

# Minutes of the Scientific Steering Committee Meeting of 22-23 April 1999

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

Prof.Dr.Pascal welcomed the participants. He apologised (for 22 and 23 April) Prof.Dr.W.Bridges and (for 22 April) Prof.Dr.K.Jones, Prof.Dr.R.Kroes and Prof.Dr.V.Silano. The list of participants is attached as annex 1.

No member declared an interest in any of the point of the agenda which 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 18-19 March 1999.

The draft minutes of the meeting of 18-19 March 1999 were approved without changes.

## 4. Work plan for the SSC

### 4.1. Progress on multidisciplinary matters: Antimicrobial resistance

The chairman of the Working Group, presented the draft report including the draft recommendations. He explained that the document was a synthesis of the inputs of the various WG members and that it still is subject to editorial changes.

The SSC welcomed the draft report which was considered multidisciplinary and well balanced.

After exchange of views it was concluded that the report could in principle be agreed upon and that the Working Group had completed its task.

The report will be further discussed and completed by the SSC with additional specific sections (e.g., on animal welfare aspects; on the environmental implications of the development of antimicrobial resistance). The SSC agreed that aiming for an encyclopaedic document which covers all possible aspects in detail would be unrealistic and needlessly delay the adoption of the basic and essential aspects of opinion as identified in the mandate. The possibilities for a further follow-up by the appropriate Scientific Committees were discussed.

The SSC members were invited to send, by 3 May 1999 at the latest, their comments, including concrete written suggestions for amendments to the chairman and to the Working Group secretariat. On the basis of these contributions, the WG chairman and the two vice-chairmen will prepare an updated draft report and draft recommendations, for discussion and possible adoption at the SSC meeting of 27-28 May 1999.

### 4.2 Multidisciplinary matters relating to TSE/BSE

#### a. *General report of the work of the TSE/BSE ad-hoc group.*

Prof.Dr.M.Gibney, chairman of the TSE/BSE ad-hoc group, provided a summary report on the recent activities of the ad-hoc group. Details are given under the subsequent points of the minutes.

#### b. *Reports on specific issues*

b.1. "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.

At the meeting of 18-19 March 1999, the opinion was adopted as a "preliminary opinion", and made available to the public for comments *via* internet. The Working Group's report was also made public and open for comments.

Today, 21 comments had been received from individuals, research institutions, Central Veterinary Offices of Member States, rendering companies and professional associations. Prof.Dr.M.Vanbelle, chairman of the Working Group presented a summary of the comments received and the results of a preliminary analysis. The Working Group is now looking into these comments in detail. The TSE/BSE ad hoc Group is expected to prepare an updated draft scientific opinion, for submission to the SSC at its meeting of 27-28 May 1999.

In parallel, an exercise has started to verify the consistency between this opinion on "fallen stock", the pending opinion on "intra-species recycling" and the opinions on gelatine, meat-and-bone meal, tallow, dicalcium phosphate and hydrolysed proteins, which were adopted in the course of 1998 and which for certain issues refer to the opinions on fallen stock and recycling. Moreover, since the adoption of the first SSC opinion on products in March 1998, science has evolved and also for this reason the verification of the consistency is thus necessary.

#### b.2. Intra-species recycling of animal waste (progress report).

It is expected that a draft will be available for discussion by the SSC at its meeting of 24-25 June 1999.

#### b.3. Safety of tallow derived from bones as a by-product in the gelatine production.

A draft report is presently being prepared under contract by a special rapporteur, who will address the issue of the quantitative assessment of the safety of bones for the production of gelatine and tallow. His report will serve as the basis for the Working Group, which is expected to deliver a final draft report before the end of June.

#### b.4. Breeding of scrapie-resistant sheep

A Working Group has been created with the mandate and composition as discussed at the SSC meeting of 17-18 March 1999. The first meeting is scheduled for 11 May 1999 and it is expected that the TSE/BSE ad hoc Group will submit a draft opinion for discussion at the SSC meeting of 24-25 June 1999.

