

Minutes of the Scientific Steering Committee Meeting of 24-25 June 1999

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

Prof.Dr.Pascal welcomed the participants. He apologised Prof.Dr.R.Kroes, Prof.Dr.Bories, Prof.Dr.K.Jones (Thursday 24 June), Prof.Dr.M.Wierup (Friday 25 June) and Prof.Dr.A.Garrido (replaced by Prof.Dr. Le Neindre). The list of participants is attached as annex 1.

No member declared an interest in any of the point of the agenda that could conflict with his independence.

2. Approval of the agenda

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

3. Approval of the minutes of the meeting of 27-28 May 1999

The minutes of the last meeting were approved with minor changes.

4. Progress on multidisciplinary matters

a. "Considerations for the evolution of scientific advice to address emerging health issues".

The working group is presently preparing a first draft report for the SSC. It will be presented at the next SSC meeting of 22-23 July 1999.

b. Harmonisation of risk assessment procedures.

The meeting of the Working Group, planned for 23 June 1999, had to be postponed for administrative reasons. A new meeting is now scheduled for September 1999. The scientific secretariat of the Working Group will from now on be assured by Mr. J.L.Jouve (DGXXIV) who recently joint unit B1 of DGXXIV.

c. Antimicrobial resistance: update

Two minor modifications to the report of the working group, needed for consistency reasons within the text. Both modifications were accepted by the SSC.

5. Multidisciplinary matters relating to TSE/BSE

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

Prof.Dr.P.James, who replaced Prof.Dr.M.Gibney at the last meeting of the ad-hoc group, provided a summary report on the recent activities of the ad-hoc group. Details are given under the subsequent points of these minutes.

5.2. Reports on specific issues

a. **"Fallen stock"**: The risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials.

On the basis of the updated report prepared by the WG at its meeting of 31 May 1999, the TSE/BSE ad-hoc Group

prepared a "final" draft opinion for the SSC. Both the report and the draft opinion were presented by Prof.Dr.M.Vanbelle, chairman of the Working Group and member of the TSE/BSE ad-hoc group. Following in-depth discussions the draft opinion was amended and adopted by the SSC. It is attached as annex 3. The report of the Working Group is attached as Annex 4.

It was noted that the public consultation via Internet of the preliminary opinion and report adopted by the SSC on 19 March 1999 had generated 27 comments, scientific contributions or proposals for amendments. These were analysed by the WG as they were received and formed the basis for the updated report prepared on 31 May 1999. The TSE/BSE ad-hoc group had thoroughly discussed and amended as necessary the draft final opinion on its meeting of 17.6.99.

b. Intra-species recycling.

Prof.Dr.P.James presented the Working Group report and reported on the discussion of the TSE/BSE ad hoc Group at its meeting of 17 June 1999. The ad-hoc group applauded the WG for the high quality of their report but felt that the conclusions drawn and the draft opinion proposed would still require work. The ad-hoc group also suggested to ask the SSC for guidance as to these conclusions.

A discussion was held and the SSC provided this guidance.

c. Overall view on the various "products" opinions (gelatine, meat-and-bone meal, tallow, etc.).

An update of the overview of the different opinions, distributed at the meeting of May, was prepared by the secretariat in collaboration with DGVI and distributed. Members were asked to further verify this update in view of a detailed discussion at a next meeting, probably September. Meanwhile, an external expert will be contracted to provide an independent view on the consistency between the various opinions. Since the first opinion on meat-and-bone meal (March 1998) and the last one on "Fallen Stock" (June 1999), science has indeed evolved. Moreover, the context of the various requests for opinion submitted by Commission services was different and therefore a verification of the overall consistency is needed. As it seems inevitably that clarifications may be needed, the ad-hoc group is asked to propose actions to be taken.

d. Breeding of scrapie-resistant sheep

The draft opinion prepared by the TSE/BSE ad hoc Group and the Working Group report on which it is based, were presented by Dr.E.Vanopdenbosch. A detailed discussion lead to a number of recommendations to the ad-hoc Group that should prepare a "final" draft opinion for adoption at the SSC meeting of July 1999.

e. BSE tests : evaluation of four candidate tests for the diagnosis of BSE

Four post-mortem BSE-tests were evaluated by the Commission with regard to their performance. A report was presented by the Commission (DG XXIV and the Joint Research Centre) to the Committee. Following discussion, the SSC issued the following statement:

The Committee examined the preliminary report of this major work carried out by the services of the Commission.

