

Draft Minutes of the Scientific Steering Committee Meeting of 25-26 May 2000

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

Prof.Dr.Pascal welcomed the participants. He apologised Prof.Dr.G.Bories for 25 May and Prof.Dr.V.Silano for 26 May. The list of participants is attached as annex 1.

Declarations of interest:

No member declared an interest that could prevent him from participating in the discussion on any of the items on the agenda of this specific meeting.

2. Approval of the agenda

The agenda was approved with minor changes. The final agenda is attached as annex 2.

3. Approval of the minutes of the meeting of 13-14 April 2000.

The minutes of the meeting of 13-14 April were adopted without changes for publication on the internet.

4. Multidisciplinary matters:

a. "Emerging health issues"

Prof.Bridges proposed a format and structure for presenting the emerging hazards that will be annexed to the forthcoming opinion. These were accepted and it was decided that all SSC members would redraft their contributions accordingly. Deadline for sending in these contributions to the SSC secretariat was Friday 16 June 2000. The latest version of the draft list of emerging hazards, is attached as annex 3.

Profs. Bridges and Kroes accepted to act as a mini-editorial board. An updated draft opinion is expected to be available for discussion and possible adoption, at the meeting of either 6-7 July 2000 or 14-15 September 2000.

In the margin of the discussions on the issue, Prof.Bridges signalled the results of a very recent re-assessment of the risk of dioxins with regard to certain cancers, carried out by the Environment Protection Agency of the USA and giving rather worrying results. The SSC raised the attention of the Commission on this development and questioned whether an urgent SSC reaction would be appropriate, for example by adopting a common view (opinion) or by establishing a Working Group that would report back to the SSC at its next meeting. It was eventually agreed that the matter would be monitored closely and taken into account by the 2 Scientific Committees (for Food and for Animal Nutrition) that were presently preparing dioxin-related opinions. The SSC further recommended that the future Food Safety Authority should be organised and equipped appropriately so that it can swiftly react when reasons for concern suddenly emerge.

b. "Emerging health issues: pilot exercise applied to GMOs"

The updated draft Working Group report "*Emerging Health Issues: the case of genetically modified organisms*" was presented and discussed. A further update will be prepared and circulated before the meeting of 6-7 July 2000. Possible adoption of an opinion of the SSC on "how to deal with emerging health issues, the example of GMOs" is expected for either the July or September 2000 SSC meeting.

c. Harmonisation of risk assessment procedures

Prof. Bridges, chairman of the Working Group, informed the SSC of the progress made. The various sub-groups held several meetings and prepared contributions to the overall report on: quantitative risk assessment of chemicals, quantitative risk assessment of microbiological agents, quantitative risk assessment of transmissible diseases, exposure assessment, interface between risk assessors and risk managers and hazard identification.

It is expected that a first draft of the overall report will be available for preliminary discussion at the SSC of 6-7 July 2000. A final draft report is expected for September.

In the margin of the discussions on this subject, a representative of the Commission services informed the SSC of the OECD Workshop on Risk Communication for Chemical Management that will be held from 18 to 20 September 2000 in Berlin. It was agreed that Prof. Bridges would attend this workshop on behalf of the SSC.

e. Statement on the functioning of the EC's Scientific Committees

A document, prepared by Prof. Wierup, was discussed in detail, amended and eventually adopted. It is attached as annex 4.

f. Short discussion on the April 2000 issue of *Chemosphere*.

Via his letter of 18 April 2000 to the secretariat, Prof. Klein informed the SSC members and the members of the Working Group "Antimicrobial resistance" of the April 2000 Special Issue of *Chemosphere*, which was entirely dedicated to Drugs in the Environment and contained several sections related to anti-microbial resistance. At the meeting, Prof. Klein briefly re-introduced the subject. A discussion was held, which also took into account the comments received from several members of the Working Group. Even if some statements were questioned, it was concluded that the *Chemosphere* articles supported and strengthened the SSC opinion and that this opinion was still up to date.

g. Interaction between risk assessors and risk managers

The SSC, at its meeting of 2-3 March 2000, and in the margin of its discussions on the Harmonisation of risk assessments, had a preliminary discussion on the interface between risk assessors and risk managers. As a follow-up Prof. Dr. W. Bridges prepared a text, which was, following the SSC's recommendation, also circulated amongst Commission Services for comments.

Prof. Bridges presented an updated draft, which took account of the comments received. This draft was discussed and slightly amended and will be sent to all Commission services involved in or concerned by scientific advice for health and consumer protection, as a "*SSC Contribution to the reflection on procedures for enhancing the effectiveness of the interface between scientific committees and Commission officials*".

