

Minutes of the Scientific Steering Committee Meeting of 22-23 July 1999

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

Prof.Dr.Pascal welcomed the participants. He apologised Prof.Dr.A.Osterhaus. The list of participants is attached as annex 1.

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

2. Approval of the agenda

The draft agenda was approved with minor changes. It is attached as annex 2.

3. Approval of the minutes of the meeting of 24-25 June 1999

The minutes of the last meeting were approved without changes.

4. Progress on multidisciplinary matters

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

The working group is presently preparing a first draft report for the SSC. It will be presented at the next SSC meeting of 16-17 September 1999.

b. Harmonisation of risk assessment procedures

Prof.Dr.J.Bridges informed the SSC that he was finalising the draft working group report, on the basis of the comments received from other EC Scientific Committees and of what is available from certain international institutions or bodies. A new meeting of the Working Group is planned for 15 September 1999.

c. Electromagnetic waves (update)

Prof.Dr.F.Kemper presented a Bibliography on Microwave Heating of Food which recently became available (Dehne, L.I., 1999). Prof.Dr.W.Klein, chairman of the SSC's working group that prepared the SSC opinion on *Possible Health Effects from Exposure to Electromagnetic Fields (0 Hz- 300 GHz)* evaluated this bibliography list and concluded that this opinion did not need to be updated. The SSC agreed to this conclusion.

d. Antimicrobial resistance: update

The Committee was presented with the comments received from industry as well as with some position papers from interest groups. After having carefully considered and discussed the various comments, the SSC concluded that the reactions did not provide any new elements and unanimously decided that they do not affect the conclusions and recommendations of the SSC opinion on antimicrobial resistance. The Committee reaffirmed the opinion which it considered to be well balanced and which is intended to avoid any further deterioration of the situation.

5. Multidisciplinary matters relating to TSE/BSE

5.1. 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.

He announced that the *ad hoc* Group had been enlarged with two members (Prof.Dr.V.Silano, and Prof.Dr.D.Heim). A further enlargement was expected in the coming months.

Prof.Gibney also reported on the results that are being obtained in Switzerland, where a stringent BSE surveillance system has been implemented which also makes use of a BSE diagnosis test on slaughtered animals and on fallen stock. It appears that the number of detected cases has been doubled, especially because of BSE found in fallen stock. These results are most relevant both for the operational exploitation of the results of the Commission's evaluation programme of BSE diagnostic tests (see previous minutes) and for the Working Group "TSE surveillance" which was recently established by the TSE/BSE *ad hoc* Group. The SSC secretariat was requested to obtain further information from the Swiss authorities on this surveillance programme, including on the age structure of the animals in which BSE is diagnosed.

Details on the other items are given under the subsequent points of these minutes.

5.2. Reports on specific issues

a. Intra-species recycling of animal waste .

Prof.Dr.P.James presented the Working Group report and reported on the discussion of the TSE/BSE ad hoc Group at its meeting of 15 July 1999. During this meeting, the ad hoc Group discussed the suggestions made by the SSC at its meeting of 24-25 June 1999 and prepared an updated draft opinion. A detailed discussion was held by the SSC and a number of recommendations were made. The SSC secretariat was requested to amend the draft opinion in the light of this discussion. Final discussion and possible adoption is scheduled for the SSC meeting of 16-17 September 1999.

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

An external expert has been contracted to provide an independent view on the consistency between the various opinions. Between the first opinion on meat-and-bone meal (March 1998) and the last one on "Fallen Stock" (June 1999), science has indeed evolved and a streamlining of the various opinions would be useful. A draft report may be expected for the September meeting of the SSC.

c. Breeding of scrapie-resistant sheep

Dr.E.Vanopdenbosh, member of the TSE/BSE *ad hoc* Group and rapporteur on this issue, presented the draft opinion adopted by the TSE/BSE *ad hoc* Group which took account of the suggestions made by the SSC at its meeting of 24-25 June 1999. A detailed discussion was held and the SSC eventually adopted the opinion (see Annex 3).

d. BSE tests (update)

The Committee was up-dated on the recent publication of the summary of the BSE test evaluation exercise in 'Nature' and of the Commission's detailed report on the internet. The Committee drew attention to the desirability of establishing a stock of positive and negative BSE samples to facilitate developments of future tests and the need to have access to tissues from animals in a pre-clinical phase of BSE.

e. Human exposure risk.

An update of the report and a preliminary draft opinion were prepared at the meeting of the TSE/BSE ad hoc Group of 15 July. The report, however, needed some further discussion by the Working Group and will be submitted to the SSC at its meeting of 16-17 September 1999.

f. Update of the May 1999 opinion on the evolution of the BSE epidemic in Great Britain.

The secretariat informed the SSC of the latest figures on the evolution of the BSE epidemic in GB, which had been provided by Dr.J.Wilesmith. They have been included in an updated version of the report.

