

Minutes of the Scientific Steering Committee Meeting of 28-29 October 1999

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

Prof.Dr.Pascal welcomed the participants. He apologised Prof.W.Klein, Prof.I.Knudsen and Prof.R.Kroes (for 29 October). Prof.Knudsen was replaced by Prof.A.Knaap, vice chairwoman of the Scientific Committee for Food. The list of participants is attached as annex 1.

Declarations of interest.

As foreseen in Section 2 of the Rules of Procedures of the Scientific Steering Committee and its Working Groups, the participants were requested whether any of them had to declare any particular interest. The Commission services pointed out that the concept "interest" had to be understood as including the notion of "intellectual interest".

With respect to item 5.2.g on the agenda, Prof.Pascal, chairman of the SSC, explained his position as Scientific Director for human Nutrition and Food Safety within INRA and informed the SSC of his function of chairman of the Scientific Council of AFSSA. The latter functions consist of providing an independent advice on the general scientific orientations but, however, do not imply participation in the elaboration of scientific opinions of AFFSSA nor a hierarchical link with the Director of AFSSA. He took up this function 6 months ago, upon the creation of AFSSA. He requested the participants to evaluate whether, during the discussions of item 5.2.g., he could attend the meeting at all, whether he should only be an observer, whether he could participate in the discussions without being chairman or whether he could assume the chairmanship. Prof.Pascal informed the SSC that he would accept whatever decision the SSC would take and then left the meeting room.

With respect to the same item, Prof. Bories explained his position as Scientific Director within INRA and his function as Chairman of the Inter-ministerial and Inter-professional Committee for Animal Nutrition, which, since the creation of AFSSA, fits also in the AFSSA structure. However, in these functions he had never been involved in BSE-related matters.

Under chairmanship of Prof.V.Silano, first vice-chairman of the SSC, the declarations were discussed by the SSC and evaluated in the light of a potential conflict of interest. After discussion, the acting chairman, together with the other members of the SSC considered that Prof.Pascal and Prof. Bories were able to act independently and in consequence to participate in the discussions. This implied that Prof.Pascal could also assume the chairmanship during the discussions of item 5.2.g.

2. Approval of the agenda

The draft agenda was approved. It is attached as annex 2. However, only items 1, 2, 5.2.g and, partly, item 5.2.e. and 7 were discussed at the meeting. All other items were referred to the agenda of the meeting of 9-19 December 1999.

3. Approval of the minutes of the meeting of 16-17 September 1999

The minutes of the last meeting were approved without changes.

5. Multidisciplinary matters relating to TSE/BSE

Abbreviations used in the sections below:

AFSSA: *Agence Française de Sécurité Sanitaire des Aliments* (the French Food Safety Agency)

BSE: Bovine Spongiform Encephalopathy

DBES: Date Based Export Scheme

ECHS: Export Certified Herd Scheme

MAFF: Ministry of Agriculture, Fisheries and Food (UK)

MBM: Meat-and-bone meal

OTMS: Over Thirty Months Scheme

SEAC: Spongiform Encephalopathy Advisory Committee (UK)

SRM: Specified Risk Materials

TSE: Transmissible Spongiform Encephalopathy

5.2.e. TSE surveillance

At its meeting of 16-17 October 1999, SSC requested the secretariat to contact the UK authorities with the question to provide the SSC with additional details on (1) the results per class of age and date of birth and (2) the nature of the difficulties encountered when applying diagnostic tests in this survey.

The secretariat provided all participants with a copy of the letter addressed to the UK Spongiform Encephalopathy Advisory Committee and of the reply sent by Dr. Ann Nolan, scientific secretary of SEAC, to the SSC secretariat.