The Committee underlined the importance of this work and recognises the rigour of the experimental protocol and its execution. Within the limitations of the experimental design, it considered the fact that three of the tests examined have succeeded in correctly identifying all positive and negative samples provided for this purpose to be very encouraging.

The Scientific Steering Committee considered that the objectives of the evaluation have been achieved in showing that these tests can identify animals clinically affected with BSE.

This is an important development. In view of the public interest, it is important to ensure that the normal rigour of scientific evaluation and publication be applied. The Committee urged caution in interpreting the results. Results obtained from animals showing clinical signs of BSE cannot be extrapolated to animals in a pre-clinical phase of BSE.

The Committee urged the Commission to aim to have the results of this evaluation published in a leading scientific journal as rapidly as possible. The current document would benefit, by being further developed, prior to public release, so that the significance, implications and as importantly the limitations of the current work would allow the achievements to be seen in perspective.

As this first phase in the development of generally applicable tests for BSE screening has been successful, the Committee recommended that work be continued in this field with special emphasis on further validation and the identification of pre-clinical cases of BSE.

f. Human exposure risk.

The report of the Working Group "Human Exposure Risk" had been distributed previously to the Committee for guidance for the draft opinion that should be prepared on this basis. A brief discussion was held and it was concluded that the TSE/BSE *ad hoc* Group should draft an opinion along the lines of the WG-Report. This should be ready for adoption of at the SSC meeting of 16-17 September 1999.

g. Assessment of the geographical BSE risk

The Secretariat informed the SSC on the progress made with finalising the reports on the re-assessments of Member-States and that the reports on the first assessment of third countries and some member states were sent out for comments and possible request for a re-assessment to the respective countries. Two countries have already signalled that they would not request a re-assessment as they regarded the reports clear and appropriate.

The next group of third countries will be assessed during the week 28 June to 03 July, and the requested re-assessments will be carried out. The reports will be finalised as soon as possible afterwards and the reports on the first assessment will be made available to the concerned countries for comments.

h. BSE-status categories (progress report and discussion)

Due to the occupation with the fallen stock opinion the TSE/BSE ad-hoc group did not find the time to discuss in detail this issue. However, it was agreed that P.James will draft a discussion paper for the next meeting of the ad-hoc group and will report to the SSC on this issue in July.

6. Organisational matters

In order to ease the workload of the members of the TSE/BSE ad-hoc group it was decided

- to increase the number of members of the ad-hoc group up-to 20;
- that one of the additional members should be one of the SSC-members not chairing another SC,
- that the ad-hoc group should nominate two co-chairmen and that these should share the workload of the chair with the chairman.

Prof. Silano, member of the SSC and not chairing another SC, accepted to become Member of the TSE/BSE ad-hoc group and was nominated by the SSC.

The secretariat invited all SSC-members to propose suitable candidates and necessary expertise to the secretariat, which then would contact the potential members.

7. Co-ordination:

Reports of the Chairmen of the 8 Scientific Committees.

The chairmen of Scientific Committees provided a written report on the activities of their committees since the last SSC meeting (27-28 May 1999). A summary of their reports is given in annex 5.

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

No information was provided by the Commission Services.

9. Any other business:

No other business were discussed

The meeting ended on Friday 25 June 1999, at 12h30.

The next meeting will be held in Brussels, on 22-23 July 1999, starting at 10:00.

Annex 1: List of participants of the Scientific Steering Committee meeting of 24-25 June 1999

Members of the SSC:

Prof. Georges Bories (not present on 24 June), Prof. James W. Bridges (not present on 24 June), Prof. Le Neindre (replacing Prof. Garrido), Prof. Michael Gibney, Prof. Anthony R. Hardy, Prof. Philip T. James, Prof. Keith H. Jones (not present), Prof. Fritz H. Kemper, Prof. Werner Klein, Prof. Ib Knudsen, Prof. Albert Osterhaus, Prof. Gérard Pascal, Prof. Vittorio Silano, Prof. Marcel Vanbelle, Prof. Martin Wierup (not present on 25 June)

Invited expert:

