

Minutes of the Scientific Steering Committee Meeting of 9-10 December 1999

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

Prof.Dr.Pascal welcomed the participants. He apologised (for 10 December). Prof.M.Wierup, Prof.W.Bridges and Prof.A.Osterhaus. The list of participants is attached as annex 1.

The chairman thanked all the members for the full collaboration they provided during the week-end of 30 October - 2 November 1999 for the final editing of the report attached to the Opinion related to the UK Date-based export scheme, adopted on 28-29 October 1999.

No member declared an interest.

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 28-29 October 1999

The minutes of the last meeting had already been approved by written procedure.

4. Progress on multidisciplinary matters:

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

The President of this Working group, Prof. Pascal, underlined that although the recent BSE crisis had delayed the work, a report, compiling the different papers had been produced by Prof. Klein. Final comments from the WG members are expected by 7 January to finalise the report before submission to the next SSC. Given the fact that the content of this SSC report is likely to be useful also in the light of the report on food safety which is being prepared by the OECD, the SSC agreed to address this item with priority at its next meeting.

b. Harmonisation of risk assessment procedures

Prof.Bridges reported in detail on the progress made by the working group. The compilation and listing of lead publications in the various facets of risk assessment was in good progress, however, the working group decided to delay the work on the establishment of a list with agreed definitions until the lead publications had been evaluated, because these may contain appropriate definitions.

An account was then presented of the progress made by the various sub-groups on "Quantitative Risk Assessment" and on "Interface between risk assessors and risk managers". With respect to the first sub-group, the SSC agreed that the work should start on the basis of a report to be written by an outstanding expert in this field.

Prof.Bridges further informed the SSC members that the aspect "Exposure assessment", an essential element in risk assessment, would be addressed at a later stage because the present resource and time constraints did not permit to handle this at the same time as the other items. The SSC considered, however, this aspect needed to be addressed more urgently and invited Prof.Bridges to create an additional sub-group. Prof.Bridges agreed to create the sub-group, to propose a membership and chairperson. This will be further discussed at the next SSC meeting.

c. Possibly emerging fields of concern with respect to health and consumer protection

An incomplete list/inventory of possibly emerging fields of concern with respect to health and consumer protection, mainly compiled from contributions by Prof. Kroes, was briefly discussed. It was agreed that all members would send their contributions to the SSC secretariat before the next meeting (20-21 January 2000), when a more complete list would be discussed.

d. Report on the activities of Profs Pascal, Kemper and James on scientific advice

Prof. W. P. James, Prof. F. Kemper and Prof. G. Pascal, presented their report on the future of scientific advice that they had delivered on December 9 to Commissioner Byrne. They clarified that the report had been prepared in their personal capacity, on request by the Director General of DGXXIV (presently: DG-SANCO). The report was therefore not to be considered as an SSC report.

In their report the 3 experts recommend that an independent European Food and Public Health Authority (EPHA) should be established. It should be a Brussels-based inter-institutional office, adequately resourced and financed mainly by public funds. However, as in the EMEA model, fees could be part of the financing. This authority would include three Steering Committees (one for Food, one for Public health and one for Environment) supported by different sectoral scientific committees. These committees should generate the scientific advice needed on these issues. The experts underlined that new modes of operation should be developed, taking due account of:

- the implications of the expansion of the EU;
- the need of coherent interaction with risk managers and stakeholders;
- the importance of operating criteria based on independence and transparency;
- the need to complement the current system with a European surveillance system for public health related matters and systematic networking with the national scientific bodies and research institutions;
- the need for a role of the new authority in risk communication and crisis management.

During the discussion, several SSC members expressed their disappointment for not having been consulted. Some felt that a professional system (like FDA with permanent in-house top scientists) should be created in order to be able to face new challenges like the rise of infectious diseases in particular in Eastern countries that might become members of the EU in the near future. Some members pointed out that it should be more clearly expressed that food, environment and public health were issues closely linked and of equal importance for protecting consumers health.