#### b.5. Human exposure risk.

The report of the Working Group "Human Exposure Risk" was distributed for discussion at the next meeting.

#### b.6. Assessment of the geographical BSE risk; modified manual for the assessment of geographical BSE risk (adoption); decision on re-assessments

The SSC continued its discussion that started at its March-meeting on the experience gained at the first risk assessment exercise, including the issue of risk classification. Recognising that the four risk classes used in the first risk assessment posed certain problems, in particular with regard to borderline cases, alternative approaches were discussed. For the time being a continuous scale was suggested, allowing differentiating between risk levels, even if it is clear that BSE is present. However, a final decision on the risk classification has to be made by the SSC before adopting the final opinion on the geographical BSE-risk is possible.

Following this discussion and its discussion at the previous meeting on the experience gained from the first risk assessment exercise, the SSC adopted a revised " [opinion on a method for the assessment of the geographical BSE-risk](#)" (- 400 KB).

This opinion does not differ from the previous one in substance but it provides a clearer presentation of the SSC's approach and clearer guidelines for the assessment process.

It will serve as a basis for the next risk assessment exercise early in May.

The SSC felt also a need to clarify its process and schedule as follows:

- The SSC started the evaluation of the epidemiological status of Member States and third countries in March by assessing the geographical BSE-risk, focussing on cattle, for a first group of 12 MS. The reports on these first risk assessments were communicated to the concerned MS with an invitation to comment. Substantial comments and appreciable additional information were received.
- Following the first risk assessment exercise the SSC recognised a need to clarify certain aspects of its approach. A revised opinion on a method for assessing the geographical BSE-risk was prepared and adopted on its meeting of 22/23 April. The manual for the assessment of the geographical BSE-risk, attached to this opinion, and its annexes 3 and 4 were overhauled in order to better communicate the approach developed by the SSC to the assessing experts. A new annex 3a was added, providing criteria for assessing the quality of an animal TSE-surveillance system. A new annex 4a contains the form to be used by the experts when preparing the assessment report.
- At the same meeting the SSC decided to assess the geographical BSE risk of all MS and Third Countries by applying the modified manual. Because the approach is not substantially changed it is not expected that the outcome of the assessment will change for the countries already dealt with in March, except if additional information was in the meantime provided.
- In the light of the valuable comments made by the relevant countries in response to the first report, the SSC intends again to ask for comments from all countries for which a risk assessment will be carried out on the basis of the revised manual.
- A group of five Third Countries and two Member States will be assessed for the first time in the first week of May. The MS that had already been assessed in March will be re-assessed in the second week of May, taking due account of the comments and additional information received at that moment. All assessed countries will receive the draft reports before the end of May with an invitation for sending comments before end August 1999. A final verification of the assessments will then be carried out in September, taking due account of the comments received.
- An additional risk assessment exercise for Third Countries and Member States that could not have been treated in May will be organised early in June in order to allow for sufficient time for commenting before September.
- In October the SSC will deliver an opinion on the geographical BSE-risk of all countries assessed, taking due account of the overall consistency of the assessments.
- In the meantime the SSC will continue to discuss a method for establishing the epidemiological BSE-status of a country or region. The outcome of the OIE-plenary in May 1999, and in particular the discussion on the BSE-chapter of the code, will be taken into account.

#### b.7. TSE surveillance

The report of the Working Group "Animal TSE-Surveillance" was distributed and discussed, particularly in view of including it into the manual for the assessment of the geographical BSE-risk. With some modifications it was agreed to and added to the manual as annex 3a.

#### b.8 BSE-status categories

A brief general discussion was held and Prof.M.Gibney proposed to draft a discussion paper and to distribute it to the Members. The issue has to be taken up at the next meeting.