In this Contribution, the SSC recommends that a small working group should be established comprising representatives from the SSC and officials from the appropriate Directorate Generals to:

- address details of implementation;
- initiate a pilot scheme along the above lines;
- report back to the SSC on its achievements.
- Consider the nature and extend of the need for transparency in their interaction.

5. Multidisciplinary matters relating to TSE/BSE

5.1. Report by the chairman of the TSE/BSE ad-hoc group

Prof.M.Gibney reported briefly on the meeting of the TSE/BSE *ad hoc* Group of 11 May 2000. All items addressed by the *ad hoc* group, as well as the tentative planning of some of the pending requests for opinions, are further dealt with in detail under point 5.2 of these minutes.

5.2. Reports on specific issues:

a. Handling and storage of possibly BSE contaminated MBM

Prof.W.Bridges presented an update of the draft *Notes on the safe handling, transport and storage of MBM and other bovine derived materials which may be contaminated with BSE or other pathogens*. This draft was amended in the light of written comments received from members of the TSE/BSE *ad hoc* Group and the Working Group "Products". The amended draft of the "notes" is attached as annex 5.

The SSC agreed that the "notes", in its present incomplete form and still including a number of open questions, should be submitted to a wide consultation via Internet.. The notes will than further be finalised by the TSE/BSE *ad hoc* Group, taking due account of the input received. The SSC expects to discuss the issue again at its September 2000 meeting.

The SSC underlined that this document is not a "scientific opinion" in its common sense, but rather a compilation of notes intended to be helpful for the risk manager when exploiting the SSC opinions related to meat-and-bone meal, disposal, production, etc.

b. Safety of hydrolysed proteins: update of the 1998 opinion

The draft update of the opinion, that was prepared by the TSE/BSE *ad hoc* Group was discussed, amended and adopted. The amended text is attached as Annex 6.

c. Use of human hair for the production of proteins (in cosmetic products).

The SSC was requested to express an opinion on *The safety of amino acids from human hair hydrolysate used in cosmetic products for topical application, with regard to Transmissible Spongiform Encephalopathy*. A draft opinion, prepared by a special working group and agreed to by the TSE/BSE *ad hoc* Group, was discussed in detail, amended and adopted. The amended text is attached as Annex 7.

The SSC agreed that this text is provisional, awaiting the provision by the industry of details on composition of the end-product used in topical applications, of a flow scheme of the production process and of the results of the ongoing experiments with spiked material mentioned in the dossier that was provided by the industry.

Whilst recognising that the risk assessment with respect to TSEs of all ruminant-derived products should be extremely carefully done on the basis of complete and appropriate dossiers and experiments, the SSC nevertheless considered that the importance/relevance with respect to consumer protection of this opinion should not be overestimated as compared to other products such as gelatine and blood.

d. Geographical risk:

In July 1998, the European Commission recommended, on the basis an SSC opinion, that Member States and Third Countries would submit, on a voluntary basis, a dossier for the "evaluation of their epidemiological status with regard to Transmissible

Spongiform Encephalopathies”. 14 MS (except Greece) and 12 TC submitted a dossier.

These dossiers were used by the SSC for the assessment of the Geographical BSE-Risk of the respective countries, following a methodology developed by the SSC since December 1998 and last refined in January 2000. The assessment was carried out with the help of independent experts from the Member States and from Third Countries. National experts, seconded by the assessed countries, assisted by explaining and complementing the country dossiers. After each cycle the draft country reports were submitted for comments to the competent authorities in the respective countries. The final consultation was finished early in May and the comments received in time were taken into account in the draft opinion on the GBR and the final draft of the country reports. Following a suggestion of the TSE/BSE ad-hoc group, this draft did not any more include a detailed account of the public health implication of the GBR but rather an outline of the general principles of this issue.

The SSC discussed in detail the draft opinion and agreed to the amendments/changes proposed by the TSE/BSE ad hoc group. The opinion was finally adopted as a *Preliminary Opinion on the geographical risk of Bovine Spongiform Encephalopathy (GBR)*. One member of the SSC manifested his reserve on some points of the document.

The SSC expressed its thanks to Prof. Silano and Dr. Heim (Member of the TSE/BSE ad-hoc group) for their substantial efforts that allowed reaching this advanced stage of the work.

The SSC also endorsed the country reports and suggested that the preliminary opinion and the final draft of country reports would be made available on the Internet as soon as possible. Comments are invited until 19 June 2000. The SSC underlined, however, that it will only take account of comments related to risk assessment aspects but ignore all risk management related comments. Comments relating to the consistency between the different country reports are particular welcome.