Prof. Pascal finally said that he regretted not having had the opportunity, for practical and time-constraint reasons, to organise a larger consultation of the SSC and an exchange of views between its members. However, the Commission's forthcoming White paper on Food Safety, including a chapter dealing with the future of scientific advice, will be open for discussion. This will give the SSC the opportunity to provide its own opportunity to contribute to the debate.

5. Multidisciplinary matters relating to TSE/BSE

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

The details of Prof. Gibney's report are covered in the sections 5.2 hereafter. In addition he invited the SSC to address the general issue of the relationship and handling of the reports produced in the context of an opinion. There are normally three layers: a report of a specialised working group, a draft opinion prepared by the TSE/BSE ad-hoc group which might take additional information into account, and the final opinion of the SSC which might again take additional information and aspects into account. The relative position of these different documents needs, in his view, clarification. There was general agreement but no further discussion.

5.2. Reports on specific issues

a. Update of the SSC opinion of 29 October 1999.

Following the publication of its opinion of 29 October 1999, the attention of the SSC was drawn to the risk assessment presented in section 3.3 "Epidemiology". The SSC agreed that this section did not make it sufficiently clear that the presented estimates for maternal transmission related to the worst case of a pre-culling analysis of potential infectivity. It presented a worst case scenario of possibly 1.3 infected animals (per 75.000) being eligible for export in 1998/99 (and less than 1 animal in subsequent years, even if exports increase substantially) if the dam survival rule was not applied.

Prof. Kemper made a personal declaration and indicated that he refused to participate in changing an agreed opinion if the scientific basis of the opinion has been valid in all points. He would only agree to amend the opinion, if all scientific reasons, events and facts that required this change or amendment, were included.

The SSC members agreed that in fact there was no change in substance needed but a clarification and re-affirmation of the opinion. It was decided to make the following text public immediately:

Following the publication of its opinion of 29 October 1999, the attention of the SSC was drawn to the risk assessment presented in section 3.3 "Epidemiology". The SSC agreed that this section did not make it sufficiently clear that the presented estimates for maternal transmission related to the worst case of a pre-culling analysis of potential infectivity. The introduction of the dam survival rule means in reality that the UK-DBES eligible animals from which meat and meat products are obtained, would not include the animals born to dams showing clinical signs of BSE within six months of delivery. Under the UK-DBES, only authenticated data on a limited number of information bases are considered to be secure enough in terms of being verified and proving that the mother survived for six months after the birth of her calf. Any failure to confirm this survival results in rejection of the calf from the scheme. The original analysis presented a worst case scenario of possibly 1.3 infected animals (per 75.000) being eligible for export in 1998/99 (and less than 1 animal in subsequent years, even if exports increase substantially) if the dam survival rule was not applied. Therefore, the risk in terms of potentially maternally infected animals being exported under the DBES is lower than it may appear from a first reading of the opinion of 29.10.99. This re-affirms the SSC opinion.

b. Formalisation of the approach to be followed and criteria to be used when assessing whether the evolution of a BSE epidemic in a country is (or not) as expected.

In the margin of the French - UK discussions on the safety of the UK deboned meat that complies with the DBES criteria, the question was raised whether it would be possible to formalise the SSC's approach followed and the criteria used for assessing if the evolution of the BSE epidemic in the UK is (or is not) as expected, so that it could be applied to other countries with BSE and/or by other instances (for example the Standing Veterinary Committee).

The SSC shared the view of the TSE/BSE *ad hoc* Group that any evaluation of a BSE epidemic will depend upon country-specific conditions and criteria. Moreover, country-specific models of the BSE epidemic exist only for the United Kingdom and, to some extent, for Switzerland and Ireland. Any assessment would therefore need to be done on a case-by-case basis and general formalisation seems to be inadequate.

c. Safety of ruminant blood

A draft opinion is expected to be ready for discussion by the SSC at its meeting of March or April 2000.

d. Quantitative assessment of safety of products

A contractor is preparing a software package for the quantitative assessment of residual infectivity in bovine-derived processed products. It will be used to assess the safety of the vertebral column for the production of gelatine and tallow (as a by-product of the degreasing process). A draft opinion is expected to be ready for discussion by the SSC at its meeting of January or March 2000.