#### b.9 Monitoring of the evolution of the BSE epidemic in the UK

A Working Group has been created with the mandate and composition as discussed at the SSC meeting of 17-18 March 1999. The first meeting is scheduled for 28 April 1999 and it is expected that the TSE/BSE ad hoc Group will submit a draft partial opinion for discussion at the SSC meeting of 27-28 May 1999. This first opinion is likely to cover only the evaluation of the present evolution of the BSE epidemic as compared to the (scientifically based) predictions made in

1996 and 1997. The other aspects of the mandate (e.g., the necessity to continue the Over Thirty Months Scheme), will be covered at a later stage.

b.10 Molecular weight of hydrolysed proteins derived from bovine hides, as a criterion for safety with respect to BSE (report, for opinion).

On request from the SSC, the TSE/BSE ad hoc group therefore addressed the question whether the condition of 10.000 Daltons, increased the safety of the product.

On the basis of the reasoning given in annex 3, the TSE/BSE *ad hoc* Group concluded at its meeting of 15 April 1999, that declaring hydrolysed proteins safe if the resulting peptides are less than 10.000 Daltons, could lead to a false sense of security. The ad hoc Group further concluded that the sourcing and (severe) processing conditions recommended in its opinion of 22-23 October 1998, together with the fact that bovine hides as such are not a specified risk material, are sufficient conditions for the final product to be safe. It further reiterated that any approval of other production processes should be done on a case by case basis and on the basis of the results of a report with research results with respect to the inactivation of TSE/BSE infectivity by the process.

The Scientific Steering Committee fully endorsed the above conclusions. It further decided that the Opinion of 22-23 October 1998 would need to be updated in view of these conclusions.

b.11 SEAC Subgroup report on Research and Surveillance for TSEs in sheep.

On 14 April 1999, the Report *Research and Surveillance for TSEs in Sheep*, prepared by a Subgroup of the UK Spongiform Encephalopathy Advisory Committee (SEAC) became available. It largely, but not exclusively, addresses issues similar to the ones addressed in the SSC Opinion of 24-25 September 1998 on *The risk of infection of sheep and goats with BSE agent*. The SEAC Report also puts a number of different accents and proposes urgent action in a number of fields.

The Commission therefore submitted the following questions to the SSC: "*The Scientific Steering Committee is invited to first provide the Commission with an opinion on whether or not the SEAC report is, in general, in line with the SSC opinion of 24-25 September 1998 on The Risk of infection of sheep and goats with the BSE agent. In addition the SSC is invited to provide an opinion on whether it is justified to take action as quickly as possible at Community level, and to what extent the SEAC recommendations are applicable to the entire Community.*"

Following discussion, the SSC adopted a statement confirming that, whilst recognising the different mandates that were at the basis of the SSC opinion and the SEAC Report, both documents are indeed in line with each other concerning the risk that BSE might have been introduced into sheep and goats and concerning the general recommendations that result from the recognition of this risk. In addition the SSC formulated a number of considerations. The full text of the statement is attached to these minutes as Annex 4.

b.12 BSE tests: Progress report

Mr. J..Moynagh, DG24, Unit B3, reported on the progress made in the Commission's programme for the evaluation of diagnostic tests for TSE in bovines. The sample preparation work, carried out by the IRMM in Geel Belgium, was now complete. The sets of samples for testing would be shipped to the four selected laboratories on 27 April with testing scheduled to commence on 3rd May. The testing phase is expected to last for 3-4 weeks. The initial results may therefore be apparent by the end of May or early June, with a more detailed analysis available a few weeks later, probably in time for the June meeting of the SSC. Prof. Osterhaus, who had been nominated to follow the project for the SSC would be kept informed of developments.

## **5. Organisational matters**

So far, the Scientific Committee on Plants has expressed opinions on 13 GMO dossiers and one dossier is still pending. Some of the applications are now being addressed by the Scientific Committee on Food, in the framework of the Novel

Food Directive.

Prof. Knudsen and Hardy briefed the SSC on a recent procedural update in the collaboration between the Scientific Committees on Food (SC-F) and on Plants (SC-P) in the field of GMOs. In order to further avoid as much as possible duplication of efforts, the work done by the SC-P on the genetic construct of GMOs would be provided to the SC-F. The rapporteur on this subject from the SC-P would also join the SC-F meetings. In addition the evaluation results on "Substantial equivalence" of GMOs (plants), will be provided to the SC-F, as these evaluations are partly include certain criteria (e.g., plant physiology) which are equally relevant for the assessment of food safety aspects.

