

Scientific Steering Committee (SSC) - Minutes of the Meeting of 25-26 June 1998

1. Welcome, apologies, introductory remarks

Prof.G.Pascal, chairman, welcomed the participants and provided the apologies of Prof. V.Silano. Prof.J.Bridges could only be present on 25.06.98 and Prof. R.Kroes could only be present on 26.06.98. The list of participants is given as annex 1.

2. Approval of the agenda

The agenda was approved after adding the point "opinion on BSE in sheep" (see annex 2).

3. Approval of the minutes of the meeting of 14-15 May 1998

The minutes of the meeting in May were adopted with changes.

4. Work plan for the SSC

4.1. Multidisciplinary matters relating to TSE/BSE

4.1.1. General report of the work of the TSE/BSE ad-hoc group

M.Gibney reports that the recent enlargement of the TSE/BSE ad-hoc group seems to be very useful. Interesting contributions have been made by the new members to the discussion at the last meeting of the TSE/BSE ad-hoc group, on 19 June 98. That meeting resulted in several draft opinions and decided on several specific issues (see below).

4.1.2. Reports on specific issues:

(a) Production systems and products

- Safety of Dicalcium phosphate

M.Vanbelle (rapporteur) gave a brief account of the single comment received on the preliminary opinion issued in May. No changes were required in the opinion but as regards sourcing a notice was introduced which takes account of the recent development at OIE. The opinion was adopted (annex 3).

- WG-Organo-phosphates

E.Vanopdenbosch (rapporteur) summarised the changes introduced in the opinion since its adoption as preliminary opinion in May. No comments were received and all changes were editorial in nature. With some minor modifications the opinion was adopted (annex 4).

- WG-Semen and Embryos

The rapporteur, A.Somogyi, could not be present and therefore the secretariat briefly presented the current version of the draft opinion, revised after the last TSE/BSE ad-hoc group meeting. The SSC discussed the draft intensively and asked the TSE/BSE ad-hoc group to look at it again against alternative approach formulated in a document drafted by a small working group during the SSC meeting.

- WG-MBM for fur animals, cross contamination and organic fertilisers.

The SSC was informed that the different working groups dealing with products derived from bovine material via rendering (i.e. MBM and derived products) were now merged. A combined report is envisaged to be ready for adoption at the July meeting.

- Safety of peptides and amino acids

The SSC was informed that the secretariat received a request to aim at a rapid adoption of an opinion on the issue. It was therefore planned to finalise the draft opinion as soon as possible and to ask the working group, the TSE/BSE ad-hoc group and finally the SSC for approval by written procedure. The SSC accepted this proposal.

- BSE in sheep

Dr. E. Vanopdenbosch, rapporteur, introduced the draft opinion, which was revised after the last meeting of the TSE/BSE ad-hoc group. The SSC appreciated the additional work put into the opinion but still felt a need to better explain the scientific base. It therefore asked the rapporteur to revise it once more, following precise guidelines given by the SSC plenary.

(b) Human exposure risk

- Specified Risk Materials

No new developments were reported on.

- Blood, blood products, implantables, sutures

The SCMPMD is still working on its opinions concerning the issues but is dependent of a report on transformation of nvCJD via human blood and blood products which is currently under preparation for the house of Commons in UK. As soon as this essential input is available the SCMPMD will finalise its own opinions.

As regards bovine blood and blood products the SSC awaits the outcome for the human blood transmission route and its scientific base.

(c) Geographical risk

- Sourcing & Modelling

The modelling group made good progress and prepared input tables which should allow to calculate a relative propagation risk factor for geographical areas for which information is provided in accordance with the SSC opinion of 23 January 1998 on geographical risk.

The sourcing group is continuing its work towards a methodology for the exploitation of the requested information but is awaiting input from the ongoing OIE discussions. It was agreed that due account shall be taken of the work at OIE level and that this international standard should be adhered to if this would be scientifically acceptable.

- Commission position after the OIE-meeting in May

The SSC was informed that the Commission has the intention to publish a recommendation regarding the information needed to establish the epidemiological status of a country or geographical area with regard to TSE. If corresponding dossiers will be received the SSC will be asked to prepare an opinion on the TSE status of the concerned countries or geographical regions.