e. Handling and storage of possibly BSE contaminated MBM

Still waiting for information from France, the rapporteur will continue preparing the report, only on the basis of UK data on the quantities of stored meat-and-bone meal awaiting final disposal and their conditions of storage.

f. Update of the opinion on the Safety of gelatine

Prof. Vanbelle reported that the results of a new INVERESK study on the inactivation of TSE agents during the production process of gelatine had been made available by the industry. These results were presently being evaluated. If the TSE/BSE ad hoc Group can discuss the matter at its meeting of 13 January 2000 a draft update of the SSC opinion on the safety of gelatine would then be submitted for discussion and possible adoption to the SSC for its meeting of 20-21 January 2000.

g. Human exposure risk.

The draft opinion prepared by the TSE/BSE *ad hoc* Group on the basis of a working group report were presented and discussed in detail.

After some amendments a final opinion was adopted. It is attached as annex 3.

h. Human Exposure Limit Line

A draft opinion is expected to be ready for discussion by the SSC at its meeting of January or March 2000.

i. TSE and culling strategies

A Working Group has been established. It is expected to submit a draft report on culling to the TSE/BSE ad hoc Group at its meeting of 13 January 2000. A draft opinion may thus be ready for discussion by the SSC at its meeting of 20-21 January 2000, although March 2000 seems to be a more realistic target.

j. Origin of BSE

An external expert is presently preparing a report on the state of knowledge on the origin of BSE and a critical review of the existing hypotheses.

The SSC was reminded on the communication "The BSE epidemic: A symptom of chemical poisoning" by Parish and Parish (1999), a copy of which had been provided on 28/10/99 to all members. The SSC members were invited to have a critical reading of the document and, if necessary, to suggest appropriate future action or amendments to existing opinions (e.g. the one on organo-phosphates).

The SSC was also made aware of the hypothesis of Prof. Ebringer who suggests an auto-immune theory for BSE. The issue is being closely monitored by the UK-Spongiform Encephalopathy Advisory Committee (SEAC). With significant help from the SEAC secretariat, the SSC secretariat compiled a dossier on the issue, which is presently being evaluated by the TSE/BSE ad hoc Group. If required, the item will be put on the agenda of a next a SSC meeting.

k. Geographical risk (GBR)

Update on the legislative proposals submitted by the Commission

- Mrs. I. Peutz (DG-SANCO) provided a short history of the various legislative proposals made by the Commission since 1996 regarding Specified Risk Materials (SRMs) and geographical BSE status. Commission Decision 97/534 foresees in the exclusion of SRMs from the food and feed chain. The entering into force of the said Decision was postponed first until 01.01.99 and later on to 31.12.99. This Decision requires the removal of an identical list of SRMs everywhere and does not take account of the geographic variation in risk. It is therefore not in line with various SSC opinions on BSE risk and specified risk material.

On 7/01/1999 the Commission transmitted to the European Parliament and Council a proposal for a "Regulation of the European Parliament and of the Council laying down rules for the prevention and control of certain transmissible spongiform encephalopathies". The proposal amongst others, refers to the relevant SSC opinions, including the aspects of incident, propagation and human exposure of the BSE risk. It shall form the basic European legislation on this issue.

Pending the adoption and entry into force of this regulation, the Commission, on 23/11/99 has adopted a proposal for a Decision revising the original SRM-Decision (Commission Decision 97/534). This decision would enter into force early in 2000 and would be repealed by the Regulation by the European Parliament and the Council, once this is adopted. In this decision the Commission proposes a provisional classification of countries into BSE-status levels and, as proposed by the SSC in its original SRM-opinion and in various opinions on the safety of products, modulated lists of SRM in line with these status levels. In this proposal, the Commission follows the available OIE international standard and the outcome of the Commission's recent programme evaluating 4 rapid *post mortem* BSE diagnostic tests. The proposal foresees the possibility to change the category of a Member State or third country, " *taking into account the results of post-mortem BSE-tests and information referred to in paragraph 2 [requesting notification by the country of any information that might require changing the status], or the recommendations of the appropriate scientific committees, or the OIE.*"

- During the discussion following on the presentation by the Commission, the members of the Scientific Steering Committee confirmed its opinion, already formulated explicitly at its meeting of December 1998 and implicitly present in its various opinions related to geographical risk and the geographical risk assessment method, that the BSE-status classification approach outlined in the OIE Code, is not fully appropriate.