It was noted that addressing certain food safety aspects never can be fully excluded from the evaluation of GMO dossiers by the SC-P when it addresses the typical "plant" aspects of a dossier. The chairmen agreed to maintain contact with a view to optimising the procedure and will communicate their conclusions in due course .

## **6. Co-ordination:**

### **6.1. Call for expression of interest: new members for Scientific Committees**

Since the eight scientific committees were established in November 1997, several members have resigned. Also practical experience has shown that certain committees are understaffed.

To replace a member who has resigned or to enlarge a committee, the Commission will choose from the list of the most suitable applicants, established in 1997, an applicant with the profile required. If the list does not contain an applicant with an appropriate profile it is necessary to launch a new appointment procedure, including a call for expression of interest.

To reach the greatest possible number of scientists, the call for expression of interest should be published in scientific journals specialised in the field of competence of the committee concerned. The members of the SSC were asked to indicate as soon as possible to the secretariat the names of appropriate scientific journals. The publication is foreseen for May.

The text of the call for expression of interest specifying the committees concerned and the expertise required has been distributed to the members.

### **6.2. Reports of the Chairmen of the 8 Scientific Committees.**

The chairmen of Scientific Committees reported on the activities of their committees since the last SSC meeting (18-19 March 1999). A summary of their reports is given in annex 5.

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

Mr.O.Rohte, Directorate General III (Industry), reported on DG III's present activities in the field of its Scientific Co-operation Programme (SCOOP). This Programme was now about to take up the following additional tasks:

- Task 3.2.6 Provision of validated methods to support the SCF recommendations regarding 3-monochloropropanediol (3-MCPD) in hydrolysed vegetable protein (HVP) and other foods.
- Task 3.2.7 Assessment of dietary intake of Ochratoxin A by the population of EU Member States ( Part II)
- Task 7.3 Collection of data on products intended for use in very low calorie diets
- Task 7.4 Study of the enzymes used in foodstuffs and collation of data on their safety.
- Task 9.1 Preparation of a working document in support of the uniform interpretation of legislative standards and the laboratory quality standards prescribed under Directive 93/99.

## **8. Any other business: internal SSC seminar on molecular biology, neuropathology and testing for prion-related diseases.**

The SSC secretariat announced that this seminar was now planned for the fourth trimester of 1999, probably October or December.

The meeting ended on Friday 23 April 1999, at 16h30.

The next meeting will be held in Brussels, on 27-28 May 1999.

### ***Annex 1 : List of participants of the Scientific Steering Committee meeting of 22-23 April 1999***

#### ***Members of the SSC :***

Prof. Georges Bories, Prof. James W. Bridges (not present), Prof. Fulgencio Garrido Abellán (not present) \*, Prof. Michael J. Gibney, Prof. Anthony R. Hardy, Prof. Philip T. James, Prof. Keith H. Jones (not present on 22 April 1999), Prof. Fritz H. Kemper (not present on 23 April 1999 afternoon), Prof. Werner Klein, Prof. Ib Knudsen, Prof. Robert Kroes (not present on 22 April 1999), Prof. Albert Osterhaus (not present on 23 April 1999), Prof. Gérard Pascal, Prof. Vittorio Silano (not present on 22 April 1999 morning), Prof. Marcel Vanbelle, Prof. Martin Wierup, \* Dr. Reinhard Ahl replaced Prof. F. Garrido Abellán on 22-23 April 1999

#### ***Participants from the Commission :***

**DG III** : M. Mieschendahl, O. Rohte; **DG V** H. Martin; **DG VI** D. André , T. Chalus, M. Florez Droop, I. Peutz; **DG XI** V. Matzeit; **DG XII** A. Fabre; **DG XXIV**: B. Carsin, T. Daskaleros, W. de Klerck, M. de Solà, C. Diez, F. Drion, J. Kreysa, G. Morosetti, G. Morrison, J. Moynagh, J.J. Rateau, A. Sanabria, J. Savio, K. Sbirrazzuoli, W. Schuller, A. Somogyi, J. Vergnettes, R. Vanhoorde, P. Vossen. Stagiaires: Amélie Raphaël

