitute fibres and that good environmental control where these fibres were used in the workplace was very important.

ii) Arsenic

The CSTEE identified a number of significant risks from the current usage of Arsenic as a wood preservative, namely:

a) effect on aquatic organisms in low phosphate marine water;

b) human lung cancer from the burning/disposal of treated wood

The CSTEE also expressed concern about:

c) the unpredictable long term leaching behaviour of Arsenic in special waste landfills

d) the risk to children regularly using playgrounds where there is a significant amount of Arsenic treated wood.

Ongoing activities include:

i) Tin, PCP, Cadmium. Opinions will be adopted by written procedure. The committee has identified a general concern that for each of the above substances the data it was initially provided with was usually only the report of a consultant. This proved to be an insufficient basis for a sound scientific opinion.

ii) Phthalates in toys. The CSTEE considered a recent unpublished/published 'Dutch Consensus Group' study on the extractability of phthalates from plastic samples. It considered that this was apparently a more valid basis for the risk assessment than findings from previous extraction methods which the CSTEE had examined.

iii) Azo dyes; Endocrine Disrupting Chemicals. Final opinions are expected to be agreed at the next plenary meeting.

Future activities include:

i) Existing chemicals under review by the ECB

ii) It was agreed that the CSTEE would serve as a review body for each completed data file. Files on four chemicals have been sent to the CSTEE during September. The estimated additional workload for the CSTEE is 20 chemicals per annum.

Annex 4: COORDINATING GROUP ON RISK ASSESSMENT

Mandate

Introduction:

The Scientific Steering Committee (SSC) and the 8 Scientific Expert Committees (SEC) advise the European Commission (EC) in matters related to the public health domain and increasingly the impact on the environment. In all these committees procedures are used which aim at identifying the risk, in most cases the absence of risk, when products are introduced to the market or when problems are envisaged with substances, products or commodities already existing in the public domain. It covers food, food additives, industrial chemicals, chemical contaminants (including pesticide residues and veterinary drug residues), cosmetics, pharmaceuticals , microbial contaminants, physical agents and contaminants, products such as toys and their impacts on human health and on the environment. It also includes the impact of physical agents such as electromagnetic radiation and noise.

In certain cases more than one SEC may be involved in advising the EC about the safety or (absent) risk of the use of an agent, depending on its use and/or application in the public health domain. The process used to set standards or to assess the potential risk should ideally be similar in all SECs although the outcome of the process may differ depending on application or use.

The Scientific Steering Committee has expressed concern that the processes used at present may not be exactly alike even in DG XXIV committees and that this may cause different outcomes in cases where one would expect a similar one.

Therefore the SSC advised the Commission to establish a Coordinating Group on Risk Assessment (CGRA) which Group should look into this matter and should develop a harmonised and integrated process for Risk Analysis, in particular risk assessment.

In this note the Risk Analysis process is defined and described, and the mandate, and the initial working procedure are described.

Risk Analysis Definitions

Risk Analysis consists of three elements : risk assessment, risk management and risk communication. The responsabilities for the three elements is assigned to different stakeholders. For risk assessment the scientists are the stakeholders.

Several risk assessment (RA) paradigms have been introduced in the last decade.

There are many definitions of the various components of the processes relating to risk. The subgroup considered that it would not be productive to produce its own definitions if there were suitable ones already in general use. The subgroup agreed to base its working definitions on those of WHO / FAO Codex but to make the minimum modifications to incorporate environmental as well as human risks.

It is hoped that these definitions could be used by all DG XXIV committees in the future. The subgroup spent some time discussing possible definition of acceptable risk, negligable risk, tolerable risk and related terms. No widely used definitions could be identified. In view of their widespread use and importance the subgroup recommended that an extensive literature search should be conducted on how such terms were used both within the European Community and by other national governments and international agencies.

The model of R.A. consists of four components:
- hazard identification
- hazard characterisation
- exposure assessment
- risk characterisation

This model has the advantage that it can be applied to chemical as well as physical and biological agents. A list of definitions which will be used by the CGRA is attached in annex I.

Mandate:

1) The CGRA will develop a common framework to perform Risk Assessment within the SSC and the 8 Scientific Expert Committees.
2) The CGRA will investigate if Quantitative Risk Assessment procedures for agents are necessary and if so, will suggest principles for doing so.
3) The CGRA will develop tools for appropriate comparison of risks (including risk benefit comparisons).
4) The CGRA intends to integrate human RA and environmental RA.
5) The CGRA will facilitate the execution of uncertainty analysis on the different elements of the RA-scheme in order to better ensure the validity and appropriateness of the data resulting from the RA-process.
6) The CGRA will focus its attention to the issues described above in the order of priority given.

Work process (only specified for 1))

1) An inventory will be made in the SSC and the 8 SEC on which systems and procedures are used when RA (including safety assessment) is performed (October-December 1998).
2) The results of the inventory will be discussed in the CGRA together with the persons responsible for the inventory in their committee (January 1999).
3) An outline for a harmonised RA process and allocations of tasks to subgroups to further develop and define the separate elements of the R.A. process will be prepared.