In view of the considerable amount of work invested by it into the geographical BSE-risk assessment, the SSC would have appreciated to be informed earlier of the Commission's intention to provisionally follow the OIE approach on geographical BSE status classification, pending the final SSC opinion on BSE status classification of individual countries and the results of an improved surveillance. The SSC expressed its concern about the lack of communication in this specific case.

- The SSC welcomed the explicit statement of the Commission that the result of the GBR-assessment exercise is still requested. The SSC confirmed its intention to finalise the geographical risk assessment as soon as possible. A preliminary timetable was agreed, foreseeing a further general discussion for the next SSC-meeting and a first detailed discussion on the reports on the assessment of the GBR and their exploitation in March. The available reports should be provided to the TSE/BSE ad-hoc group and the SSC as soon as possible. A proposal for an up-date of the opinion on the method for the assessment of the GBR (April 1999) should be provided for the next SSC-meeting when the SSC will decide if it is required. .

Exploitation of the results of the Commission's recent programme for the evaluation of rapid post mortem BSE diagnosis tests.

- Mrs.K.Hakulin (DG-SANCO) informed the SSC of the Commission's intention to introduce post-mortem tests in BSE-surveillance in all Member States. For the time being, the tests envisaged are the rapid post mortem tests successfully evaluated by the Commission in the first half of 1999. But other tests could be used when available and evaluated upon their performance. The intention was to propose targeting the testing at fallen stock and emergency slaughtered animals following the Swiss example, as mentioned in the opinion of the SSC of 28-29 October 1999. As, apart from Switzerland, there were no examples available of similar exercises in other parts of the world on which the final sample design and size could be tailored, it was recognised that the proposed sampling scheme may need to be updated after some years in the light of the gained experience and on the basis of further scientific advice.

- The SSC welcomed the initiative, but also recommended the Commission to take into account its statement on the rapid diagnostic tests (included in the minutes of the SSC meeting of 24-25 June 1999) and certain limitations in applicability listed in the Opinion of 28-29 October 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.*

- The SSC finally reiterated its recommendation for the urgent development and evaluation of BSE-tests for pre-clinical BSE and for differential scrapie/BSE tests.

l. Recent JRC report (November 1999) on the processing of meat-and-bone meal.

A copy of the recent (November 1999) publication of the Joint Research Centre on the *Prevention of epidemic diseases and BSE by appropriate sterilisation of animal waste* was distributed to all SSC members. It had already been distributed to the members of the TSE/BSE *ad hoc* Group on 25.11.99. Like other final scientific publications related to TSE, this report could be important in relation to scientific opinions already adopted or in the pipeline of being adopted by the SSC.

It was therefore agreed that some experts of the SSC's Working Group "Products" be invited to comment on the report. They would, in a first instance, assess its relevance in relation to the SSC's reports and opinions related to meat-and-bone meal and cross-contamination. These experts would report to the TSE/BSE *ad hoc* Group, who will then in turn assess whether further work or discussions by the SSC is desirable.

6. Organisational matters

No organisational matters were discussed

7. Co-ordination

a. 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 (28-29 October 1999). (See annex 4)

b. Structure of opinions and technical reports.

This point was referred to another meeting for further discussion.

8. Information by the Commission services on matters related to consumer health: Implementation of Scientific Advice in EU legislation on animal waste, gelatine, tallow and meat-and-bone meal

Mrs.P.Colombo (DG-SANCO.E.3.) made a summary presentation of the legislative Proposal for a *Regulation of the European Parliament and of the Council laying down the health conditions concerning animal by-products not intended for human consumption*. In this proposal, which is presently going through the whole chain of legislative decision making, an legislative exploitation is made of the SSC opinions on "Fallen stock" (June 1999) and "Intra-species recycling" (September 1999)

Mrs. Colombo also presented briefly an inventory of the legislative decisions that had already been adopted so far, and in which the various SSC opinions related to the safety of products had been taken into account. These concern the opinions on the safety of meat-and-bone meal, tallow, gelatine, hydrolysed proteins and dicalcium phosphate.