### ***Annex 2: VERIFY MODIFICATIONS !!!!!***

#### ***Agenda of the Scientific Steering Committee Meeting of 22-23 April 1999***

1. Welcome, apologies, introductory remarks, declarations of interest
2. Approval of the agenda
3. Approval of the minutes of the meeting of 18-19 March 1999.
4. Work plan for the SSC
  - 4.1. Progress on multidisciplinary matters:
    - a. Antimicrobial resistance (report and possible adoption of an opinion).
  - 4.2. Multidisciplinary matters relating to TSE/BSE
    - a. Report by the chairman of the TSE/BSE ad-hoc group, including:  
listing of newly established working groups and their respective progress reports
    - b. Reports on specific issues:  
*Production systems and products* .
      - b.1. "Fallen stock": presentation of the comments received on the preliminary opinion; adoption of a final opinion.

- b.2. Intra-species recycling of animal waste (progress report).
- b.3. Safety of tallow derived from bones as a by-product in the gelatine production (progress report and first discussion).
- b.4. Breeding of scrapie-resistant sheep (progress report)

*Human exposure risk .*

- b.5. Discussion of the draft report.

*Geographical risk .*

- b.6. Assessment of the geographical BSE risk; modified manual for the assessment of geographical BSE risk (adoption); decision on re-assessments
- b.7. TSE surveillance (progress report, possible adoption of an opinion)
- b.8 BSE-status categories (progress report, discussion)
- b.9 Monitoring of the evolution of the BSE epidemic in the UK (progress report)

*Other items :*

- b.10 Molecular weight of hydrolysed proteins derived from bovine hides, as a criterion for safety with respect to BSE (report, for opinion).
- b.11 SEAC Subgroup report on Research and Surveillance for TSEs in sheep.
- b.12 BSE tests: progress report

5. Organisational matters.

6. Co-ordination:

- Call for expression of interest: new members for Scientific Committees
- reports of the Chairmen of the 8 Scientific Committees.

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

8. Any other business.

- internal SSC seminar on molecular biology, neuropathology and testing for prion-related diseases.

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**Annex 3 : Short report to the SSC, adopted by the TSE/BSE *ad hoc* Group at its meeting of 15 April 1999 on the basis of a Working Group report drafted by Dr.D.M.Taylor.**

***Subject : Hydrolysed proteins: are they more safe if their molecular weight is less than 10kD?***

It has been argued that these products might be considered to be safe if the hydrolysed proteins have a MW of <10 kD. The basis for such a suggestion would be the knowledge that PrP<sup>sc</sup> has a MW of 27-30kD.

The TSE/BSE ad hoc Group is of the opinion that the use of such a criterion could lead to a false sense of security

