

Minutes of the Scientific Steering Committee Meeting of 26-27 October 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.James and Prof.DrKroes (for both 26 and 27 October) and Prof.Dr. Bories (for 26 October only). 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 meeting agenda.

2. Approval of the agenda

The agenda was approved without changes. The final agenda is attached as annex 2.

3. Approval of the minutes of the meeting of 14-15 September 2000

The minutes of the meeting of 14-15 September 2000 were adopted without changes.

4. Multidisciplinary matters:

a. "Emerging health issues"

An updated draft, prepared by Prof. Bridges and with revised contributions from several SSC members was discussed in detail. The title was changed into: "*Strategies for dealing with emerging and re-emerging scientific issues that have the potential to impact human health, directly or mediated through the environment*".

The opinion provides a preliminary and incomplete list of emerging and re-emerging scientific issues that have the potential to impact human health, as identified by individual SSC members. It is recommended that this list is regularly revised and amended. This list is not intended to be fully comprehensive. It is not ranked in terms of priority or in any other way. The SSC members stressed 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.

The SSC proposed to introduce a regular review or watching brief on emerging health issues as a formal part of the brief of a multidisciplinary committee such as the SSC. A possible procedure is to enable this role to be fulfilled for the SSC is attached as an annex to the opinion. The SSC further proposed that a discussion forum should be held on approaches for describing and characterising emerging and re-emerging scientific issues that have the potential to impact public health.

The opinion was adopted after amendments to the draft text and is attached as Annex 3. It however needed some further editorial work and would therefore not be made public via Internet before 10 November.

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

A new update of the draft opinion, based on the discussions of 15-16 September, was discussed in detail. The title was changed into: "*Risk assessment in a rapidly advancing field: the case of genetically modified plants (GMP)*".

Following further amendments, the opinion was adopted. It however needed some further editorial work and would

therefore not be made public via Internet before 10 November. It is attached as Annex 4.

c. Harmonisation of risk assessment procedures

A final draft report, prepared by Prof. Bridges and including comments from the Working Group members, was submitted for adoption. Following detailed discussions and amendments, the opinion was adopted. It however needed some further editorial work and would therefore not be made public via Internet before early December. It is attached as Annex 5.

d. Safety of cotton (new question)

The SSC was asked to advise the Commission on how best to address a new interdisciplinary question regarding the safety of cotton products such as feminine hygiene products (e.g. tampons, sanitary pads etc), baby or adult incontinence products (e.g. nappies, etc), "medical cotton" product (cotton balls, make-up pads, gauze, etc) and cotton fabrics and garments.

Due to a lack of time, this item was not further explored and will thus be handled by the new SSC.

5. Multidisciplinary matters relating to TSE/BSE

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

Prof. Silano reported briefly on the meeting of the TSE/BSE *ad hoc* Group of 12 October 2000. All items addressed by the *ad hoc* group are further dealt with in detail under point 5.2 of these minutes.

5.2. Reports on specific issues:

a. Safety of blood

Dr. Jones presented the report prepared on 11 October by a special working group (WG) on the implications of the *Houston et al paper in The Lancet of 16 September 2000 on the Transmission of BSE by blood transfusion in sheep. (The Lancet, Vol. 356, pp 999-1000; 955-956; 1013)*. Prof. Osterhaus reported on the discussions held on 12 October 2000 by the TSE/BSE *ad hoc* Group on the basis of the oral report provided by Dr. E. Vanopdenbosch, rapporteur of the WG.

The report was discussed in detail and an opinion was adopted on the basis of the WG report, the verbal report on the discussions of the TSE/BSE *ad hoc* Group and the SSC's own reflections. This opinion, as well as the report of the working group, is attached as annex 6.

b. Handling and storage of possibly BSE contaminated MBM

Prof. W. Bridges presented a brief account of the useful and numerous comments received so far, following the public consultation process via Internet of a preliminary series of s on the Handling and storage of possibly BSE contaminated MBM that ended on 28 July. The draft s were further amended and adopted. (See Annex 7). The SSC considers them to be helpful for decision-makers when developing measures to contain this hazard. The s are however not meant to be comprehensive. (The document needed some further editorial work and would therefore not be made public via Internet before 10 November.)

c. Quantitative risk assessment.