The SSC highly appreciated the exploitation of the opinions.

9. Any other business

Dr.Oscar Rohte, representing the Directorate General for Enterprises (the former DGIII) at most of the meetings of the Scientific Steering Committee and the former Multidisciplinary Scientific Committee (MDSC) announced his retirement as from the first of February 2000. On behalf of all participants, Prof.G.Pascal, chairman of the SSC, thanked Dr.Rohte for his constructive presence in all these meetings and, especially, for having established and

maintained the link between the Scientific Advisory System of the European Commission and the International Collaborative Research. A warm applause followed and the SSC members wished Dr.Rohte the best for his new future.

The meeting ended on Friday 10 December 1999, at 17h00.

The next meeting will be held in Brussels, on 20 and 21 January 2000 .

Annex 1: List of participants of the Scientific Steering Committee meeting of 9-10 December 1999

Members of the SSC:

Prof. Georges Bories, Prof. James W. Bridges (not present on 10 December 1999), Prof. Fulgencio Garrido Abellán, Prof. Michael Gibney, Prof. Anthony R. Hardy, Prof. Philip T. James, Prof. Keith H.Jones (not present on 10 December 1999 afternoon), Prof. Fritz H.Kemper, Prof. Werner Klein, Prof. Ib Knudsen, Prof.Robert Kroes, Prof .Albert Osterhaus (not present on 10 December 1999), Prof. Gérard Pascal, Prof. Vittorio Silano, Prof. Marcel Vanbelle, Prof. Martin Wierup (not present on 10 December 1999)

Participants from the Commission:

DG ENTR: O. Röhte

JRC : G. Caratti

DG SANCO: B. Carsin, J.J. Rateau, C. Berlingieri, P. Colombo, T. Chalus, M. de Solà, C. Diez, G. Fracchia, K.Hakulin, J.L. Jouve, J.Kreysa, G.Morrison, W. Penning, I. Peutz, A. Somogyi, J. Vergnettes, P. Vossen

Stagiaires: L. Döbeli

Annex 2: Agenda of the Scientific Steering Committee Meeting of 9-10 December 1999

1. Welcome, apologies, introductory remarks, declarations of interest
2. Approval of the agenda
3. Approval of the minutes of the meeting of 28-29 October 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).
 - d. Report on the activities of Profs Pascal, Kemper and James on scientific advice
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:
 - a. Update of the SSC opinion of 29 October 1999;
 - b. Formalisation of the approach to be followed and criteria to be used when assessing whether the evolution of a BSE epidemic in a country is (or not) as expected.

Production systems and products.

- c. Safety of ruminant blood (progress report)
- d. Quantitative assessment of safety of products (progress report).
- e. Handling and storage of possibly BSE contaminated MBM (progress report)
- f. Update of the opinion on the Safety of gelatine (February 1999) (information)

Human exposure risk.

- g. Discussion of the report and possible adoption of an opinion.
- h. Progress report on the WG "Human Exposure Limit Line" (HELL)

Geographical risk.

- i. TSE and culling (progress report)

Other issues:

- j. Origin of BSE (progress report).
- k. Geographical risk : update and possible new items
- l. Recent RJC report (November 1999) on the processing of meat-and-bone meal.

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.

- Implementation of Scientific Advice in EU legislation on animal waste, gelatine, tallow and meat-and-bone meal.

9. Any other business.

Annex 3

Opinion of the Scientific Steering Committee on the Human Exposure Risk via food with respect to BSE. Adopted by the Scientific Steering Committee at its meeting of 9-10 December 1999 and edited following a written procedure (13-20 December 1999) (Distributed separately, and available on Internet)

Annex 4: Reports from the secretariats of Scientific Committees on the major activities and milestones since the SSC meeting of 28-29 October 1999.