(d) Monitoring

- Validation of diagnostic tests for TSE in bovines

The SSC was informed that the Commission has published a call for expressions of interest to participate in the

validation exercise for a post-mortem BSE-test. It has received 10 expressions of interest which are currently under evaluation. Those tests, which meet the criteria published in the call will be invited to participate in the validation exercise.

Also the other preparatory activities are making good progress. The SSC will be asked to deliver an opinion on the validation protocol, which is approaching finalisation, as well as on the final outcome of the validation exercise.

- Validation of methods for identifying mammalian MBM in feed

Dr.E.Anklam, JRC, informed the SSC on the progress made with the validation of different tests which claim that they would be able to identify MBM contamination in composite feed supposed to be free of mammalian protein. The validation protocol is established and the validation will be undertaken simultaneously in several laboratories in different Member States.

The validation of a method for proving that MBM has been appropriately heated is at a similar state of advancement.

4.2. Progress on multidisciplinary matters, not primarily related to TSE/BSE:

- resistance to antimicrobials (progress report K.Jones)

The mandate of the working group, attached as annex 3 to the minutes of the SSC meeting of 14-15 May 1998 was further discussed and slightly amended. It is part of the minutes of 14-15 May, adopted during the meeting.

Prof.K.Jones, chairman of the working group, reported that the membership of the working group was now finalised. Because of the expected workload for the chairman, the SSC decided to strengthen the group with two vice-chairmen, namely Prof.M.Wierup and Prof.M.Vanbelle.

- exposure limits to electromagnetic fields.

Prof.Klein, rapporteur, presented the revised version of the draft opinion, which takes account of the comments made at the last SSC meeting. The opinion was adopted (annex 5).

- Genetically modified organisms (progress report, Silva-Fernandes)

Prof. Silva-Fernandes, chairman of the Scientific Committee Plants, reported on the 4 opinions that were adopted since the last SSC meeting. Because of time constraints, only a general discussion was held, but the 4 opinions would be presented into more detail during the SSC meeting of 16-17 July 1998.

5. Organisational matters:

5.1 Declaration of independence and confidentiality; exchange of CVs

The last declarations of independence and confidentiality were received at the meeting as well as the last CVs. The secretariat will make the information available to all members.

6. Co-ordination

6.1. Reports of the Chairmen of the 8 Scientific Committees (for information)

Because of time constraints, no reporting by the Chairmen of the 8 Scientific Committees was done.

It was decided that from now onwards, the Secretaries of the Committees would prepare a 1/2 - 1 page note on the activities since the last SSC meeting of their respective Committees. These notes would serve as a guide for the

presentations and discussions during the SSC meetings and also be annexed to the minutes. Annex 6 provides the account of activities of those Committees which had activities since the SSC meeting of 14-15 May 1998.

6.2. Harmonisation of working procedures, in particular in relation to risk assessment methodologies.

K.Bridges, designated rapporteur, introduced the topic but was still waiting for input from the other chairman as to currently applied working procedures of the different scientific committees. K.Bridges proposed to prepare a first draft of a position paper and to e-mail it to all chairman for comments before the end of the following week.

In the general discussion K.Bridges was asked to address

- criteria for the identification of threshold values
- how to handle a situation where threshold values can not be established
- transparent approaches to the definition of no-effect levels (safety factors)
- use of modelling techniques in risk assessment
- approaches to the risk assessment for mixtures of chemicals and physical impacts
- how to define default values if data are lacking.

As input to the envisaged discussion document a paper on risk assessment methodologies was mentioned, recently prepared for the UK treasurer. A similarly relevant paper was prepared for the UK health minister. Also the SCF guidelines are discussing the problems mentioned above.

It was agreed that K.Bridges should circulate a first draft paper in the following week and that a small group, consisting of K.Bridges (rapporteur), F.Kemper, P.James, G.Maroni and I.Knudsen would work on it in September. Close co-ordination with the more general work initiated by R.Kroes (see below) has to be guaranteed.

6.3. The role of the Scientific Committees and the SSC in relation to risk assessment and risk management. Definition of "acceptable" or "negligible" risk levels.