The SSC took note of the fact that the TSE/BSE *ad hoc* Group had not submitted for adoption the draft reports on the quantitative assessment of the residual TSE risk in (1) gelatine and tallow derived from bones, (2) tallow in milk replacers and calf feed and (3) cross-contaminated feed. At its meeting of 12 October 2000 the *ad hoc* Group considered that the method needed further clarifications especially regarding its limitations and that the interpretation of

the results in practice needed to be addressed. Prof.Dr.Vanbelle presented these considerations of the *ad hoc* Group, as well as a draft summary explanation of the method and its limitations prepared by Dr.Marcus Doherr (rapporteur of the Working Group.)

The SSC discussed these in details and referred the reports back to the TSE/BSE *ad hoc* group with a request to ensure re-writing of the opinion in the light of the *ad hoc* Group's comments and the document prepared by Dr.Doherr. More precisely:

- (a) the limitations of the method should be clearly stated,
- (b) all assumptions on which the model is based should be clearly stated and justified, and
- (c) the results should be put into an appropriate context by

- Providing a "real life" example

- Compare the results generated by the "deterministic" (worst-case calculation) and by the "stochastic" method and show, how unlikely it is that indeed all parameter are simultaneously falling on the worst possible value.

In order to appreciate the extreme values it was requested that the calculations were so often repeated that a confidence value for the most extreme figures could be established. Without that some members would not feel comfortable to endorse the results.

The SSC also recommended that, in addition to the above, an internal SSC workgroup would be established to address the overall thematic of the assessment in quantitative terms of risks of consumer products for human health. The group should in more generalised terms address the issues and problems encountered by the TSE/BSE when trying to establish in a quantitative way the residual TSE risk of certain ruminant-derived products, including methods and their limitations, impact of (ranges of) assumptions on the results, interpretation of results, etc.

This proposal will be further discussed at a next meeting, when also the link with the present SSC Working Group on Harmonisation of Risk Assessment Procedures will be clarified.

d. cross-contamination of animal feed with ruminant MBM (updating of the 1998 opinion)

Although the quantitative expression of the BSE risk for bovines resulting from the consumption of potential cross-contaminated feedstuffs had not been finalised (see above), the SSC nevertheless agreed on the following clarification of its 1998 opinion on cross-contamination:

"The SSC wishes to confirm that in principle, cross-contamination with mammalian meat-and-bone meal of ruminant feedstuffs is not acceptable. Feed cross-contaminated above levels that are reliably quantifiable should be condemned. In 1998, this level was put at 0,5% because of technical limits of quantification. At the same time, the SSC carried out a preliminary assessment of the risk for cattle resulting from a feed contaminated at that level of 0.5% if the MBM was produced in accordance with the SSC opinion on meat-and-bone meal i.e. if the MBM was produced exclusively from material fit for human consumption, without SRM and under pressure standards. "

The complete version of the amended 1998 opinion is attached as Annex 8.

e. The proposal for controlled use of ruminant SRMs as feed for fur animals in Finland.

Finland proposed to feed SRMs, after rendering, to fur animals instead as a way of disposal of SRMs that is equivalent in terms of safety to incineration or controlled landfill as requested in the recent SRM legislation. On the basis of a report prepared by the TSE/BSE *ad hoc* Group, the SSC concluded that it could not support this claim for equivalency, mainly on environmental grounds. The complete opinion is attached as Annex 9.

f. Geographical BSE-risk: Update

Due to time constraints no information was given to the SSC.

g. Update of the opinion of May 1999 on the evolution of the BSE epidemic in the UK.

Due to a lack of time, this item was not further discussed.

h. 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.

Due to a lack of time, this item was not reported on and will thus be handled at a next SSC meeting.

i. Upcoming new questions

The SSC was informed of the broadening of the question on the safety of the bovine intestine, so as to include the possible infectivity reduction during its processing (cleaning) into casings.

The present draft formulation of the question is as follows:

"Are there currently scientific justifications to consider bovine intestine as a possible risk tissue? Do these justifications apply to the whole intestine or only to the ileum? If there are possible risks associated with the ileum and/or the whole intestine, as from what age of the animal should this risk be considered to be significant enough to justify risk management measures? Is the treatment of intestines for the production of casings able to reduce/eliminate the residual TSE risk if any. Pending upon the answer given to these questions, the SSC is invited to possibly amend its opinion on tissue infectivity of December 1997. "

6. Organisational matters

Date of next meeting:

Whether or not an SSC meeting will be held on 7-8 December 2000, will depend upon the final establishment of the 8 sectorial scientific committees and the selection of their chairpersons. If not all these chairpersons have been selected by then and if the SSC needs to meet, for example to address an urgent or emerging issue, a meeting may be held composed of the already identified 8 SSC members plus the already selected chairpersons of the 8 committees in their new composition plus the previous

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 10)

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

This point was not addressed, due to a lack of time.