because it is not known whether protein sub-components or peptides of low MW derived from PrP<sup>Sc</sup> can trigger the conversion of PrP<sup>C</sup> to PrP<sup>Sc</sup>. However, one needs to bear in mind that the 27-30 kDa PrP<sup>Sc</sup> is itself a sub-component. It is the resistant 'core' that remains after proteolytic digestion of the full-length PrP<sup>Sc</sup> protein that has a MW of 33-35kDa. Therefore, there is existing formal proof that a somewhat truncated form of PrP<sup>Sc</sup> can convert PrP<sup>C</sup> into PrP<sup>Sc</sup>. It is known that more severely truncated forms of PrP<sup>C</sup> can be converted to PrP<sup>Sc</sup>. For example, a PrP<sup>C</sup> peptide consisting of only 21 residues had properties akin to PrP<sup>Sc</sup>.<sup>6</sup> It was neurotoxic, and had a tendency to form amyloid fibrils analogous to the scrapie-associated fibrils (SAF) found in brain extracts from TSE-infected individuals. It must be assumed that this truncated form of PrP<sup>Sc</sup> might convert non-truncated PrP<sup>C</sup> to PrP<sup>Sc</sup>. Also, a form of PrP<sup>C</sup> containing only 106 residues (MW approximately 10 kDa) was converted to PrP<sup>Sc</sup> *in vitro*.<sup>7</sup> In addition, when this truncated PrP was expressed in transgenic mice that were deficient for wild-type PrP, these mice developed scrapie when challenged with the RML strain of mouse-passaged scrapie agent, demonstrating the convertibility of this 106 residue PrP<sup>C</sup> to PrP<sup>Sc</sup>.<sup>8</sup> More importantly, when brain-tissue from the scrapie-infected PrP106 mice was passaged into mice of the same genotype, they developed scrapie.<sup>8</sup> These data confirm that PrP<sup>C</sup> peptides with a MW of approximately 10 kDa can not only be converted to PrP<sup>Sc</sup>, but that they can also convert PrP<sup>C</sup> to PrP<sup>Sc</sup>. The above data tend to confirm the opinion that declaring hydrolysed proteins safe if the resulting peptides are <10 kDa could lead to a false sense of security.

The TSE/BSE *ad hoc* Group considers that only low levels of BSE infectivity could be present in the raw materials. The two typical manufacturing processes described in the SSC opinion of 22-23 October 1998 are likely to completely inactivate even considerably higher levels of BSE infectivity than could ever be present under worst-case conditions. This is because of the combinations of heat (especially steam under pressure) and alkali that are used. A variety of data are available that show the effectiveness of heat combined with alkali on BSE and scrapie agents.<sup>1-5</sup>

## References

1. **Ernst, D.R. and Race, R.E. 1993.** Comparative analysis of scrapie agent inactivation. *J. Virol. Methods*,41; 193-202.
2. **Prusiner, S.B., McKinley, M.P., Bolton, D.C., Bowman, K.A., Groth, D.F., Cochran, S.P., Hennessey, E.M., Braunfeld, M.B., Baringer, J.R. and Chatigny, M.A. 1984.** Prions: methods for assay, purification, and characterisation. In: K. Maramorosch and H. Koprowski (Editors), *Methods in Virology*, 8. Academic Press, New York, pp 293-345.
3. **Taguchi, F., Tamai, Y., Uchida, K., Kitajima, R., Kojima, H., Kawaguchi, T., Ohtani, Y. and Miura, S. 1991.** Proposal for a procedure for complete inactivation of the Creutzfeldt-Jakob disease agent. *Arch Virol*, 119; 297-301.
4. **Taylor, D.M, Fernie, K. and McConnell, I., 1997.** Inactivation of the 22A strain of scrapie agent by autoclaving in sodium hydroxide. *Vet Microbiol* 58. 87-91.
5. **Taylor, D.M., Fernie, K. & Steele, P.J., 1999.** Boiling in sodium hydroxide inactivates mouse-passaged BSE agent. Abstracts of a Meeting of the Association of Veterinary Teachers and Research Workers. p 22. Scarborough; 29 March-1 April 1999.
6. **Forlini, G., Angeretti, N., Chiesa, R., Monzani, E., Salmona, M., Bugiani, O. & Tagliavini, F., 1993.** Neurotoxicity of a prion protein fragment. *Nature* 362, 543-546.
7. **Muramoto, T., Scott, M., Cohen, F.E. & Prusiner, S.B., 1996** Recombinant scrapie-like protein of 106 amino acids is soluble. *Proc Nat Acad Sci* 93, 15457-16462.
8. **Supattapone,S., Bosque, P., Muramoto, T., Wille, H., Aagaard, C., Peretz, D., Nguyen,H.O., Heinrich, C., Torchia, C., Safar, J., Cohen, F.E., DeArmond, S.J. Prusiner, S.B. & Scott, M., 1999.** Prion protein of 106 residues creates an artificial transmission barrier for prion replication in transgenic mice. *Cell* 96, 869-878.