5.2.g. Monitoring the BSE epidemic in the UK and UK Date Based Export Scheme: Opinion of the French Group of Experts on Sub-acute Transmissible Spongiform Encephalopathies.

a. The secretariat provided a detailed account of all the background documents made available to the participants at the meeting. The list is included in annex 4.

b. Professor Silano, who had chaired the meetings of 14 and 25 October 1999 of the TSE/BSE *ad hoc* Group, presented the 3 questions submitted to the SSC, following the Advice of 30 September 1999 of the French Food Safety Agency (the *Agence Française de Sécurité Sanitaire des Aliments*, AFSSA), to the French Government on the Draft Decree amending the Decree of 28 October 1998 establishing specific measures applicable to certain products of bovine origin exported from the United Kingdom. These questions are:

1. Do the opinions and documentation provided by the French authorities contain scientific information, epidemiological data or other evidence that has not been taken into account by the SSC?
2. If, in the above documentation, there is new information, data or evidence, or if the SSC has at its disposal any such new information, would this require a re-examination of any of the four SSC Opinions directly related to the scientific rationale of the DBES?
3. In the light of the answers to the above question, could the SSC confirm (or not) its position that the conditions of the DBES, if appropriately respected, are satisfactory with regard to the safety of the meat and meat-products produced?

c. Professor Silano then presented in detail the report based on these meetings (version of 28.10.99, including the comments of 4 *ad hoc* Group members). The secretariat pointed out other comments that arrived after closure of the preparation of the set of documents prepared for the SSC meeting.

d. 3 issues were discussed in detail by the SSC which also considered the views of the *ad hoc* Group. These were:

1. The possibility of verifying the distribution of PrP^{Res} in the various body tissues and fluids of infected (incubating)

cattle. Linked to this was the question of the usefulness of the increasing sensitivity of the BSE laboratory tests and assays.

2. The evolution in 1999 of the epidemiology of the disease in the UK and its importance for the DBES, and linked to it, the issue of possible new transmission routes.

3. The potential of the recently evaluated rapid diagnostic BSE-tests and of new analytical possibilities with regard their use in surveillance and monitoring of TSEs.

On traceability of the meat and meat products, the SSC had a short exchange of views on the latter element, but considered that the control and traceability of DBES meat and meat products are not within its mandate.

e Following a first session with plenary discussions, 4 drafting groups were formed around the first 3 of the above elements, as well as to prepare the background section of the opinion.

f. The 4 drafts were discussed in detail and amended during a second plenary session. The final conclusions, providing an answer to the questions submitted to the SSC were adopted unanimously. The sections containing the background note and the scientific justifications were adopted as a draft, but referred to a written (e-mail) procedure for final editing.

The complete text of the opinion (conclusions, background and justification) is attached as annex 3 and is made available on the internet as a separate document.

g. The SSC also prepared and adopted unanimously the press-release which was issued after the meeting.

h. The SSC further decided that the draft epidemiological/surveillance report prepared by Dr.S.Gore in preparation of the TSE/BSE *ad hoc* Group meeting, would - after editing and including the 1996-1999 projections of BSE incidence in Great Britain derived from the Cohen & Valleron model (1999), but excluding the surveillance sections - be included as updated amendment in the SSC opinion of 28 May 1999 on "*Monitoring some important aspects of the evolution of the epidemic of BSE in Great Britain*". The section covering surveillance aspects, should be included in the report which is presently being prepared by the Working Group on Surveillance and Culling.

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 (16-17 September 1999). (See annex 5)

The meeting ended on Friday 29 October 1999, at 17h30.

The next meeting will be held in Brussels, on 9 and 10 December 1999 .

Annex 1: List of participants of the Scientific Steering Committee meeting of 28-29 October 1999

List of presence

Members of the SSC :

Prof. Georges Bories, Prof. James W. Bridges (not present on 28 October 1999 morning), Prof. Fulgencio Garrido Abellán, Prof. Michael Gibney, Prof. Anthony R. Hardy, Prof. Philip T. James (not present on 28 October 1999 morning), Prof. Keith H.Jones, Prof. Fritz H.Kemper, Prof. Ada Knaap (replacing Prof. Knudsen) (not present on 28 October 1999 morning), Prof. Robert Kroes (attended on 28 October 1999 only), Prof. Albert Osterhaus, Prof. Gérard Pascal, Prof. Vittorio Silano, Prof. Marcel Vanbelle, Prof. Martin Wierup.