9. Any other business

The meeting ended on Friday 27 October 2000, at 18h00

Annex 1: List of participants in the Scientific Steering Committee meeting on 26-27 October 2000

List of presence

Members of the SSC:

Ing. Georges Bories (*excused for 26 October 2000*), Prof. James W. Bridges, Dr. Fulgencio Garrido Abellán, Prof. Michael Gibney, Prof. Anthony R. Hardy, *Prof. Philip T. James (excused)*, Dr. Keith H. Jones, Prof. Fritz H. Kemper, Prof. Werner Klein, Dr. Ib Knudsen, *Prof. Robert Kroes (excused)*, Prof. Albert Osterhaus, Prof. Gérard Pascal, Prof. Vittorio Silano, Prof. Marcel Vanbelle, Prof. Martin Wierup

Participants from the Commission:

DG SANCO: B. Carsin, C. Berlingieri, P. Vossen, J. Kreysa, J.L. Jouve, J. Vergnettes, M. de Sola, G. Fracchia, F. Drion, A. Sanabria, G. Morrison, V. Van Haepere.

Annex 2: Agenda of the Scientific Steering Committee Meeting of 26-27 October 2000

Draft agenda of the Scientific Steering Committee Meeting of 26-27 October 2000

1. Welcome, apologies, introductory remarks, declaration of interest.
2. Approval of the agenda.
3. Approval of the minutes of the meeting of 14-15 September 2000
4. Multidisciplinary matters:
 - a. "Emerging health issues"
 - b. "Issues requiring scientific advice: The case of genetically modified plants".
 - c. Harmonisation of risk assessment procedures.
 - d. Safety of cotton (draft mandate)
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:

Tissue infectivity

 - a. Safety of blood (progress report);
Production systems and products.
 - b. Handling and storage of possibly BSE contaminated MBM.
 - c. Quantitative risk assessment applied to:
 - the Residual TSE Risk in Gelatine and Tallow Derived from Bones (Report and opinion)
 - the use of ruminant-derived tallow in bovine feed
 - the use of ruminant-derived tallow in milk replacers for calves
 - cross-contamination of animal feed with ruminant MBM (updating of opinion)

Alternative ways for the disposal of SRMs

 - d. The proposal for controlled use of ruminant SRMs as feed for fur animals in Finland.

Geographical BSE-risk.

e. Update

f. Update of the opinion of May 1999 on the evolution of the BSE epidemic in the UK.

Other issues:

g. 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.

h. Upcoming new questions

i. Update of the SSC opinion on Di-calcium phosphate (June 1998)

6. Organisational matters.

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

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

9. Any other business.

Annex 3: Opinion on: Strategies for dealing with emerging and re-emerging scientific issues that have the potential to impact human health, directly or mediated through the environment adopted by The Scientific Steering Committee at its meeting of: 26-27 October 2000 (Distributed separately)

Annex 4: Opinion on: Risk assessment in a rapidly advancing field: the case of genetically modified plants (GMP). Adopted by The Scientific Steering Committee at its meeting of 26-27 October 2000 (Distributed separately)

Annex 5: Opinion and Reports on: Harmonisation of Risk Assessment Procedures adopted by the Scientific Steering Committee at its meeting of: 26-27 October 2000 (Distributed separately)

Annex 6: Opinion and Report on: The Implications of the Houston *et al* paper in *The Lancet* of 16 September 2000 on the Transmission of BSE by blood transfusion in sheep. (The Lancet, Vol. 356, pp 999-1000; 955-956; 1013) adopted by the Scientific Steering Committee at its meeting of: 26-27 October 2000 (Distributed separately)

Annex 7: THE SAFE HANDLING, TRANSPORT AND TEMPORARY STORAGE OF MEAT-AND-BONE MEAL WHICH MAY BE CONTAMINATED WITH A TSE AGENT OR OTHER PATHOGENS - s adopted by The Scientific Steering Committee at its meeting of: 26-27 October 2000 (Distributed separately)

Annex 8: Statement of the Scientific Steering Committee (SSC) on its Report and Scientific Opinion on mammalian derived meat and bone meal forming a cross-contaminant of animal feedstuffs, Adopted on 24-25 September 1998 adopted at the SSC meeting of 26-27 October 2000

In 1998, the Scientific Steering Committee (SSC) was invited to address the following question:

"Does there exist an acceptable level of cross-contamination with mammalian meat-and-bone meal of ruminant feed? If yes, which one and under which conditions is it applicable?"