## **Annex 4 :**

### **Statement of the Scientific Steering Committee on the SEAC Subgroup report on *Research and surveillance for TSEs in sheep*, released in April 1999. Adopted at the SSC meeting of 22-23 April 1999**

Following the release in April 1999 of the SEAC Subgroup report on Research and surveillance for TSEs in sheep, the European Commission invited the Scientific Steering Committee « *to provide the Commission with an opinion on whether or not the SEAC report is, in general, in line with the SSC opinion of 24-25 September 1998 on the Risk of infection of sheep and goats with the BSE agent . In addition, the Commission invited the SSC to provide an opinion on whether it is justified to take action as quickly as possible at Community level, and to what extent the SEAC recommendations are applicable to the entire Community*».

Recognising the different mandates that were at the basis of the SSC opinion and the SEAC Report, the SSC considers that:

- 1) Both documents are indeed in line with each other concerning the risk that BSE might have been introduced into sheep and goats and concerning the general recommendations that result from the recognition of this risk.
- 2) Whilst the SEAC report emphasises the situation in the UK, a focus should also be developed on other European countries with a population of sheep and/or goats, for example with respect to tracing the history of feeding practices with ruminant MBM.
- 3) Discrimination between BSE and scrapie in sheep and goats is a key-question. Surveillance and other efforts (e.g., the development of methods) to identify the presence of BSE in sheep and goats should therefore be initiated as soon as possible.
- 4) Along the same lines, an exercise should be conducted to assess of the possible geographical risk that BSE has been introduced into sheep. The method to assess the geographical BSE risk in cattle which has been developed by the SSC, could be adapted for that purpose.
- 5) The TSE/BSE ad hoc Group is invited to urgently evaluate the SSC and SEAC documents with respect to actions that need to be taken. It should report back to the SSC for an opinion at its meeting of 27-28 May 1999.

The SSC further invites the various Commission services to evaluate their ongoing research programmes in the light of the research priorities proposed in both documents, and to take appropriate action.

### **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 for Food***

At the SCF Plenary of 24 March 1999 the following opinions were adopted:

- An opinion on substances requested for nutritional purposes, which may be used in the manufacture of foods for particular nutritional purposes ('PARNUTS'). The SCF was asked for advice on the establishment of a list of substances with specific nutritional purposes (vitamins, minerals, trace elements, amino acids and other substances) intended to be added to foodstuffs for particular nutritional uses (dietetic foods), and, where appropriate, the conditions under which they should be used.
- Opinion on the safety of propane, butane and iso-butane as propellant gases for vegetable oil-based aerosol cooking sprays and water-based emulsion cooking sprays.
- Opinion on ethylhydroxyethyl cellulose as food additive, which is released as addendum to the "Opinion on re-evaluation of five modified celluloses" of 13 March 1992.
- Opinion on Bisphenol A diglycidyl ether (BADGE) used in food packaging. The Committee previously evaluated the substance in November 1986 and in June 1996 as a monomer used in the production of plastic food contact materials. The Committee had been asked to re-evaluate this substance in view of new information.

- Opinion on an additional list of monomers and additives for food contact materials. The Committee evaluated a number of monomers and additives for food contact materials.

A workshop, jointly organised by DGXXIV and DGIII on approaches for the toxicological evaluation of chemically defined flavouring substances took place on 25 March. Participants were the members of the SCF and a number of experts from university, Industry, US FDA and Council of Europe. In view of the involvement of the SCF in establishing an evaluation program for chemically defined flavouring substances, the purpose of the workshop was to establish the state of play in this field on the international level and to give the opportunity to discuss the different approaches applied under the different systems.

The workshop will be followed shortly by meetings of an SCF task force mandated to elaborate a proposal on this matter.

### ***Scientific Committee on Plants***

The Scientific Committee Plants has not met in plenary session since the last meeting of the SSC. However, discussions and the preparation of draft opinions have continued in Working Groups on mycotoxins in baby food and the contained use of genetically modified micro-organisms. The next plenary meeting will be 17-18 May 1999.