R.Kroes introduced a discussion paper on the issue. The SSC will continue its discussion on the subject at the next meeting. It was proposed that eventually, the discussion papers by Prof.Kroes and Prof.Bridges should be merged into one working document, including a mandate for a single working group on the harmonisation of working procedures and risk assessment approaches/methods.

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

7.1. Follow-up given by DG VI to the SSC-opinions on the safety of MBM, Gelatine and Tallow, adopted on 26-27 March 1998.

Mr.P.Colombo (DGVI-Agriculture) informed the SSC that the Commission is currently modifying the European legislation in order to respond to the mentioned opinions of the SSC:

(a) Gelatine: A draft proposal is under discussion by the Member States. The industry is now commenting and questions the validity of the "appropriate production process" mentioned in the opinion. One industry has come forward with an alternative process which has to be verified.

(b) Tallow: The tallow opinion is in line with international standards and will therefore not pose any problem. As regards tallow-derivatives the industry is questioning the proposed standard of T³ 200°C and p³ 40bar. The SSC is asked to verify this.

(c) MBM: Opinion is generally accepted as far as to the "safe" processing standard of 133/20/3. The need to also apply it if material from animals fit for human consumption is rendered is still questioned. An opinion on rendering fallen stock into MBM is urgently needed, as is an opinion on safe disposal of MBM made from potentially BSE-infected material.

(d) The SSC was also informed that the Commission has proposed a "date based export scheme", following the favourable opinion of the SSC. However, this proposal is not yet accepted by the Member States. A combination of criteria from the certified herd scheme with those in the DBES has been proposed.

The SSC thanked the Commission for the information and asked the Commission to (a) send clearly formulated written questions to the SSC and (b) to establish the priority of each question.

7.2. The update on the 5th Framework Programme for Research and the progress made which were provided by Dr.B.Hansen (DGXII), were welcomed quite positively by the SSC.

7.3. Dr.E.Anklam (DG-JRC) reported on the activities on the identification of GMOs carried out by the Joint Research Centre.

8. Any other business

No other matters were discussed

The meeting ended on Friday 26 June, 13h30.

Annex 1

List of participants of the Scientific Steering Committee meeting of 25-26 June 1998 (26/06/98 morning only)

List of presence

Members of the SSC:

- Prof. Georges Bories
- Prof. W.Bridges (not present on 26 June 1998)
- Prof. F.Garrido-Abellán
- Prof. Michael J. Gibney
- Prof. Philip James
- Prof. Keith H.Jones
- Prof. Fritz H.Kemper
- Prof. Werner Klein
- Prof. Ib Knudsen
- Prof. Robert Kroes (not present on 25 June 1998)
- Prof. Albert Osterhaus
- Prof. Gérard Pascal
- Prof. Antonio Silva Fernandes
- Prof. Marcel Vanbelle
- Prof. Martin Wierup
- Dr. Emmanuel Vanopdenbosch

Participants from the Commission:

DGIII: O.Rohte

DG V H. Buchow

DG VI P. Colombo (25 June 1998)

DG XI H. Martin

DGXII: . B. Hansen (26 June morning), M.L.Vidal, A. Fabre

DG XV A. Matton (25 June 1998)

DGXXIV: B.Carsin, S.Clarke, C.Deckart, M.de Sola, C.Diez Ubierna, F. Drion, J.Kreysa, M.Lauridsen, G.Morrison, J.Moynagh, A. Sanabria, A.Van Elst, R. Vanhoorde, P.Vossen, P. Wagstaffe, A. Wilhelm, M. Zampaglione.

Stagiaire: C. Fischer, A. Matéo

JRC E. Anklam

Annex 2

Agenda of the Scientific Steering Committee meeting of 25-26 June 1998

1. Welcome, apologies, introductory remarks

2. Approval of the agenda

3. Approval of the minutes of the meeting of 14-15 May 1998

4. Work plan for the SSC

4.1. Multidisciplinary matters relating to TSE/BSE

- General report of the work of the TSE/BSE ad-hoc group (M.Gibney)

- Reports on specific issues:

(a) Production systems and products (M.Vanbelle)

- Safety of Dicalcium phosphate (account of the comments received on the preliminary opinion and possible adoption of the final version);
- WG-Organo-phosphates (report and opinion);
- WG-Semen and Embryos (report and possible adoption of an opinion);
- WG-BSE in sheep (report and possible adoption of an opinion);
- WG-MBM for fur animals, cross contamination and organic fertilisers (progress report);

Safety of peptides and amino acids (progress report)

- Information by the Commission on the draft proposals for Decisions on gelatine, tallow and meat and bone meal and the UK Date Based Export Scheme.