On the basis of the report of a working group, the Scientific Steering Committee adopted on 24-25 September 1998 the following opinion.

"The Scientific Steering Committee is of the opinion that in principle, cross-contamination with mammalian meat-and-bone meal of animal feedstuffs is not acceptable and that only a zero level of cross-contamination can exclude any risk

resulting from it. The risk for cross-contamination should be avoided by appropriate measures during the production, transport, storage and processing of the raw materials and of the produced feedstuffs.

For practical reasons and taking into account the present technical limits of detection as well as a risk analyses based on present knowledge, the SSC considers that levels of cross-contamination of ruminant feeds with mammalian meat-and-bone meal - derived from raw materials sourced and processed according to the conditions laid down in the SSC's opinion on the safety of MBM - which exceeds 0.50% MBM (or 0.15% animal bone fragments or 0.25% proteins, whichever is the lowest) should be condemned."

The SSC wishes to confirm that in principle, cross-contamination with mammalian meat-and-bone meal of ruminant feedstuffs is not acceptable. Feed cross-contaminated above levels that are reliably quantifiable should be condemned. In 1998, this level was put at 0,5% because of technical limits of quantification. At the same time, the SSC carried out a preliminary assessment of the risk for cattle resulting from a feed contaminated at that level of 0.5% if the MBM was produced in accordance with the SSC opinion on meat-and-bone meal i.e. if the MBM was produced exclusively from material fit for human consumption, without SRM and under pressure standards.

The SSC further confirms that it is presently updating the quantitative risk assessment of cross-contaminated feedstuffs presented in the report of September 1998, in the light of new information that meanwhile has become available, especially the one presented in its opinion of *Opinion of 13-14 April 2000 on Oral exposure of humans to the BSE agent: infective dose and species barrier.*

Annex 9: Opinion and Report on: The proposal for controlled use of ruminant SRMs as feed for fur animals in Finland adopted by the Scientific Steering Committee at its meeting of: 26-27 October 2000 (Distributed separately)

Annex 10: Reports from the secretariats of Scientific Committees on the major activities and milestones since the SSC meeting of 14-15 September 2000.

Scientific Committee for Plants

At the Plenary meeting of 22 September, the following 4 opinions were adopted:

1. Opinion of the Scientific Committee on Plants regarding the evaluation of ethoxysulfuron in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market. (Preliminary opinion)
2. Opinion of the Scientific Committee on Plants regarding the evaluation of thiabendazole in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market.
3. Opinion of the Scientific Committee on Plants regarding the evaluation of a document concerning the FOCUS groundwater scenarios in the EU registration process.
4. Opinion on the submission for placing on the market genetically modified maize (*Zea maize*) Line GA 21 with tolerance to glyphosate, notified by Monsanto - (notification C/ES/98/01).

Scientific Committee on Animal Nutrition (SCAN)

SCAN met twice between 15 September and end of October. The Committee discussed several draft reports but adopted only updates of reports on safety of micro-organisms and on safety of enzymes.

It concentrated also on its draft opinion on dioxins, which was discussed especially in an extraordinary plenary meeting organised on 20 October. The Committee agreed at the end of this dedicated plenary meeting to adopt its opinion using the Written Procedure.

Concerning other matters currently on SCAN agenda, the respective working groups continue their work.

Scientific Committee Veterinary Measures relating to Public Health

Scientific Committee on Animal Health and Animal Welfare

1. Animal Health

2. Animal Welfare

Scientific Committee for Toxicity, Ecotoxicity and the Environment

Since the last briefing on CSTE's activities (included in the minutes of the SSC plenary meeting held in 6/7 July 2000) the 17th and 18th plenary meetings of the CSTE took place respectively on the 5th of September and 9th of October 2000. In terms of progress made on the opinion requests submitted to the CSTE and other CSTE activities the following is of note:

A. During the 17th CSTE plenary meeting, opinions were adopted on the following topics:

1. *Methylene chloride and textile dyes.*

2. *BKH report "Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption".*

3. *Validation of testing methods for phthalate migration.*

4. *Cadmium in fertilisers - Programme of procedures for the assessment of risk to health and the environment from cadmium in fertilisers.*

B. In conformity with the CSTE opinion (adopted in 4 February 2000) on "*Technical s for Guidance on Data requirements, version 4.3 December 1999, in support of Biocides Directive 98/8/EEC*", a revision of the respective *chapter 1, lines 412 to 449*, took place and was presented to the CSTE. This related essentially to the so-called "*Waiving section*". The CSTE held the view that the changes introduced to that section were in conformity with the comments made by the committee in its opinion. This position was stated in the minutes of the September 2000 plenary meeting without a need for a formal new opinion to state it.