Prof. Emmanuel Vanopdenbosch (24 June only)

Apologies: Prof. Robert Kroes, Prof. Garrido Abellàn

Participants from the Commission:

DG III: O. Rohte, **DG VI** D. André, T. Chalus, C. Micmacher, I. Peutz, **DG XI** A. Tommey, **CCR** G. Caratti, **JRC-IRMM** H. Schimmel,

DG XXIV: B. Carsin, W. de Klerck, C. Diez, J. Kreysa, G. Morosetti, G. Morrison, J. Moynagh, J.J. Rateau, A. Sanabria, A. Somogyi, J. Vergnettes, R. Vanhoorde, P. Vossen, P. Wagstaffe

Stagiaires: M. Plemp, A. Raphaël, S. Stefanidis

Apologies: H. Buchow (DGV)

Annex 2: Agenda of the Scientific Steering Committee Meeting of 24-25 June 1999

1. Welcome, apologies, introductory remarks, declarations of interest
2. Approval of the agenda
3. Approval of the minutes of the meeting of 27-28 May 1999.
4. Progress on multidisciplinary matters:
 - a. "Considerations for the evolution of scientific advice to address emerging health issues" (progress report)
 - b. Harmonisation of risk assessment procedures (progress report)
 - c. Antimicrobial resistance: update

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. "Fallen stock" (final opinion).

b. Intra-species recycling of animal waste (possible adoption of an opinion).

c. Overall view on the various "products" opinions (gelatine, meat-and-bone meal, tallow, etc.): discussion of the handling proposed by the TSE/BSE *ad hoc* Group.

d. Breeding of scrapie-resistant sheep (for opinion)

e. BSE tests (update and discussion of the preliminary results)

Human exposure risk.

f. Discussion of the written comments by members.

Geographical risk.

g. Assessment of the geographical BSE risk: (progress report)

h. BSE-status categories (progress report and discussion)

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: Scientific Opinion on The risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials.

Adopted by the Scientific Steering Committee at its meeting of 24-25 June 1999.

(Distributed separately)

Annex 4: Scientific Report on The risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials.

(This annex was distributed separately)

Annex 5: Reports from the secretariats of Scientific Committees on the major activities and milestones since the SSC meeting of 18-19 March 1999.

Scientific Committee on Plants

At the thirteenth Plenary Meeting held on 18 May 1999, a total of six opinions were adopted, three dealing with the authorisation of plant protection products and three with genetically modified plants. In the case of the plant protection product opinions, the committee dealt with the relevance of metabolites for the environment and human health, the relevance for man of certain carcinogenic and development effects. The three opinions related to the invocation of safeguard clauses by Member States relative to Directive 90/220/EEC on the deliberate release of genetically modified organisms.

No meeting in June for budgetary reasons

Scientific Committee on Animal Nutrition

Several meetings were organised for working groups. The SCAN plenary adopted four reports on feed additives at its last meeting (10-11 June) respectively on:

- formaldehyde,
- micro-organisms (update)
- a particular micro-organism,
- enzymes (update).

New questions have been submitted to the Committee and working groups have been created accordingly.

The Committee continues its work on the other questions.

Scientific Committee for Toxicity, Ecotoxicity and the Environment

A. Since the May 99 SSC plenary meeting no plenary meeting of the CSTEE took place. The budgetary problem that prevented the organisation of working group meetings is now solved (confirmation arrived on the 22nd of June) and at the next plenary decisions will be taken on organisation of working group meetings.

For the topics still pending adoption of opinions the situation is the following:

B. As already mentioned in the previous briefing to the SSC the opinion request '*Terrestrial environment*' - '*Available scientific approaches to assess the potential effects and risks of chemicals on terrestrial ecosystems*' could not be pursued given that the next logical step (organisation of working group meeting, in the meantime cancelled) could not take place. The requester Commission service has in the meantime communicated that one of the documents submitted still needs the addition of an annex.

C. On the subject '*Selection of a Community wide mineral oil marking system - Safety of the preferred product*' a data pack was received by the CSTEE secretariat from the Commission requester service (DG XXI) and immediately sent to CSTEE members. We are expecting progress on this subject at the CSTEE July plenary. This will probably involve one or two working group meetings.