Scientific Committee for Food

The SCF has held in this period its 119th meeting, on 1/2 December. At this plenary, the Committee adopted the following opinions:

- Opinion on the mycotoxin deoxynivalenol (DON) one of the toxins produced by *Fusarium* moulds, that may be present in certain foods as a contaminant. This is the first of a number of *Fusarium* toxins that the Committee is evaluating.
- Opinion on a programme for the evaluation of flavouring substances. The opinion will be the basis for the Commission's programme for evaluation of the 2800 flavouring substances listed in the EU Register in Commission Decision 1999/217/EC.
- Opinion on imazalil as a food additive for incorporation in certain cheese coatings.
- Opinion on mannitol manufactured by fermentation (food additive).
- Opinion on a maltitol syrup not covered by the current specifications (food additive).
- Opinion on synthetic lycopene as a colouring matter for use in foodstuffs.
- Opinion on an additional list of monomers and additives for food contact materials. This list contains the following 10 substances:
 - Laurolactam
 - 6-amino-1,3-dimethyl-uracil
 - Antimony trioxide
 - Di-tert-dodecyl disulfide
 - Glutaraldehyde
 - Phthalic acid, diester with primary saturated C₇-C₁₁ branched alcohols, more than 60% C₉
 - Phthalic acid, diester with primary saturated C₉-C₁₁ branched alcohols, more than 90% C₁₀
 - Poly-[[6-[n-2,2,6,6-tetramethyl-4-piperidiny]-n-butylamino]-1,3,5-triazine-2,4-diyl] [(2,2,6,6-tetramethyl-4-piperidiny)imino]-1,6-hexanediyl[(2,2,6,6-tetramethyl-4-piperidiny)imino]]-alpha-[n,n,n',n',-tetrabutyl-n''-(2,2,6,6-tetramethyl-4-piperidiny)-n''-[6-(2,2,6,6-tetramethyl-4-piperidinylamino)-hexyl]-[1,3,5-triazine-2,4,6-triamine]-omega-n,n,n',n'-tetrabutyl-1,3,5-triazine-2,4-diamine
 - Trimethylolpropane trimethacrylate-methyl methacrylate copolymer
 - 2,4,6-tri-tert-butyl-phenyl-2-butyl-2-ethyl-1,3-propanediol phosphite

At this 119th plenary session, the SCF also adopted the following statements:

- on the status of evaluation of the 4 Hexyl resorcinol as food additive
- on the use of novolac glycidyl ethers as additives in food contact materials
- on a recent survey on bisphenol A diglycidyl ether (BADGE) and bisphenol F diglycidyl ether (BFDGE) in canned food

In this period, also a significant number of meetings of Working Groups of the SCF have taken place:

- the initial meeting of the Task Force on Dioxins. The Committee is asked to advise the Commission on the scientific basis for the establishment of limits and on any other alternative measures relating to PCBs and dioxins in food.

- meetings of the Working Groups on Food Contact Materials, Novel Foods, Nutrition, Food Additives, and meetings of the Task Forces on Upper Levels for Vitamins and Minerals and on Flavourings.

Scientific Committee on Animal Nutrition (SCAN)

The SCAN as well as several working groups met during the period of 28 Oct. to 10 Dec. The Committee itself adopted two updated reports at its plenary meeting of December.

Scientific Committee Veterinary Measures relating to Public Health

The SCVPH plenary of October was cancelled. The work of the different working groups is continuing. Two draft reports are expected for the December plenary meeting.

Scientific Committee on Animal Health and Animal Welfare

At its meeting on 8 December the Committee adopted three reports:

1. Report on Bacterial Kidney Disease

This disease is a serious problem in salmonids. The report considered the epidemiology and aetiology of this disease discussed the possibilities of eradicating the disease, methods of monitoring for it and also methods for reducing the risk of transmitting the disease to free areas. The Committee was of the view that further work would be appropriate to better develop eradication tools (vaccines etc.) before attempts are made to eradicate from areas where it is endemic.