The TSE/BSE ad hoc Group should prepare a draft final opinion and final country reports, integrating the comments as appropriate. A final opinion should be adopted at the next SSC meeting (6-7 July 2000) if no substantial comments, requiring new in-depth analysis, would be received. Otherwise an adoption was envisaged for the September 2000 meeting of the SSC. The final opinion and the final country reports would than be put on the Internet.

e. GME protocol on TSE inactivation

In December 1999, the Gelatine Manufactures of Europe (GME) provided the secretariat with a detailed technical dossier containing a protocol for the evaluation of the inactivation/removal effect of the gelatine manufacturing process on TSE-infectivity. This dossier was provided to all members of the SSC, the TSE/BSE *ad hoc* Group and the Working Group “Products” who expressed an interest to obtain a copy.

Professor Vanbelle informed the SSC that he had sent some comments to GME in his personal capacity as a scientist/chemist.

The SSC decided not to pursue this issue any further as it is not its task to approve such protocols.

f. TSE and culling

No progress was made in this field, as priority had been given to the Geographical BSE Risk (GBR) assessment. The item is now expected to be finalised in July.

g. Origin of BSE

No progress was made in this field. The SSC would appreciate seeing a draft opinion on it in September.

h. Export from the UK of bone-in veal

The Scientific Steering Committee was informed of a request of the Commission to assess the safety of whole carcasses from young bovines (6-9 months) exported from the UK to other countries while being eligible under the date based export scheme. The TSE/BSE *ad hoc* Group, at its meeting of 11 May has already created a small working group that will prepare a draft report, for discussion by the SSC, possibly at its meeting of 6-7 July 2000. The SSC agreed to this procedure.

i. Quantitative risk assessment (vertebral column);

The Preliminary Report on *Quantitative Risk Assessment on the Use of the Vertebral Column for the production of Gelatine and Tallow*, is on the Internet, open for public comments until 10 June. The TSE/BSE *ad hoc* Group will discuss all comments received by that date at its next meeting (22/06/2000) and, where and if appropriate, integrate them into an updated version. This update will then be discussed by the SSC at its meeting of 6-7 July 2000.

j. Update of certain opinions (including on cross-contamination) in the light of the opinions on Human Exposure Risk and Infective Dose and Species Barrier.

Once the above final version of the Report on *Quantitative Risk Assessment on the Use of the Vertebral Column for the production of Gelatine and Tallow* is available, a number of updates may be necessary of SSC opinions related to the safety of ruminant-derived products. The SSC agreed to the principle to verify, in the light of the finalised quantitative assessment, the need to up-date and to embark on that process thereafter. Of particular importance is the opinion of 25 September 1998 on *Mammalian-derived meat-and-bone meal forming a cross-contaminant of animal feedstuffs*. It contains a quantitative risk assessment that will need updating.

k. Update of the opinion of December 1997 listing risk tissues, in the light of the recent opinions on safety of bones and on SRMs in small ruminants.

At its meeting of 13-14 April 2000, the SSC considered that the opinion of December 1997 on Specified Risk Materials (SRM) needed to be updated in the light of its SRM-related opinions adopted since then. The TSE/BSE *ad hoc* Group has created a working group that will prepare a draft report, for discussion by the SSC at one of its next meetings.

l. Pro-active opinion on risk scenarios, should BSE in sheep be found under natural conditions. Monitoring of research results on experimental BSE in small ruminants.

Following the recommendation made in the SSC opinion on *Specified Risk Materials of Small Ruminants*, adopted at the meeting of 13-14 April, a working group was established by the TSE/BSE *ad hoc* group to address these issues. Given its complexity, it is not expected that a draft report will be ready for discussion before October 2000. The SSC agreed to this schedule.

m. Preparation of a discussion paper on the hypothesis of "the 3rd route of transmission of BSE", in the light of the SSC opinion of 28-29 October 1999.

Following the recommendation made at the SSC meeting of 20-21 January 2000, a working group was established by the TSE/BSE *ad hoc* group to address this issue. It is not expected that a draft report will be ready for discussion before October 2000. The SSC agreed to this schedule

n. Update of the annexes to the opinion of May 1999 on the evolution of the BSE epidemic in the UK.

The TSE/BSE *ad hoc* Group is preparing an update of the epidemiological annex to the SSC opinion of May 1998 on the evolution of the BSE epidemic in the UK. It will then be assessed whether this evolution is, to date, still according to scientific projections and whether the conclusions of the May 1999 opinions are still valid. The SSC requested to be kept informed on the progress made and to have a substantial discussion on the issue at its September meeting, at the latest.