(b) Human exposure risk (P.James)

- Specified Risk Materials (state of affairs)
- Blood, blood products, implantables, sutures (state of affairs)

(c) Geographical risk (Osterhaus)

- Sourcing & Modelling (progress report)
- Report on the OIE Code (BSE) adopted on 29.05.98 (Secretariat)
- Commission position after the OIE-meeting in May (DG VI)

(d) Monitoring (Osterhaus)

- Evaluation of diagnostic tests for TSE in bovines (progress report)
- Validation of methods for identifying mammalian MBM in feed (progress report).

4.2. Progress on multidisciplinary matters, not primarily related to TSE/BSE:

- resistance to antimicrobials (progress report K.Jones)
- exposure limits to electromagnetic fields (possible opinion, Prof.Klein)
- Genetically modified organisms (progress report, Silva-Fernandes)
- other ongoing activities.

5. Organisational matters:

5.1 Declaration of independence and confidentiality; exchange of CVs (state of affairs, secretariat).

6. Co-ordination

6.1. Reports of the Chairmen of the 8 Scientific Committees (for information)

6.2. Harmonisation of working procedures, in particular in relation to risk assessment methodologies. (Report by K.Bridges and adoption of a draft mandate for a working group)

6.3. The role of the Scientific Committees and the SSC in relation to risk assessment and risk management. Definition of "acceptable" or "negligible" risk levels. (Introductory report by R.Kroes, discussion)

7. Information by the Commission services on matters related to consumer health, including:

- > update on the 5th Framework Programme for Research (DG XII);
- > Activities on the identification of GMOs carried out by the Joint Research Centre (JRC, for information);

8. Any other business.

> Conference on TSE Legislation on Pharmaceuticals, London, 28-29 September 1998.

> Invitation to study of Animal Production in Sweden (3-4.09.98)

Annex 3

THE SAFETY OF DICALCIUM PHOSPHATE PRECIPITATED FROM RUMINANT BONES AND USED AS AN ANIMAL FEED ADDITIVE

Report and opinion adopted at the meeting of the Scientific Steering Committee of 25-26 June 1998, following a public consultation on the preliminary opinion adopted on 14-15 May 1998

(Document distributed separately)

Annex 4

OPINION ON POSSIBLE LINKS BETWEEN BSE AND ORGANOPHOSPHATES USED AS PESTICIDES AGAINST ECTO- AND ENDOPARASITES IN CATTLE

Report and opinion adopted at the Scientific Steering Committee meeting of 25-26 June 1998

(Document distributed separately)

Annex 5

OPINION ON POSSIBLE HEALTH EFFECTS FROM EXPOSURE TO ELECTROMAGNETIC FIELDS (0 Hz- 300 GHz)

Report and opinion adopted at the meeting of the Scientific Steering Committee of 25-26 June 1998,

(Document distributed separately)

Annex 6

Reports from the secretariats of Scientific Committees on the major activities and milestones since the previous meeting of the Scientific Steering Committee.

Scientific Committee for Food

The SCF adopted two opinions at the plenary session of 3-4 June 1998.

The first opinion is a further advice on a previous opinion concerning pesticides in baby foods. It was requested as a matter of extreme urgency by the Commission in order to prepare legislation in this area. Members of the SCP and invited experts had taken part in the discussions for the preparation of this advice. This question had been outlined in the previous SSC meeting. The SCP was also involved with some other questions on similar matters.

The second opinion adopted concerns the risks to public health from fruits and vegetables and their products grown in countries where cholera has reached epidemic levels. The Committee provided with a thorough opinion evaluating these risks on the basis of the report from the Working Group Food Hygiene and Microbiology.