2. Standards for the Microclimate inside Animals Transport Vehicles.

This is an important report concerning the welfare of animals on long distance road transport in the EU. The report sets out the temperature and humidity requirements that should be maintained on board. To further reduce the risk, the Committee also recommends that each lorry be equipped with sensors to warn the driver of any problems and to allow recording of the conditions in the lorry. This recording will also have the advantage of making enforcement of the requirements much easier.

3. The Infective Period for Bluetongue

This report was a follow up to an earlier report and involved the consideration of whether a quarantine period approximating to the estimated infective period for this disease was an effective risk reduction measure for an importing country.

The Committee concluded that the risk to an importing country was not sufficiently reduced by this procedure (in the absence of any diagnostic testing).

Scientific Committee for Toxicity, Ecotoxicity and the Environment

A. The 12th CSTEE plenary meeting took place on the 25th of November 1999. In terms of progress made on the opinion requests to the CSTEE and CSTEE 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 17th of November 99. Progress was made and there are now *rapporteurs* appointed to deal with all the chapters of the report. This activity will require several more months.

C. On the subject of a CSTEE position on two letters received from i) the UK LGC and ii) on behalf of the Dutch TNO contesting the CSTEE's conclusions on the reports respectively elaborated by those groups on the validation of the so-called '*Dutch consensus Group study*', given the sensitivity of the issue the decision was taken to organise, on the 24th of November 99, a working group meeting with representatives of the two laboratories concerned. The

conclusions of the working group were then passed on to the CSTEE at the plenary meeting the following day and a letter will be sent to TNO and to LGC answering formally their queries. The essential message contained therein is that, while the CSTEE still cannot consider at this stage that either of the exercises validates the Dutch Consensus group study method for enforcement purposes, given time and with the necessary improvements they can be expected to reach the status of having validation.

D. 'The use of measured exposure data in risk assessment' - An update of the draft text prepared by the *rapporteur* was made available to the committee. The decision was taken to enlarge the scope of this exercise to include representatives of the European Chemicals Bureau who have an interest on the subject and also to involve the European Environment Agency for a similar reason. Both the CSTEE and the working group chairpersons participated recently in a meeting in Copenhagen where the specific modalities of such a co-operation were explored.

E. Regarding the opinion request on a *report from a study on Technical specifications for classification and presentation of ecological status of surface waters and a report from a study on technical specifications for monitoring of ecological status of surface waters*, the information was received from the responsible Commission service (ENV/D/1) that the two outstanding studies on classification and monitoring of ecological status for the Water Framework Directive are still in draft form. This has prevented the CSTEE working group from making progress. DG ENV has also indicated that the studies should be available for submission in time for the January 2000 CSTEE plenary meeting. From the good news side, the Council adopted on the 22nd of October 1999 a common position on the proposed Water Framework Directive.

F. On the subject of the text of a **draft Commission Decision Adopting measures prohibiting the placing on the market of toys and childcare articles intended to be placed in the mouth by children under three years of age made of soft PVC containing one or more of the substances Di-iso-nonyl phthalate (DINP), Di(2-ethylhexyl) phthalate (DEHP), Dibutyl phthalate (DBP), Di-iso-decyl phthalate (DIDP), Di-n-octyl phthalate (DNOP), and Butylbenzyl phthalate (BBP)**, a discussion took place at the November 99 plenary meeting to address the following developments: a) the position taken by two CSTEE members, its chairman and the "Phthalates" working group chairman, who expressed in a letter to the Director of SANCO/B their disagreement with the way in which the CSTEE's opinions had been used to back the ban on phthalates; b) the answer to such a letter from the Director General of DG SANCO; c) a position of the CSTEE on the subject by means of a statement the final terms of which will be attached to the minutes of the meeting when these are adopted by the committee (normally this should take place at the occasion of the next CSTEE plenary, see point **L** below). After the meeting Commission services changed the text of the draft Commission decision to take account of the concerns expressed by the CSTEE.