C. Regarding **Regulation 793/93** no opinions on the respective Risk Assessment reports have been adopted since the SSC July 2000 plenary but the following ones are in the agenda of the 19th CSTE plenary:

a) *1,4 Dioxane*; b) *1,4 Dichlorobenzene*; c) *4-Chloro-2-Methylphenol*; d) *Acetonitrile*; e) *Methacrylic acid*; f) *Acrylonitrile*; g) *Anisidine*.

D. On the subject "*Terrestrial environment - Available scientific approaches to assess the potential effects and risks of chemicals on terrestrial ecosystems*" and after various submissions of a series of drafts the final one should be submitted and adopted at the next, 19th, CSTE plenary which is also the last one of the CSTE before the new committee takes over. It is to be noted that a pre-final draft has been presented during the meeting of the Classification and Labelling working group (Directive 67/548) that took place in Ispra in September 2000, where it was welcomed.

E. Activities continued on the topic "*Exposure data in risk assessment*" and a new topic ("*Margins of safety*") was started by the CSTE; a working group was set up and met already once. This activity, like the one previously mentioned, is set to be continued by the next CSTE.

F. The CSTE also started again the tackling of the subject *EU Water Framework Directive* since it was finally submitted the outstanding report "*Development of a specification for the intercalibration of biological monitoring methods - Final Draft (European Commission Directorate General XI), Report No: CO 4751/1 - October 1999*". Two working group meetings will have taken place before the November 2000 plenary.

G. During the 18th CSTEEN plenary (9 October 2000) a new opinion request was submitted by Directorate General Environment of the Commission on the subject *Evaluation of sludge treatments for pathogen reduction*; a working group was also set up to address this subject.

H. The next (19th) CSTEEN plenary meeting is due to take place on the 9th of November 2000. The 1st meeting of the new CSTEEN (20th plenary meeting) is scheduled for the 5th of December 2000.

Scientific Committee for Cosmetics and Non-Food Products

Since the last SSC plenary meeting, one Plenary meeting and five Working Party meetings of the SCCNFP took place, during which the following items were discussed :

1. Alternatives : An updated version of the ' s of Guidance for Testing of the Cosmetic Ingredients for their Safety Evaluation' has been adopted. This work concerned mainly the revision of Annex 7 'Guidelines for the safety assessment of the finished cosmetic product'.

Future issues, such as the safety of so called 'natural cosmetics', evaluation criteria for the metabolism of cosmetic ingredients in human skin, or the need for a well organised cosmetic surveillance as requested by the sixth amendment, have been proposed.

2. Inventory : An opinion on the 1st update of Section II of the Inventory on perfume and aromatic raw materials has been adopted. The identity of the 2750 ingredients listed in Section II, either of a chemical or botanical origin, has been considerably improved.

The opinion forms a complement to the opinion on the 1st update of Section I of the inventory and common nomenclature on cosmetic ingredients adopted on 28 June 2000.

3. Preservatives, Colorants & Fragrances : Opinions were adopted on 2 polycyclic musks: AHTN and on HHCB. The substances were given a classification 3, which means 'Substances under consideration/evaluation but already in use and on the market for an extended period may remain under special provisions but only for a limited time which is recommended, scientifically based, by the SCCNFP depending on the content of the existing submission file.'

The additional data requested (percutaneous absorption, photo-toxicity) for AHTN and HHCB must be provided within 12 months.

An opinion was adopted on the presence of methyleugenol in cosmetics and on advance consumer information on the presence of oakmoss/treemoss extracts in cosmetic products.

4. UV Filters : An opinion was adopted on the use of Titanium dioxide in sun screen formulations.

Scientific Committee for Medicinal Products and Medical Devices

The SC-MPMD had neither a plenary session nor a working group meeting since the last SSC meeting.