Apologies: Prof. Werner Klein and Prof. Ib Knudsen

Participants from the Commission:

DG RESEARCH: M.Vidal-Ragout (on 28 October only)

DG SANCO: B. Carsin, J.J. Rateau, C. Berlingieri, J. Costa-David, T. Chalus, C. Deckart, M. de Solà, C. Diez, F. Drion, T. Emmerling, G. Fracchia, K.Hakulin, D. Heel, J.L. Jouve, J.Kreysa (on 29 October only), G.Morrison, J. Moynagh, W. Penning, I. Peutz, A. Sanabria, J. Savio, A. Somogyi, A. van Elst, R. Vanhoorde, J. Vergnettes, P. Vossen

Annex 2: Agenda of the Scientific Steering Committee Meeting of 28-29 October 1999

1. Welcome, apologies, introductory remarks, declarations of interest
2. Approval of the agenda
3. Approval of the minutes of the meeting of 16-17 September 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. Possibly emerging fields of concern with respect to health and consumer protection (preliminary 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. Safety of ruminant blood (progress report)
- b. Quantitative assessment of safety of products (progress report).
- c. Handling and storage of possibly BSE contaminated MBM (progress report)

Human exposure risk.

- d. Discussion of the report and possible adoption of an opinion.

Geographical risk.

- e. TSE surveillance (progress report and possible adoption of an opinion).
- f. Culling (progress report).
- g. Monitoring the BSE epidemic in the UK and UK Date Based Export Scheme: Opinion of the French Group of Experts on Sub-acute Transmissible Spongiform Encephalopathies.

Other issues:

- h. Origin of BSE (progress report).

6. Organisational matters.

7. Co-ordination:

- a. Reports of the Chairmen of the 8 Scientific Committees.
- b. Structure of opinions and technical reports.

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

9. Any other business.

Annex 3: Opinion of the Scientific Steering Committee on the Scientific Grounds of the Advice of 30 September 1999 of the French Food Safety Agency (the *Agence Française de Sécurité Sanitaire des Aliments*, AFSSA), to the French Government on the Draft Decree amending the Decree of 28 October 1998 establishing specific measures applicable to certain products of bovine origin exported from the United Kingdom. Adopted at its meeting of 28-29 October 1999 and edited following a written procedure (30-31.10.99)

(Document subject to further editorial changes)

(Distributed separately, and available on Internet)

Annex 4: overview of the background documents made available to the participants at the meeting.

- The AFFSSA advice of 30 September 1999, the underlying opinions of the French Group of Experts on Transmissible Sub-acute Spongiform Encephalopathies of 1.07.99 ad 30.07.99, their translations into English;
- Comments from Prof.M.Gibney on the above report;
- The comments of the UK Government on the AFSSA opinion.
- Comparison of the list of documents, data and scientific publications provided by French authorities (8.10.99) and the list of scientific papers, data and documents consulted by the SSC and its working groups, in preparation of the 4 DBES-related and other indirectly related opinions (e.g., vertical transmission, specified risk materials).
- Compliance matrix DBES/SSC opinions related to DBES
- An updated version of the draft working document presenting the account of the TSE/BSE ad hoc Group meetings of 14 and 25 October 1999, including 4 comments received from TSE/BSE ad hoc Group members on 27 October 1999 and 28 October 1999 (received before 09h00 am),
- Copies of the written comments received on the above draft working document (version 26.10.99) from *ad hoc* Group members;
- the latest epidemiological data provided by the UK authorities;
- Graph with the monthly evolution of BSE in the UK, showing the change in slope after 1996.
- Comment provided by various epidemiologists on the evolution of the BSE epidemic in UK in the light of the most recent data received from the UK; (Including: Gore, Wilesmith, De Koeijer, Doherr,)
- The risk assessment of the probability that maternally infected animals would be exported under the DBES carried out by MAFF in January 1998, and referred to in the SSC opinion of February 1998; an update of this risk assessment (October 1999).
- Independent risk assessment of the probability that maternally infected animals would be exported under the DBES, carried out by a Dr.A.De Koeijer Dutch (ID-DLO, the Netherlands (unpublished)).