The secretariat further informed the SSC of its intention to launch a small study contract for the provision of predicted numbers and confidence intervals of BSE cases in GB (1999-2001), based on a scientific model developed at the Institute for Animal Husbandry and Animal health (ID-DLO), Lelystad (The Netherlands).

Finally, the Commission announced its wish that a separate opinion be prepared on the effects of selective cull programmes on the evolution of BSE epidemics. This opinion should not be limited to the UK, but also be based on information from Ireland, Portugal and Switzerland. The SSC asked the Commission to formulate a detailed question. The TSE/BSE ad hoc Group should then set up a Working Group.

g. Assessment of the geographical BSE risk:

The secretariat informed the SSC on the state of progress of the geographical risk assessment exercise.

During the last exercise in June, experts have assessed 16 countries in total: 5 Member States (The Netherlands, Norway, Portugal, Ireland and Spain), which were re-assessed on the base of the comments received from the countries on the draft reports prepared in May, and 11 Third Countries. 7 of them were assessed for the first time (Australia, Canada, Chile, The Czech Republic, The Slovak Republic, India and Paraguay), and 4 were re-assessed (Argentina, Switzerland, New Zealand and The USA). All the reports followed the structure of the method revised by the SSC on 23 April 1999. The reports are currently being finalised in terms of editing and, in certain cases, by taking account of additional information provided by the countries after the assessment exercise.

A proposal for a common scale for stability and challenge was suggested. The scale for the stability varies from "Totally unstable" to "Optimal" (this one being the best) and the scale for the challenge varies from "Extremely high" to "Zero" (this one being the best).

The following common preamble was also proposed: "*This risk assessment is based on a simplified concept of the origin of BSE. Possible but not confirmed sources such as sporadic cases, other TSEs, exotic animals, ...are currently ignored. However, should any of these sources be confirmed, the risk assessment should be repeated.*"

The final review of all assessed countries is scheduled for the week 28 September to 02 October. However, some countries that expressed their intention to be assessed, did not yet deliver sufficiently complete dossiers. A special session might be organised for these countries, in order to allow them to be reviewed before the final review. A final opinion on the geographical BSE-risk of the assessed countries could then be delivered by the SSC in December 1999.

h. BSE-status categories

No further progress was made in this field. A working group meeting will be convened for September 1999 and a draft opinion is expected to be submitted to the SSC at its October 1999 meeting.

i. "Fallen stock": adoption of the executive summary.

The draft executive summary of the opinion adopted on 24-25 June, prepared by Prof.Dr.W.Bridges, was discussed, amended and adopted. The version of the opinion presently available on internet will be completed with this summary. In addition, editorial changes in the opinion itself were agreed upon. The executive summary and re-edited opinion are attached as annex 4.

j. "Closed herds".

The draft report and opinion, prepared by the working group and discussed by the TSE/BSE ad hoc Group at its meeting of 15 July, was presented by Dr.E.Vanopdenbosch (rapporteur). The SSC discussed and amended the documents and eventually adopted the opinion attached as annex 5.

k. Quantitative risk assessment: progress report & possible workshop.

The SSC secretariat briefed the participants on the preliminary results of a contractual study on the quantitative risk assessment of ruminant derived gelatine and tallow which is presently being carried out by an external contractor. A final report, including a spread-sheet model, will be available in September. The SSC suggested that the model should also be able to cater for the interspecies barrier and for the route of administration of a product (e.g., parenteral, oral, ...).

The SSC agreed that a technical seminar would be organised for a limited audience, to validate the model. The seminar is scheduled for September or October. Invited will be: the members of the WG "Safety of Products", the interested members of the TSE/BSE *ad hoc* Group and of the SSC and experts from the gelatine and tallow industry.

Finally, the SSC secretariat was requested to contact GME (Gelatine Manufactures of Europe) and to ask the results of the TSE infectivity clearance experiment mentioned in the SSC opinion of March 1998.

6. Organisational matters

Following the discussions held at the last SSC meeting, the membership of the TSE/BSE *ad hoc* Group has been enlarged. So far, Prof.Dr.V. Silano, and Prof.Dr.D.Heim accepted to become Member of the TSE/BSE *ad-hoc* group.

The secretariat invited all SSC-members to propose additional suitable candidates and necessary expertise to the secretariat, which then would contact the potential members. Eventually, the *ad hoc* Group should be composed of up to 20 members.