PROCEDURE FOR RISK CHARACTERISATION

It is important to the improvement of harmonisation to identify similarities and differences in the ways that each Scientific Committee carries out risk characterisation and to establish whether the differences have a scientific rationale, are historical and/or are determined by the legislative requirements. To facilitate this pocess set out below is a general framework for risk analysis. Scientific Committees are asked to identify particularly where the way they conduct risk characterisation of both human and environmental effects differs from this framework and the reasons for those differences.

Exposure assessment

Hazard identification & hazard characterisation

↘ ↙

Risk characterisation

?

Risk comparison(s)

1. Components of exposure assessment

   a) Estimate of potential exposure of humans / specified other species (from sources under consideration) through air, ingestion, direct surface contact and other routes of exposure

   b) Determination of metabolic fate , levels and persistence of the agent and its metabolic products (if any) in the tissue of the species of concern or surrogate species (definition of species of concern)

   c) Estimate of potential exposure to other sources of the agent and / or other agents, which may be relevant to the overall risk.

   d) Application of exposure assessment models (if used)

2. Components of the hazard identification and characterisation

   a) Use of physicochemical data (including structure activity relationships SAR to identify likely effects of concern (definition of effects of concern).

   b) Studies in animals / plant test species to identify and characterise adverse acute and chronic effects of the agent (definition of adverse)

   c) Establishment of dose response relationships including NOEL (no observable effect level) for each effect of concern in each test species

   d) Consideration of mechanisms of toxicity for the lead effects in the test species

   e) Identification of the amount (level / persistance) of the lowest NOEL for an effect of concern in the test species

   f) Application of mathematical modelling to dose response data where a NOEL cannot be identified

   g) Estimate of potential for interactions with other agents which may influence the overall risk

3. Components of risk characterisation

   a) Specific selection of an uncertainly factor for exposure on the basis of the degree of completeness of the data set available

   b) Specific selection of an uncertainly factor / default value / safety factor for the lead effect(s) of concern (on the basis of both its nature and the degree of completeness of the data set available)

   c) Calculation of ratios / risk probabilities etc based on a formal comparison of the calculated worst case / conservative / best practice exposure situation and the lowest value identified in the hazard characterisation

4. Risk comparison

   a) Comparison of the estimated risk with known risks from other agents, etc

   b) Comparison of the estimated risk with likely benefits

Attachment:

HAZARD:	A biological, chemical, or physical agent that may have an adverse effect on the environment or on the health.
RISK:	A function of the probability of an adverse effect and the magnitude of that effect, consequential to a hazard(s).
RISK ANALYSIS:	A process consisting of three components: risk assessment, risk management and risk communication.
RISK ASSESSMENT:	The scientific evaluation of known or potential adverse effects resulting from exposure to hazards. The process consists of the following steps: (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment, and (iv) risk characterisation. The definition includes quantitative risk assessment; which emphasises reliance on numerical expressions of risk, and also qualitative expressions of risk, sometimes also called safety assessment, as well as an indication of the attendant uncertainties.
HAZARD and IDENTIFICATION:	The identification of known or potential environmental / or health with a particular agent.
HAZARD CHARACTERIZATION:	The qualitative and/or quantitative evaluation of the nature of the adverse effects associated with biological, chemical, and physical agents. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data is obtainable.
EXPOSURE degree of ASSESSMENT:	The qualitative and/or quantitative evaluation of the intake or exposure likely to occur.
RISK characterisation and CHARACTERIZATION:	Integration of hazard identification, hazard exposure assessment into an estimation of the adverse effects likely to occur in a given population or compartment, including attendant uncertainties.
RISK MANAGEMENT:	The process of weighing policy alternatives to accept, minimise or reduce assessed risks and to select and implement appropriate options.
RISK COMMUNICATION	An interactive process of exchange of information and opinion on risk among risk assessors, risk managers, and other interested parties.
DOSE –RESPONSE magnitude of ASSESSMENT:	The determination of the relationship between the exposure and the magnitude and/or frequency of adverse affects.

Annex 5: REPORT AND SCIENTIFIC OPINION ON MAMMALIAN DERIVED MEAT AND BONE MEAL FORMING A CROSS-CONTAMINANT OF ANIMAL FEEDSTUFFS ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE AT ITS MEETING OF 24-25 SEPTEMBER 1998

This annex was distributed separately

Annex 6: SCIENTIFIC OPINION ON THE SAFETY OF ORGANIC FERTILISERS DERIVED FROM MAMMALIAN ANIMALS ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE AT ITS MEETING OF 24-25 SEPTEMBER 1998

This annex was distributed separately

Annex 7: OPINION ON THE RISK OF INFECTION OF SHEEP AND GOATS WITH BOVINE SPONGIFORM ENCEPHALOPATHY AGENT ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE

This annex was distributed separately

Annex 8: UPDATED SCIENTIFIC REPORT ON THE SAFETY OF MEAT-AND-BONE MEAL DERIVED FROM MAMMALIAN ANIMALS FED TO RUN RUMINANT FOOD PRODUCING FARM ANIMALS, SCIENTIFIC STEERING COMMITTEE, MEETING OF 24-25 SEPTEMBER 1998

This annex was distributed separately