Scientific Committee Veterinary Measures related to Public Health

At its plenary of 22 June the SCVMPH adopted the following opinions:

1. Detection of *Trichinella spiralis* in pork with a pooled sample digestion method using a magnetic stirrer and two separatory funnels.
2. Detection of *Trichinella spiralis* in horse meat.

It also discussed the draft scientific opinion concerning the 9th code of Federal Regulations Part 304, et al. Pathogen reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final rule;. In order to avoid any

misunderstanding, the US was invited to explain the Megareg to the Committee and to answer any possible questions. This was however, without participation in the scientific debate or in the drafting of the final opinion. It is foreseen to adopt the draft opinion at the next plenary that is scheduled for 20 July.

Considering the comprehensiveness of the issue there was ample time left to discuss other issues.

Working group meetings were held on the following subjects:

1. Final decontamination

The working group concerning the use of antimicrobial treatments of poultry carcasses, the various methods of carcass rinsing including trisodium monophosphates (TSP), organic acids and hyperchlorinated water finalised its draft opinion at the end of May. The final draft is circulated to all the members of the Committee with a view of its discussion and possible adoption at the plenary on 20 July.

2. BST

At its second meeting on 16 June the working group discussed a first draft report. The latter will be reviewed in the light of the discussion and considering the outcome of the work in the second group that is concentrating on the animal health and animal welfare aspects of the issue.

3. Simplification

On 18 June a working group had an exchange of views on a first reflection document concerning the evaluation of microbiological criteria and temperatures for storage and transport of products of animal origin intended for human consumption. The next meeting is scheduled for 29 September.

Members of SCVMPH also contributed to the following working groups:

- working group hygiene and microbiological criteria of the Scientific Committee on Food that adopted an opinion on cholera,
- BST (animal health and animal welfare aspects),
- Johne's / Crohn's disease

Activities of the Scientific Committee on Animal Health and Animal Welfare

18 May 1998: Subcommittee on Animal Welfare

The subcommittee approved a report on gas stunning which was forwarded to the plenary meeting of the Committee. The subcommittee also set up a working group to examine the welfare of broiler chickens.

19 May 1998: Subcommittee on Animal Health

The subcommittee approved a report on the eradication of scrapie and on research developments in Swine Vesicular Disease. Both reports were forwarded to the plenary meeting of the Committee. The subcommittee also nominated an expert to participate in the steering group on antimicrobial resistance.

23 June 1998: Plenary meeting of the Committee. Two reports were adopted unanimously by the Committee

- The use of gas mixtures containing CO₂ for the stunning or killing of poultry.
- Standards for running eradication programmes for Scrapie

A third report on Swine Vesicular Disease was discussed. This is now undergoing written procedure for adoption.

The following working group meetings have also been held:

- 28 May 1998: Meeting Working Group of Animal Health subcommittee on Directive 64/432 - Diagnostic Methods for Tuberculosis, Brucellosis and Enzootic Bovine leucosis. A working document is now being drafted which will form the basis of the report.
- 8 June 1998: Working group on BST. This group is looking at the welfare and health aspects of the use of BST. Areas identified for examination include, increased incidence of mastitis, lameness and injection site reactions. This report will need to be carefully drafted and be based on solid science .
- 10 June 1998: Meeting Working Group of Animal Welfare Subcommittee on Forced Feeding of Ducks and Geese - Gavage. Difficult issue needing much discussion. The text of the report is now complete and discussions are taking place on the conclusions and recommendations.
- 17 June 1998: Meeting Working Group of Animal Health subcommittee on Emergency vaccination for Foot and Mouth Disease. The text is now virtually finalised. One final meeting will be necessary in September to complete this.

Scientific Committee on Plants

The SCP met on 23 June 1997 and dealt with issues relating to plant GMOs, plant protection products and pesticide residues. The Committee adopted two plant GMO opinions viz DFL-Trifolium, Monsanto and Danisco fodder beet tolerant to glyphosate and Zeneca tomato with reduced activity of the expression of the endogenous tomato fruit PG gene. These opinions are available respectively as SCP/GMO/045-Final and SCP/GMO/073-Final. The meeting continued its examination of the three plant protection active substance dossiers viz kresoxim-methyl, fenthion, isoxaflutole and two pesticide residue questions. It is the intention to finalise the kresoxim-methyl, fenthion opinions and the pesticide residue opinions at the Plenary meeting of 14 July.