- Copy of the letter & attachments provided by Dr.S.Dealler on the evolution of the BSE epidemic in UK (including: results, data, calculation method, discussion);
- Comments on these results, on the basis of the age distribution of the BSE cases in UK.
- Copy of a mail from Parish & Parish on organophosphates and BSE (received, 28.10.99, +/- 08h00 am)
- Print-outs from the MAFF website on the BSE epidemic;
- Monthly report on CJD in UK (figures)
- The Advice of 21 September 1999 from the Chief Medical Officer for Scotland, on beef bone regulations;
- A copy of the 4 DBES-related opinions adopted by the SSC since December 1997.
- Other recent relevant scientific publications (e.g., on slaughter methods)
- The set of French documents, submitted to the Commission on 8 October 1999, in support of the AFSSA opinion of 30 September 1999.

Annex 5: Reports from the secretariats of Scientific Committees on the major activities and milestones since the SSC meeting of 16-17 September 1999.

Scientific Committee for Food

The SCF has hold in this period its 118th meeting on 22/23 September. At this plenary, the Committee:

- adopted an opinion on a tomato fruit genetically modified to down-regulate the production of polygalacturonase (PG), and solely intended for processing. This opinion is requested by the Council Regulation on Novel Foods.
- adopted an updated opinion on the flavouring substance coumarin, reviewing new data since the previous opinion of the Committee in 1994.
- adopted an opinion on an additional list of monomers and additives for food contact materials. This list contains 9 substances.
- issued a statement of the status of the evaluation of the food additive lactoperoxydase.
- issued a statement relating the adequacy in terms of consumer health protection of the measures taken by the European Commission during the management of the contamination of the Belgian food supply with PCBs and dioxins
- issued a statement relating to the request for an opinion of the SCF concerning an update of the opinion on nitrate and nitrite in the light of new information
- issued a statement on aqueous solutions as acceptable previous cargoes for the bulk transport of fats and oils

In this period also a number of Working Groups held meetings also.

Scientific Committee on Plants

The SCP held its sixteenth meeting on 28 October 1999. The Committee had on its agenda a number of generic issues relating to plant protection product, questions relating to specific plant protection products active substances and genetically modified plants. The generic plant protection product issues included guidance on risk assessment for pesticide residues in agricultural products / food and the adequacy of the current testing requirements for detecting endocrine disrupting effects in plant protection products in the context of Directive 91/414/EEC. In the case of pesticide

residues, the Committee decided to defer adopting an opinion in order to allow for an enlargement of the scope of the discussions on the appropriate dietary data to be used for the different risks encountered (chronic, semi-chronic, acute). Given the multi-disciplinary nature of the issues involved, the Committee suggested that the Chairman should raise the matter in the SSC with a view to the possible involvement of other scientific committees, particularly the SCF.

The Committee adopted one opinion relating to development effects of vinclozolin.

Scientific Committee on Animal Nutrition (SCAN)

SCAN met three times in September and October and concentrated on the revision of the guidelines for submission of dossiers of authorisation of additives. It finally adopted its opinion on 22 October 1999. This opinion does however not cover the enzymes and micro-organisms guidelines which will be dealt with in a second step. In addition, SCAN adopted a report on the use in animal feed of protein-rich biomass and updated two other reports, respectively on micro-organisms and on enzymes.

Scientific Committee Veterinary Measures relating to Public Health

The Committee adopted two opinions at its plenary meeting of 23-24 September, respectively on Microbiological Criteria and on *Listeria monocytogenes*.

Scientific Committee on Animal Health and Animal Welfare

Activities of the Sub-committee on Animal Welfare:

The Working Groups established by the Subcommittee continued their work on the following questions.