### ***Scientific Committee on Animal Nutrition***

The working groups continue their work on the various questions addressed to SCAN. Some draft reports are finalised or close to completion and should be proposed to the next plenary for possible adoption."

### ***Scientific Committee Veterinary Measures relating to Public Health***

No plenary session took place since the last SSC. Working Groups on the following topics were convened: Hormones, *Listeria monocytogenes* in ready-to-eat food, "Simplification exercise".

### ***Scientific Committee on Animal Health and Animal Welfare***

Meetings were held on two subjects in the period. These involved modifications to Directive 64/432/EEC which is at an advanced stage and a report on ventilation standards for vehicles transporting animals for long distances. It was noted that the question on the ventilation standards had been expanded to include periods while the vehicle was stationary. Substantial progress was made in both issues. It is anticipated that these reports will be discussed at the meetings of the respective subcommittees in May.

### ***Scientific Committee for Medicinal Products and Medical devices***

The Scientific Committee for Medicinal Products and Medical devices adopted two opinions by written procedure on 24 March 1999:

- The policy regarding the use of blood and blood products.
- The safety of hides and skins.

Two others were adopted in the Plenary Meeting of 14 April 1999:

- Guidelines on the concept of "clinical superiority" regarding legislation on orphan medicinal products.
- Toxicological data on colouring agents for medicinal products: Aluminium.

### ***Scientific Committee Cosmetic and non-Food Products***

Prof. Kemper, the chairman, reported on the topics dealt with since the last SSC meeting. Only two Working Parties meetings took place, during which the following items were discussed :

*1. Inventory* : A discussion Paper on Guidelines for botanical ingredients and derivatives, which addresses the 12 essential specifications to be taken into account in order to better identify botanical ingredients, the nomenclature conventions, examples of labelling and the toxicological warnings, was presented to the meeting. Nevertheless, there was discussion on the need for such detailed information in an inventory.

The necessity for a precise identification of those plants which are considered as dangerous and which use in cosmetic products should be formally forbidden or at least limited has been discussed. The issue will be the subject of a report.

The nomenclature conventions to be used in the inventory have been reviewed.

*2. Preservatives, Colorants & Fragrances* : this meeting was mainly devoted to the fragrance allergy issue and in this context, industry was invited and afforded the opportunity to contribute to the scientific review process concerning fragrance ingredient allergy. In the first place, the perceived size of the problem as well as its definition were discussed. There was also agreement on the importance of primary prevention, as the crucial parameter in addressing fragrance ingredients allergy, and on secondary prevention : to provide the necessary information to the consumer.

Furthermore, the WP approved the fragrance labelling document, which answers one of the four questions asked by DG III concerning the safety of fragrance materials.

Draft opinions were prepared and preliminary discussed on Musk Ketone and Xylene, on Ketoconazole and on the use of hydrogen peroxide in tooth paste and certain mouth washes.

### *Scientific Committee for Toxicity, Ecotoxicity and the Environment*

**A.** Since the mentioned SSC meeting only a working group meeting on '**Tropospheric ozone**' took place (16 April 1999). In the meantime a draft opinion is being worked at. Given progress made it seems likely that an opinion will be adopted at the next CSTEE plenary ( 7 May 1999, copy of draft agenda is attached).

**B.** A first meeting of the working group '**Terrestrial environment**' took place on the 27<sup>th</sup> of April 1999. This is an initiative of the CSTEE. They will be developing an opinion on '**Available scientific approaches to assess the potential effects and risks of chemicals on terrestrial ecosystems**'. This will be a comprehensive document the table of contents of which was extensively discussed and assignments given to the different WG members (It will be necessary for different members to take on the task of being *rapporteurs* of individual chapters).

**C.** An opinion request was just received (27 April) from DG XXI. The terms of reference indicate that the consultation concerns '**Selection of a Community wide mineral oil marking system - Safety of the preferred product**'. Essentially the opinion of the CSTEE is being requested on the health risks of a marker product in oils used for different purposes (fuel for road vehicles as opposed to heating gas oil).

**D.** The next CSTEE plenary is confirmed for the 7<sup>th</sup> of May 1999.