6. Organisational matters.

a. Renewal of the Scientific Steering Committee and of the Scientific Committees; call for expression of interest.

The SSC members were informed that a call for expression of interest to become a member of the SSC or another SC has been issued on 18 May 2000. The deadline for expressions of interest to arrive at the Commission is 17 June 2000 for the SSC and 01 July 2000 for the other SCs. They received a copy of the corresponding Calls for expressions of interest.

The SSC-members were also reminded that their term of office will continue until the new members are nominated by the Commission. This is not expected to occur before the September meeting of the SSC (14/15 September 2000) and the current members were asked to be available for that meeting.

b Scientific experts in toxicology, ecotoxicology and Environmental (Public) Health

Profs. Bridges, Bories, Knudsen, Jones and Hardy jointly submitted to the other SSC members a discussion paper "*Scientific experts in toxicology, ecotoxicology and environmental (public) health: planning for the future*". The paper had been drafted by J.W.Bridges and H.Greim (president, resp. vice-president of the Scientific Committee for Toxicity, Ecotoxicity and the Environment) and E.Dybing from Norway (member of the SC-TEE).

The paper indicates that a sustainable strategy needs to be developed by the Commission and other appropriate instances to ensure that there is a sufficient supply of properly prepared experts available in these key areas of risk assessment. It also proposes a number of concrete lines of action.

The paper was unanimously welcomed by the SSC. In fact it was felt that the concern developed in the paper was general and applicable to many more scientific fields. The SSC therefore asked the authors to put it in a broader context.

The issue will be discussed again on 6-7 July. A statement will then be made available to all Commission Services involved in or concerned by scientific advice for health and consumer protection.

7. Co-ordination: Reports of the Chairmen of the 8 Scientific Committees.

The chairmen of all Scientific Committees provided written reports on the activities of their committees since the last SSC meeting (see annex 34)

8. Information by the Commission services on matters related to consumer health: follow-up given by Commission services to the BSE-related opinions adopted on 13-14 April 2000.

The Commission service responsible for veterinary legislation informed the SSC about the exploitation of the various BSE-related opinions of the SSC and in particular those adopted in April. Special reference was made to specified risk materials, safety of blood, slaughter methods, beef-on-the bone and vertebral column. Regarding specified risk materials, a draft proposed legislation is under way which foresees two modulated lists, accommodating the different risk levels in the United Kingdom and Portugal on one hand and in the other EU Member States on the other hand.

The representative of the Commission service responsible for the proposal could, however, not provide the SSC with a written copy of these 2 lists, given the fact that it was still an internal proposal of the Services and subject to further changes. The SSC expressed its discontent with this. Although recognising that it was not within the SSC's remit to interfere in the risk management process or in the legislative process, the SSC considered advanced information on such issues to be essential. Members of the SSC are often contacted by external bodies (press, consumer associations, institutions) as soon as legislative proposals are in the public domain, and requested for their (personal) opinion on it. The SSC considered it preferable if such reaction could be based on knowledge of the legislative process and its outcome.

9. Any other business.

The Secretary General of the French Senate's "Groupe du Rassemblement Démocratique et Social Européen" introduced a request for a member of the SSC to participate in a Colloquium on BSE organised by the Senate. This initiative was also going to be attended by eminent French, UK and other international TSE specialists. The request was favourably welcomed, but it appeared that all of the suitable SSC members had already commitments for that date. It was agreed that the Secretariat would further contact a number of members of the TSE/BSE *ad hoc* Group to attend the colloquium and inform the French Senate representative accordingly.

The meeting ended on Friday 25 May 2000, at 13h30.

The next meeting will be held in Brussels, on 6-7 July 2000, starting at 10h00.

Annex 1: List of participants of the Scientific Steering Committee meeting of 25-26 May 2000

List of presence

Members of the SSC:

- Prof. Georges Bories (not present on 25 May 2000)
- Prof. James W. Bridges
- Prof. Fulgencio Garrido Abellán
- Prof. Michael Gibney
- Prof. Anthony R. Hardy
- Prof. Philip T. James
- Prof. Keith H.Jones
- Prof. Fritz H.Kemper
- Prof. Werner Klein
- Prof. Ib Knudsen
- Prof. Robert Kroes
- Prof. Albert Osterhaus
- Prof. Gérard Pascal
- Prof. Vittorio Silano (not present on 26 May 2000)
- Prof. Marcel Vanbelle
- Prof. Martin Wierup