Scientific Committee on Toxicity, Ecotoxicity and the Environment

The meeting of the working group on '**Endocrine disrupters**', foreseen for the 29th of June 1998, was called off and the decision taken to postpone it for the 8th of September 1998.

Before the summer period only two other meetings, one of the working group '**Chrysotile asbestos**' and another of the working group '**Creosotes**' are foreseen. The former will take place on the 22nd of July and the latter on the 10th of August. It is expected that at both meetings the final working group draft opinions will be agreed with a view to submission to the next CSTEE plenary (14/15 September 1998).

DG III finally sent to the CSTEE secretariat the terms of reference for the consultation of the committee on the subject '**Azo dyes**'. These have just been sent, together with a few background documents, to CSTEE members. A working group had been set up at the CSTEE plenary meeting of April 98 and consideration is being given to what may be the best working arrangements to tackle this opinion request (either a straight drafting of an opinion in view of its discussion at the next plenary or organising a working group meeting- unlikely before the summer break).

On the subjects '**Tin, Arsenic, Cadmium and PCP**', DG III, the opinion requesters, organised a meeting with M. States (working group on Directive 76/769/EEC on restrictions of marketing and use of certain dangerous substances and preparations) that took place the 7th of July. The CSTEE secretary attended and presented, for information of M. States, the draft opinions (in a not yet finally adopted form by the committee, something explicitly emphasised by the CSTEE secretary and the DG III officials present). The general reaction of M. States was positive but Industry representatives complained at the fact that the draft PCP opinion, as presented, did not reflect correctly (their views) on the real risks posed by that chemical.

The subject '**Phthalates in toys**' is currently being followed up in the form of a meeting of the Emergencies committee scheduled for the 14th of July 98. The meeting is being organised by Unit XXIV/A/4 (Consumers' safety and Environment) and staff from the Dutch RIVM were invited to present the so-called '*Dutch study*', the aim of which is to allow for the standardisation of a test method on phthalate release (the CSTEE had indicated in its opinion on 'Phthalates in toys' that the results of such study could lead them to revise their opinion).

The chairman of the working group '**Water framework directive - WFD**', Dr Tarazona, was invited by Unit XI/E/1 of

the Commission to attend the meeting they organised with M. States on the 2nd and 3rd of July 98. The meeting was an opportunity to inform M. States of the status of development of the procedure for selection of priority substances for the WFD. The CSTEE secretariat could only be present at the start of the meeting but Dr Tarazona will provide later a short report on the meeting where he had a chance to explain to those present the opinion adopted by the CSTEE on the selection of priority substances.

Scientific Committee for Medicinal Products and medical Devices

The Committee met in plenary meeting on 24 June 1998. Before this meeting several Working Group meet several times.

The Working Group concerning "Equivalency of alternative products for the use of intestine of animal origin for surgical sutures" prepared a draft report that would be approved by written procedure, if necessary, or in the next plenary meeting of the SCMPMD.

Concerning "Orphan Medicinal Products: guidance on the notion of 'same medicinal product' and 'clinical superiority' for the purpose of marketing exclusivity", the Working Group made progress with its reports, but while for the notion of "same medicinal product" the report is almost finalised, the report on "clinical superiority" needs further improvement.

The Working Group on "Transmission of CJD by blood and its derivatives, and transplantation of human organs" met several times, and an interim report was presented to the Plenary. An overview on the general scope of the issue is now available, but the specific reply to the request made by the Commission will be redrafted in a next meeting of the W.G. in September. Several request are, according to the group, very difficult or impossible to answer given the actual scientific knowledge.

The Working Group on "Antimicrobial Resistance (partim: medicinal products)" had met two times, and is presently establishing the issues that will be addressed in the report.

Other Working groups such as "GMP for starting materials", "Colouring matters for use in medicinal products", "Draft guidelines on the use of specified risk materials for the manufacture of implantable medical devices" made also progress, particularly for what concerns the subject of "Colouring matters".