1. Working group on the welfare of broiler chickens

This group met on 25 October. The draft document is going to be finalised. The contents of some chapters were reviewed and the questions to be dealt with in the last missing chapter on the socio-economic aspects were discussed and agreed. The group is now preparing the conclusions and recommendations and will have one more meeting before presenting the document to the Subcommittee plenary.

2. Ventilation standards for animal transport vehicles

The document was completed and revised by circulating it among the Subcommittee members and by the rapporteur. The document will be submitted for discussion and possible approval at the next Sub-committee plenary on 23 November and if approved it will be for discussion and possible approval on the agenda of the plenary of the Committee on 8 December.

At the last Plenary meeting of the Committee, a report on progress and future arrangements of the working group on methods of risk analysis (of the Steering Committee) was presented by Dr Ahl and Dr Le Neindre who are members of this working group.

Activities of the Sub-committee on Animal Health:

Activities in this period were concentrated on the following items.

Inactivation of viruses in blood: The document is in preparation

Diagnosis of Crimean Congo Haemorrhagic Fever Virus Infections in Ratites . The document was discussed and adopted by the Scientific Committee on its plenary on 11 October.

Revision of the annexes to Council Directive 64/432/EEC. The report was discussed and adopted with minor amendments by the Scientific Committee

Eradication of Bacterial Kidney Disease. The final working document is almost ready. The Working Group met on 29 October and updated some sections. It will be presented, discussed and possibly approved at the next Sub-committee plenary on 24 November. If approved, this report could be ready for presentation at the next Plenary meeting of the Committee on 8 November.

Possible Links between Crohn's disease in man and paratuberculosis in animals. The latest draft is being circulated by e.mail among the members of the WG. Several chapters are being updated and rewritten. A further meeting of the working group will be held shortly with a view to having a document ready for the next meeting of the Committee.

Scientific Committee for Toxicity, Ecotoxicity and the Environment

A. The 11th CSTEEN plenary meeting took place on the 27/28 of September 1999. Due to the passing away of Prof. Philip Chambers, vice-chairman of the CSTEEN, the election of a substitute had to take place. Dr José Tarazona was elected 2nd vice-chairman of the CSTEEN.

In terms of progress made on the opinion requests of the CSTEEN and CSTEEN initiatives the outcome was the following:

B. On the subject '*Terrestrial environment*' - '*Available scientific approaches to assess the potential effects and risks of chemicals on terrestrial ecosystems*' -A working group meeting took place on the 20th of September and a draft status report was submitted to the September CSTEEN plenary.

C. On the subject '*Selection of a Community wide mineral oil marking system - Safety of the preferred product*' an opinion was adopted at the September CSTEEN plenary. The main conclusion was that the purported risks attributable to "solvent yellow 124", based on concerns stemming from a so-called "Swedish accident", appear to be essentially due to a change of specification of the diesel oil and not to the solvent yellow itself.

D. '*The use of measured exposure data in risk assessment*' - A brief discussion on the remit took place at the meeting. A more detailed report will be elaborated by the working group.

E. On the opinion request on '*Water framework directive*' an opinion was adopted on the part B of the opinion request on the *revised proposal for a List of Priority Substances in the Context of the Water Framework Directive (COMMPS Procedure)* prepared by the Fraunhofer-Institut (Germany) - Final report.

The part of the opinion request on a study on *Technical specifications for monitoring of ecological status of surface waters* is still pending the submission of an update.

F. '*Toxicological characteristics and risks of certain citrates and adipates used as a substitute for phthalates as plasticisers in certain soft PVC products*' and '*TNO*' and '*LGC*' reports on validation attempts of the so-called '*Dutch consensus group study*' - An opinion on 'Phthalates substitutes' was adopted, the main conclusions of which were that, for the time being and on the basis of the evidence submitted to the CSTEEN, the alternatives considered (Citrates-adipates) could not be considered suitable alternatives to phthalates (the CSTEEN also made the important point that matrix materials other than PVC, if they were to be considered as alternatives, should also undergo a risk assessment identical to that used for phthalates and their possible substitutes). An opinion was also adopted on the two reports prepared by LGC (UK) and TNO (NL) on the development and validation of a test method to assess phthalates migration from PVC. The conclusion of the CSTEEN was that neither test is currently suitable for regulatory purposes but the Committee made recommendations on the nature of improvements needed.