Participants from the Commission:

DG SANCO: B. Carsin, C. Berlingieri, C. Diez, A. Fokkema, J.L. Jouve, J.Kreysa, G. Morrison, E. Poudelet, J. Vergnettes, P. Vossen, W.Penning

Annex 2: Agenda of the Scientific Steering Committee Meeting of 25-26 May 2000

1. Welcome, apologies, introductory remarks, declaration of interest.
2. Approval of the agenda.
3. Approval of the minutes of the meeting of 13-14 April 2000
4. Multidisciplinary matters:
 - a. "Emerging health issues" (further discussion)
 - b. "Emerging health issues: pilot exercise applied to GMOs" (discussion and possible adoption).
 - c. Harmonisation of risk assessment procedures (progress report, discussion and further planning)
 - e. Statement on the functioning of the EC's Scientific Committees (discussion and possible adoption)
 - f. Short discussion on the April 2000 issue of *Chemosphere*.
 - g. Interaction between risk assessors and risk managers (discussion)
5. Multidisciplinary matters relating to TSE/BSE
 - 5.1. Report by the chairman of the TSE/BSE ad-hoc group
 - 5.2. Reports on specific issues:

Production systems and products.

 - a. Handling and storage of possibly BSE contaminated MBM (possible adoption)
 - b. Safety of hydrolysed proteins: update of the 1998 opinion (possible adoption)
 - c. Use of human hair for the production of proteins (in cosmetic products).

Geographical risk.

 - d. Geographical risk: position paper and reports on the risk assessments of Member States and Third Countries (further discussion).

Other TSE/BSE related issues:

 - e. GME protocol on TSE inactivation

Planning of TSE/BSE related issues still to be addressed:

 - f. TSE and culling (possible adoption of an opinion).
 - g. Origin of BSE (progress report).
 - h. Export from the UK of bone-in veal;
 - i. Quantitative risk assessment (vertebral column);
 - j. Update of certain opinions (including on cross-contamination) in the light of the opinions on Human Exposure Risk and Infective Dose and Species Barrier.
 - k. Update of the opinion of December 1997 listing risk tissues, in the light of the recent opinions on safety of bones and on SRMs in small ruminants.
 - l. Pro-active opinion on risk scenarios, should BSE in sheep be found under natural conditions. Monitoring of research results on experimental BSE in small ruminants.
 - m. Preparation of a discussion paper on the hypothesis of "the 3rd route of transmission of BSE", in the light of the SSC opinion of 28-29 October 1999.
 - n. Update of the annexes to the opinion of May 1999 on the evolution of the BSE epidemic in the UK.

6. Organisational matters.
 - a. Renewal of the Scientific Steering Committee and the Scientific Committees; call for expression of interests.
 - b. Scientific experts in toxicology, ecotoxicology and Environmental (Public) Health (discussion).
7. Co-ordination: Reports of the Chairmen of the 8 Scientific Committees.
8. Information by the Commission services on matters related to consumer health.
 - a. Follow-up given by Commission services to the BSE-related opinions adopted on 13-14 April 2000.
9. Any other business.

Annex 3:

Draft initial* list of possible fields for concern in the medium-term future

(Updated listing as on 26 May 2000)

Item
1. <u>Agents and media</u>
a) Viruses (including genetically modified viruses), prions.
b) Antibiotic resistant micro-organisms (including new infections because of antimicrobial resistance and/or because of increased virulence of agents).
c) Natural toxins (including "natural" medications), including, amongst others, mycotoxins and toxins in algae;
d) Non-ionizing radiation (including new claims on supposed diseases (re cancer) due to cellular phones.
e) Climate change , (including extreme weather events and results of increased temperatures)
f) Macronutrient imbalance and its direct and indirect consequences for disease;
g) Industrial chemicals in the environment (including non communicable chronic diseases, causes and prevention: role of industrial chemical and chemical pollutants from food and environment).
h) Physical and psychological stress
i) Addictive substances
j) Urban terrorism using chemical or biological agents
k) Gene therapy ; safety of vectors used in gene therapies;
2. <u>Media for transmission</u>
a) Drinking water (including ground water) , (including Unexpected microbial diseases linked with (drinking) water);
b) Blood transfusions (including upcoming diseases due to blood transfusion).
c) Xeno transplants
d) New processes of waste treatment , eg: recycling (including health hazards due to the recycling of toxic substances for example when recycling animal waste);
e) Indoor air.
3. <u>Particular effects of concern</u>
a) Endocrine disruption (human and environmental) (including environmental pollutants and endocrine disrupters and their interference with the immunosystem).
b) Allergenicity,
c) Behavioural changes
d) Special and protected environments
e) Musculo-skeletal damage,
f) Synergy between chemicals/chemicals and micro-organisms , (with increased life expectancy as an exacerbating factor).