G. Evaluation of Technical s for Guidance (TNsG) in support of Directive 98/8/EC concerning the placing of biocidal products on the market - Two sub-working groups and one full working-group meeting took place to discuss/finalise the draft opinion prepared by the *rapporteur*. However, because of difficulties linked to the now three different versions available of the Technical s for Guidance provided to the CSTEE (one was submitted in June, a 2nd one in September and a 3rd in October and it was realised that not all working group members had commented on the same version) it was decided to postpone adoption of the opinion until the next CSTEE Plenary Meeting. In the meantime the information came that a 4th version will be available in December 99. Therefore a working group meeting will take place in January to take another look at the draft text in the light of the changes in the 4th version.

H. "Ready Biodegradability Test Methods of Surfactants in Detergents" - An opinion was adopted by the CSTEE at its November plenary meeting. The CSTEE basically endorsed the view that a ready biodegradability approach was an improvement in respect of the approach based on primary biodegradability. The CSTEE also concluded that, should a surfactant fail the ultimate test, a risk assessment, with special emphasis on possible metabolites, is needed before making a decision on a derogation for the surfactant.

I. On the subject '**Construction products in contact with drinking water**' an informal decision was taken within DG SANCO to make the CSTEE the responsible committee for the future opinion request(s) to be submitted by DG ENTR. A working group will be formed, essentially made up of CSTEE members and chaired by one of them but it is requested that there is participation of representatives of the Scientific Committee for Food as well. A meeting of the

regulators group for construction products in contact with drinking water will take place on the 15/16 December 1999. It is possible that more light will be shed then on the questions to be submitted to the committee.

J. Regarding 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] a working group meeting took place on the 19th of November 99 to look at a draft prepared by the rapporteur/chairman of the working group.

The discussion has essentially centred on question **i)** as the problems posed by question **ii)** (outlined in the previous CSTEE summary report to the SSC minutes of its September 99 Plenary Meeting) have not been solved yet. In principle the answer to question **i)** should be ready for adoption at a forthcoming CSTEE plenary meeting.

K. About one week before the November 99 plenary the CSTEE secretariat was informed that an opinion request will be formally submitted soon to the CSTEE on the subject of four chemicals, with others to come, which have been risk assessed under Regulation 793/93 on existing substances. The four chemicals are: Nonylphenol (straight and branched chain) CAS 84852-15-3, 25154-52-3, Pentabromodiphenyl ether CAS No.32534-81-9, Octabromodiphenyl ether CAS No.32536-52-0 and Decabromodiphenyl ether CAS No.1163-19-5

L. The exact date of the next **CSTEE** plenary has yet to be confirmed but should take place either during the last week of January 2000 or the first one of February.

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* : 13 hair dye dossiers were discussed by Working Party 'Hair Dyes' during its meeting of 7 December 1999. 5 draft opinions were addressed the plenary meeting of 17 February 2000 for formal adoption. Further data are required for the other 8 dossiers.
- 2. UV Filters: S75 (coated Titanium dioxide)*: the state of the art was discussed during the plenary meeting of 8 December 1999. It might be necessary to prepare draft opinions for each type of coating. The next meeting of the Working Party is planned on 1 February 2000.
- 3. Alternatives/Dossier* : An opinion was adopted on the basic criteria of the protocols for the skin compatibility testing of potentially cutaneous irritant cosmetic ingredients or mixtures of ingredients on human volunteers. The issue of the use of human volunteers in the testing of potentially cutaneous sensitising cosmetic ingredients will be further discussed.
- 4. Preservatives, Colorants & Fragrances* : Opinions on Musk Ketone and Musk Xylene were adopted. These two opinions are phrased in such a way that the overall exposure to Musk Ketone and Musk Xylene through the use of cosmetics will be reduced by approximately 50%. Besides this, the opinion advocates to consider as well the other sources of exposure. The Committee adopted as well an opinion on fragrance allergy. This opinion aimed at an advanced information of the consumer concerning possible allergic substances present in cosmetics.
- 5. Inventory*: the work will resume upon receipt of the final draft of the 1st update, which is due by mid-December 1999.

Scientific Committee for Medicinal Products and Medical Devices

No plenary meeting was held since the last SSC meeting of 28-29 October 1999.