G. **Evaluation of technical guidance document (TGD) in support of Directive 98/8/EC concerning the placing of biocidal products on the market** - Following the submission by the competent Commission service (DG ENV/E/2) of the terms of reference a working group was set up and already one sub-working group meeting has taken place, with another subgroup and main working group meetings foreseen for the month of November 99. The aim is to have a draft submitted for adoption at the November CSTEEN plenary.

H. '*Ready Biodegradability Test Methods of Surfactants in Detergents*' - a progress report was made at the meeting

by the WG chairperson. It is expected that an opinion will be adopted at the November 99 CSTEE plenary.

I. On the subject '*Construction products in contact with drinking water*' feed back was obtained from the responsible Commission requester service. It would now look as if the working group set up under the auspices of DG ENTERPRISE expressed a preference for submitting the opinion request to the Scientific Committee for Food instead. Dg ENTERPRISE will send a note to Health and consumer protection DG with their position on the matter.

J. On the 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 problems highlighted before were confirmed at the meeting. In summary, the CSTEE cannot address question **ii)** given its very broad basis which covers practically all aspects of lead effects (all human health and environment related effects/risks for all exposure scenarios). The committee agrees to give priority to addressing question **i)**.

K. The next CSTEE plenary is confirmed for the 25th of November 1999 in Brussels.

Scientific Committee for Cosmetics and Non-Food Products

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

1. *Hair Dyes* : 15 hair dye dossiers were reviewed and draft opinions prepared by a special Task Force. These drafts are to be discussed by Working Party 'Hair Dyes' during its next meeting of 7 December 1999 prior to their formal presentation and possible adoption by the plenary.

2. *UV Filters* : S75 (coated Titanium dioxide) : a further letter was sent to industry insisting industry to respond specifically to the questions asked. The discussion will resume upon receipt of the information required.

Although 4-Isopropylbenzylsalicylate (S16) is not longer used as a sunscreen, a mandate from DG III was received requesting the SCCNFP to assess the safety of this substance as an UV absorber used in cosmetic products. A rapporteur has been assigned and he will report in a future meeting.

3. *Alternatives/Dossier* : Different issues related to the s of Guidance for testing of cosmetic ingredients for the safety evaluation were discussed during the last WP meeting : consumer exposure to cosmetic ingredients, elaboration of new annexes on physical, chemical and microbiological specifications of cosmetic products.

4. *Preservatives, Colorants & Fragrances* :

An opinion was adopted on acrylamide residues in cosmetic products.

Draft opinions on Musk Ketone and Musk Xylene were discussed during the plenary meeting of 30.9.99. However, there was concern about the carcinogenicity and the accumulation in mother's milk. Also, the sensitisation data were considered unsatisfactory. A further Working Party meeting is planned on 10.11.99 to clarify these points.

A draft pre-opinion on fragrance allergy was adopted by the plenary. The document was put on the internet inviting interested parties for comments. These comments will be assessed and the draft opinion adapted, if appropriate, prior to its formal adoption by the plenary.

5. *Inventory* :

All the issues raised during the last years in relation to the 1st update of the Inventory and common nomenclature have been discussed with and accepted by the parties concerned, namely COLIPA and the SCCNFP.

In view of an urgent publication, a time table for the edition of this 1st update was proposed and approved, which should lead to an official adoption of the 1st update by the SCCNFP within 4 months following the presentation of the draft update.

Scientific Committee for Medicinal Products and Medical Devices

No plenary session was held since last SSC meeting. Two Working Groups had meetings, namely on:

- Blood safety
- Harmonisation on Risk Assessment (as contribution to the work of the SSC WG on the same subject.