D. A paper prepared by one member on '*The use of measured exposure data in risk assessment*' was received by the CSTEE secretariat and will be discussed at the Oslo plenary where a decision will be taken on what activity of the CSTEE this should trigger. In principle it should be a CSTEE own initiative report.

E. No progress on the new opinion request on the subject '*Water framework directive*' was possible because of the

reasons mentioned in A.

F. Some data was finally obtained by the Commission requester service on the subject *'Toxicological characteristics and risks of certain citrates and adipates used as a substitute for phthalates as plasticisers in certain soft PVC products'*. Data sent by M. States and Greenpeace to DG III was also received and sent to the CSTEE and relevant working group members.

G. A new opinion request has just been submitted by DG III on the subject *'Ready Biodegradability Test Methods of Surfactants in Detergents'*. A formal presentation will take place at the Oslo plenary.

H. Contacts have been established with also DG III (Unit D/3) with a view to involve the CSTEE in a foreseeable future, probably after the summer break, on the subject *'Construction products in contact with drinking water'*.

I. An opinion request will very likely be submitted soon on the subject of *'Lead'* following a notification submitted by Denmark. No more information is available to the CSTEE secretariat at the time of writing this note other than that the terms of reference are still being discussed at the level of the relevant Commission services (DGs III and XI).

J. The next CSTEE plenary is confirmed for the 1st of July 1999 in Oslo, Norway.

Scientific Committee for Cosmetics and Non-Food Products

Four Working Parties meetings and a Plenary meeting took place, during which the following items were discussed:

1. *Hair Dyes*: 19 opinions were prepared by the Working Party and formally adopted by the SCCNFP during its 8th Plenary meeting of 23.6.99.

2. *UV Filters*: Further to a request from the Committee, additional data were received from industry on S75 (coated Titanium dioxide) for use in sun screen formulations. The Working Party, however, felt that these data did not answer the questions asked.

Another letter will be sent insisting industry to respond specifically to the questions asked.

Although 4-Isopropylbenzylsalicylate (S16) is no longer used as a sunscreen, a mandate from DG III was received requesting the SCCNFP to assess the safety of this substance as a UV absorber. A rapporteur has been assigned and he will report in a future meeting.

A specific Working Party will be created in the near future in order to assess the safety aspects related to sun beds.

3. *Alternatives*: Several documents, approved by the Working Party 'Alternatives', were formally adopted by the plenary meeting, namely :

- Basic criteria for the in vitro assessment of percutaneous absorption of cosmetic ingredients.
- Guidelines on the use of human volunteers in skin compatibility testing of finished cosmetic products.
- Update of the s of guidance for testing of cosmetic ingredients for their safety evaluation integrating recent adopted opinions relating to the safety evaluation of cosmetic ingredients.
- Present development and validation of adequate alternative methodologies to the use of animals in the safety testing in cosmetics.

4. *Preservatives, Colorants & Fragrances*: A series of opinions were prepared by the WP and presented to the plenary for adoption.

Safety review of perfumery materials : in order to have some more time to further 'streamline' its opinion on the issue, the SCCNFP decided to adopt and to publish on the internet an interim position on fragrance allergy. The paper

outlines, besides the questions asked, the strategy of the Committee to respond to this mandate.

Opinions were adopted on :

- P91(3-Iodo-2-propylbutylcarbamide)
- the use of carbamide peroxide in teeth bleaching products (clarification of the earlier adopted opinion)
- the use of hydrogen peroxide in oral care products
- revised opinion on Strontium Lactate, Nitrate and Polycarboxylate
- Opinion on the use of ketoconazole in certain cosmetic products.

Scientific Committee for Medicinal Products and Medical Devices

A Plenary Meeting was held on 2 June 1999. The Subject "Anti-cariogenic Properties of Xylitol" and the work of the Co-ordination Group "Harmonisation Risk Assessment", were discussed.

An opinion concerning "Anti-cariogenic Properties of Xylitol" was adopted.

Information by the Commission services was given on "Quality and safety for the collection, processing, storage and distribution of whole blood, blood components and blood precursors in order to ensure a high level of human health protection in the Community".

Concerning «Latex medical gloves», DGIII explained the 16 requests put to the Committee on scientific matters concerning these products.

As a result, two Working Groups, one to study the "Quality and Safety of Blood" and another to prepare an opinion on "Latex", were established.