4. Methodology
a) Identification of susceptible individuals / groups,
b) Harmonisation of risk assessment,
c) Quantitative risk assessment (including Increase pressure to deliver quantitative estimates of risks involved with (unexpected) exposures to agents (chemical, biological and physical);
d) Sustainability (Including: implementing the sustainability principle across the various scientific committees; its implications for risk assessment and scientific advice).
e) Risk communication, (Including scientific illiteracy as a possible (emerging) (individual and public) health hazard; including aspects such as risk perception and risk communication).
f) improved testing methods (human and environmental),
g) Use of human volunteers (including: the need for a world-wide acknowledgement and agreement on the use of human (volunteers) in biological experiments: > amendments to the "Declaration of Helsinki" (World Association of medical Doctors) > rules for participation of humans in potential harmful trials (e.g., aiming the immune system; intentional sensitisation; corrosivity on the skin or mucous membranes;)
h) Better international collaboration (including: mutual recognition of results in the same [above] fields of science and regulatory/administrative acknowledgement (e.g., EC, EU, Council of Europe, OECD, ...).
i) Improved monitoring and surveillance systems for early detection of adverse effects (including?:better prediction of harmful effects of chemicals and other products on humans and the environment (e.g., carcinogenic effects): > support of appropriate methodologies (R&D).

* Note: This list should still be considered to be the result of a brainstorming. It is not ranked in terms of priority or in any other way. The SSC stresses that it is in no way to be considered as list of priority public health concerns. Many other, and in many cases more important, public health and consumer protection issues do not figure on the list, for example because they are being addressed already, because they are not a "possibly emerging risk", because they are not within the mandate of the SSC, etc.

Annex 4



Scientific Steering Committee

STATEMENT OF THE SCIENTIFIC STEERING COMMITTEE ON:

**SCIENTIFIC ADVICE TO THE COMMISSION FROM ITS SCIENTIFIC COMMITTEES,
WITH SPECIAL REFERENCE TO THE SCIENTIFIC STEERING COMMITTEE (SSC)
AND ITS INTERDISCIPLINARY ADVICE ON TSE/ BSE**

**ADOPTED BY THE SSC AT ITS MEETING
OF 25-26 MAY 2000**

(Distributed separately)



PRELIMINARY AND INCOMPLETE NOTES ON

THE SAFE HANDLING, TRANSPORT AND STORAGE OF MBM AND

OTHER BOVINE DERIVED MATERIALS WHICH MAY BE

CONTAMINATED WITH THE BSE AGENT OR OTHER PATHOGENS

DRAFT, FOR COMMENTS

COMPILED BY THE SCIENTIFIC STEERING COMMITTEE
AT ITS MEETING OF 25-26 MAY 2000

TEXT SUBJECT TO FURTHER CHANGES

THIS DRAFT IS STILL INCOMPLETE AND
SUBJECT TO CHANGES. SEVERAL ASPECTS
ARE NOT YET BEING ADDRESSED OR ARE
FLAGGED WITH QUESTIONMARKS.

IN ORDER TO PREPARE AN AS GOOD SERIES
OF NOTES AS POSSIBLE, THE SSC IS
INVITING THE PUBLIC TO COMMENT AND
SUGGEST AMENDMENTS.

They can be sent to (UNTIL 28 JULY 2000):

paul.vossen@cec.eu.int



***UPDATED* REPORT AND SCIENTIFIC OPINION ON
THE SAFETY OF HYDROLYSED PROTEINS
PRODUCED FROM BOVINE HIDES.**

**Initially adopted by the Scientific Steering Committee
at its meeting of 22-23 October 1998**

and updated at its meeting of 25-26 May 2000

(Distributed separately)



OPINION ON

**CONSIDERATIONS ON THE SAFETY OF AMINO ACIDS FROM HUMAN HAIR
HYDROLYSATE USED IN COSMETIC PRODUCTS FOR TOPICAL APPLICATION, WITH
REGARD TO TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY RISKS:**

ADOPTED BY THE

THE SCIENTIFIC STEERING COMMITTEE

AT ITS MEETING OF 25-26 MAY 2000

(Distributed separately)



**Preliminary Opinion of the
Scientific Steering Committee
on the**

**GEOGRAPHICAL RISK OF
BOVINE SPONGIFORM
ENCEPHALOPATHY (GBR)**

Adopted on 25-26 May 2000

THE SSC INVITES COMMENTS ON THIS PRELIMINARY OPINION AND THE DETAILED COUNTRY REPORTS UNTIL 19 JUNE 2000.

ONLY RISK ASSESSMENT RELATED COMMENTS WILL BE TAKEN INTO ACCOUNT BY THE SSC WHEN DRAFTING THE FINAL OPINION AND THE FINAL COUNTRY REPORTS

RISK ASSESSMENT RELATED COMMENTS SHOULD REACH THE SECRETARIAT OF THE SCIENTIFIC STEERING COMMITTEE BEFORE 19 JUNE 2000

e-mails: joachim.kreysa@cec.eu.int or paul.vossen@cec.eu.int

Fax: ++32-2-2959579

Postal Address: European Commission,

DG Health and Consumer Protection – B1,

Secretariat of the SSC – B232-7/61

Rue de la Loi, 200; B-1049 Brussels

(Distributed separately)



**25 reports on the assessment of
the geographical BSE-risk of
14 EU Member States
and
11 Third Countries**

May 2000

(Distributed separately)

Annex 34: Reports from the secretariats of Scientific Committees on the major activities and milestones since the SSC meeting of 2-3 March 2000.

Scientific Committee for Plants

No meetings of Scientific Committee Plants were held in the reporting period.

Scientific Committee on Animal Nutrition (SCAN)

The Committee adopted several opinions on feed additives (enzymes, micro-organisms, an antibiotic) at its plenary meeting of 27-28 April. an opinion was also issued on the way to assess efficacy of enzymatic feed additives.

The other *ad hoc* working groups continue their work.

Scientific Committee Veterinary Measures relating to Public Health

The Committee adopted by Written Procedure on 03 May an opinion on hormones used in cattle as growth promoters

The working groups continue their work.

Scientific Committee on Animal Health and Animal Welfare

1. Animal Health

A Meeting of the Subcommittee on Animal Health was held on 24.05.2000. The following draft reports were on the agenda for discussion and possible approval:

1. *Avian Influenza: Definition and Vaccination*
2. *Possible zoonotic risk from Infectious Salmon Anaemia*
3. *Bluetongue Vaccination*

The documents are expected to be finalised and presented for possible adoption at the next meeting of the Committee(27.06.00)

Inactivation of viruses in blood

The document is in preparation and will be discussed at the next meeting of the Sub Committee on Animal Health in September.

Infectious Bovine Rhinotracheitis,

This group will meet for the first time in mid June.

2. ANIMAL WELFARE

The Welfare of Animals kept for fur production.

This WG is continuing the work and will meet in June

The Welfare of Fattening Cattle

A group was set up and had its first meeting on 5.05.00 and will meet again in Mid June.

Scientific Committee for Toxicity, Ecotoxicity and the Environment (since March 2000)

- A. Two CSTEEN plenary meetings took place since the last briefing on CSTEEN's activities (included in the minutes of the SSC plenary meeting held in 2/3 March 2000). The 14th plenary meeting of the CSTEEN took place on the 11th of April 2000 and the 15th plenary meeting took place on the 5th of May 2000. In terms of progress made on the opinion

requests submitted to the CSTEE and other CSTEE initiatives the outcome was the following:

- B. The plenary meeting held on the 5th of May was the opportunity to adopt one opinion on each of the five substances evaluated under **Regulation 793/93** and whose risk assessments had to be peer-reviewed by the CSTEE. The substances were: **Hydrogen Fluoride, Dimethyl sulphate, 4'4-Methylenedianiline, Cumene and Acrolein.**
- C. On the subject '*Terrestrial environment*' - '*Available scientific approaches to assess the potential effects and risks of chemicals on terrestrial ecosystems*' – Subsequent to the working group meeting that took place on the 1st of March 2000 another one was held on the 8th of May with still another one being foreseen for the 16th of June. Progress is well on course for an adoption of the report soon.
- D. Several CSTEE members were assigned to a working group being presided by the Scientific Committee on Plants (*Plant Protection Products Joint Working Group on Environmental Assessment/Toxicology for Relevant Metabolites and FOCUS Groundwater Scenarios*). A working group took place already (19th of May – subgroup environment) and the human health effects subgroup will meet on the 5th of June.
- E. Regarding the two outstanding opinion requests on '**Lead**' [(i) a notification of the Danish authorities informing Commission services of their intention to ban lead in a significant number of applications and (ii) a general opinion request on hazards and risks posed by lead and its compounds to human health and the environment] the opinion on the former was finally adopted at the 15th CSTEE plenary (5th of May).
- F. With regard to the ongoing subject of "*Measured exposure data in risk assessment*" a working group will take place on the 7th of June. In principle, and as already indicated before, the working group will, for the immediate future at least, integrate its activities with those of the new working sub-group of the **Harmonisation of Risk Assessment** working party of the **SSC**.
- G. On the opinion requests submitted to the CSTEE on:
 - (i) "*Cadmium in fertilisers*" (where a CSTEE opinion on a report on the subject of a "Programme of procedures for the assessment of risk to health and the environment from cadmium in fertilisers" had been requested) a working group meeting was held on the 23rd of May. Tasks were assigned to WG members and the decision was taken to held another working group meeting possibly in September 2000 in view of adopting the opinion shortly after.
 - (ii) "*Methylene chloride and textile dyes*" (where a CSTEE opinion of the CSTEE on risk assessments on Methylene chloride and certain chemicals in textiles has been requested) a working group meeting took place also on the 23rd of May 2000. The group concluded that, for methylene chloride, there was enough information available to reach an opinion. For the textile dyes there was a serious lack of data. The WG will present to the next plenary a guideline on a minimum data set for the possibility of conducting a science based risk assessment. The attention of the responsible Commission service will be drawn to this.
- H. A group was set up within the CSTEE to address the subject "*Scientific experts in Toxicology, Ecotoxicology and Epidemiology for risk assessments – planning for the future*". The initial idea was to draft a CSTEE report on the subject but the activity will probably be pursued within the **SSC** instead as the next step.
- I. The next (16th) CSTEE plenary meeting is taking place on the 19th of June 2000.

Scientific Committee for Cosmetics and Non-Food Products

Five Working Party meetings and one Plenary meeting took place, during which the following items were discussed :

1. Alternatives : An opinion was adopted concerning the Murine Local Nymph Node Assay (LLNA), a method which can be used in the hazard assessment of potential human contact sensitizers. The LLNA is a refinement test method, not a non-animal method as the method uses fewer animal and it is shorter. Secondly, a further revision of the Notes of Guidance was discussed and a new annex on the predictive testing of potentially cutaneous sensitising cosmetic ingredients or mixtures of ingredients will be inserted.
2. Detergents : the very first meeting of the WP took place on 8 June 2000 during which the appropriate sectors within the field of competence were discussed according to the existing legislation in this domain.
3. Hair Dyes : An opinion was adopted on one hair dye and on 2,4-DPO, a chemical used in hair care formulations. Furthermore, a reply to comments from a Member State on a series of opinions adopted on hair dyes was drafted.
4. Inventory : A consensus was reached with the representatives of the European cosmetic industry (COLIPA) on the content of the 1st update of the inventory. The final draft of the 1st update will be submitted by 10 June 2000 at the latest. It was also agreed that, if all the corrections are incorporated , the document will be accepted without further revision and addressed to the plenary of 28 June 2000 for formal adoption.

Concerning section II –perfume and aromatic raw materials – of the inventory, the Commission was asked to require from industry the data to make the necessary modifications to be incorporated in the 2nd update.

5. Preservatives, Colorants & Fragrances : Opinions were adopted on the use of Lithium - and Calcium hydroxide as pH adjusters in cosmetics and concerning an initial list of perfumery materials which may not form part of a fragrance compound to be used in cosmetics.
6. UV Filters : the evaluation of the safety of Titanium dioxide, coated/uncoated, is still on-going.
7. 2nd Postponement of the animal testing ban : The committee was consulted on the draft Commission Directive postponing for a second time the date after which animal tests are prohibited for ingredients or combinations of ingredients in cosmetic products. Article 4.1 (i) of Directive 76/768/EEC on cosmetic products stipulates that '*before submitting such measures, the Commission will consult the Scientific Committee on Cosmetology*'. The Committee took notice of the draft directive and, as a result, decided to issue a favourable opinion.

In this context, the draft 7th Amendment of Directive 76/768/EEC was tabled for information. The 7th Amendment focuses on the prohibition of animal tests on the territory of the European Union performed on ingredients of cosmetic products, on combinations of ingredients and on finished cosmetic products. The Committee took notice of the draft Directive and expressed their great concern about the intention to completely ban the performance in the European Union of any animal experiments at present necessary for an appropriate scientific evaluation of the safety of cosmetic products and their ingredients.

Scientific Committee for Medicinal Products and Medical Devices