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 (24-25 June 1999). (See annex 6)

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

Mr. Rohte of DGII/E/1 reported on the latest developments of Council Directive 93/5/EC on "assistance to the Commission and co-operation by the Member States in the scientific examination of questions relating to food". Actually the group is dealing with 10 different tasks, whereof 4 have been started this year. A Draft Commission Decision amending Commission Decision 94/652/EC has been published in the O.J. Tasks 2.3 on microbiological risk assessment has been completed in due time by the French co-ordinator and is available on request. The printing of this publication will take some time due to the limitations in staff. To complete task 3.2.5 on the "Preparation of a working document in support of a EU risk evaluation on dioxins and related PCBs as food contaminants, covering the estimated dietary intakes in individual Member States" a reminder has been written to the participating institutes to ensure meeting the deadline of 31.12.1999. The other tasks are on schedule.

9. Any other business:

No other business were discussed

The meeting ended on Friday 23 July 1999, at 12h00.

The next meeting will be held in Brussels, on 16-17 September 1999, starting at 10:00.

Annex 1: List of participants of the Scientific Steering Committee meeting of 22-23 July 1999

List of presence

Members of the SSC :

Prof. Georges Bories, Prof. James W. Bridges (not present on 23 July), Prof. Fulgencio Garrido Abellán, Prof. Michael Gibney (not present on 23 July), Prof. Anthony R. Hardy, Prof. Philip T. James, Prof. Keith H. Jones (not present on 23 July), Prof. Fritz H. Kemper, Prof. Werner Klein, Prof. Ib Knudsen, Prof. Robert Kroes, Prof. Gérard Pascal, Prof. Vittorio Silano, Prof. Marcel Vanbelle, Prof. Martin Wierup

Invited expert:

Prof. Emmanuel Vanopdenbosch (23 July only)

Apologies: Prof. Dr. A. Osterhaus

Participants from the Commission:

DG III: G. Gallhoff, O. Rohte

CCR- Ispra M. Balls

DG XXIV: B. Carsin, C. Berlingieri, T. Daskaleros, C. Diez, J.L. Jouve, G. Morrison, J.J. Rateau, A. Somogyi, R. Vanhoorde, P. Vossen, P. Wagstaffe

Stagiaire: S. Stefanidis

Annex 2:

Agenda of the Scientific Steering Committee Meeting of 22-23 July 1999

1. Welcome, apologies, introductory remarks, declarations of interest
2. Approval of the agenda
3. Approval of the minutes of the meeting of 24-25 June 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. Electromagnetic waves (update)
 - d. Antimicrobial resistance: comments from FEDESA (2x), FEFANA (2x), Eurocoop, and Les amis de la Terre (2x).
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. Intra-species recycling of animal waste (possible adoption of an opinion).
- b. Overall view on the various "products" opinions (gelatine, meat-and-bone meal, tallow, etc.): update

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

d. BSE tests (update)

Human exposure risk.

e. Discussion and possible adoption of an opinion

Geographical risk.

f. Update of the May 1999 opinion on the evolution of the BSE epidemic in Great Britain.

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

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

Other issues:

i. "Fallen stock": editorial changes and adoption of the executive summary.

j. "Closed herds" (for opinion).

k. Quantitative risk assessment: progress report & possible workshop.

6. Organisational matters.

7. Co-ordination:

- reports of the Chairmen of the 8 Scientific Committees.

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

9. Any other business.

Annex 3

Scientific Opinion on the policy of breeding and genotyping of sheep, i.e.

The issue whether sheep should be bred to be resistant to scrapie

Adopted by the Scientific Steering Committee at its meeting of 22-23 July 1999.

(Distributed separately)

Annex 4:

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

Adopted By the Scientific Steering Committee at its meeting of 24-25 June 1999 and re-edited at its meeting of 22-23 July 1999 (Text subject to editorial changes)

(Distributed separately)

Annex 5:

Scientific Opinion on The conditions related to "Negligible risk (closed) bovine herds"

Adopted by the Scientific Steering Committee at its meeting of 22-23 July 1999.

(Distributed separately)

Annex 6: Reports from the secretariats of Scientific Committees on the major activities and milestones since the SSC meeting of 24-25 June 1999.

Scientific Committee for Food

The Committee in its meeting on 16-17 June 1999 discussed and adopted the following scientific opinions:

- 1) Opinion on Dioxins in milk derived from cattle fed on contaminated feed in Belgium.** The Committee was asked as a matter of urgency to advise the Commission whether, on the basis of consumer health considerations, there are grounds to treat milk and milk products (with the exception of butter) differently from other products specified in Article 1 (1.A) of Commission Decision 1999/368/EC.
- 2) Opinion on stevioside as a sweetener.** The opinion was prepared by the working group on food additives.
- 3) Opinion concerning the scientific basis for determining whether food products, derived from genetically modified soya and from genetically modified maize, could be included in a list of food products which do not require labelling because they do not contain (detectable) traces of DNA or protein.** This opinion was prepared by the working group on Novel Foods in application of Article 2 of Regulation 1139/98 on labelling of novel foods (consultation of the Scientific Committee on Food).
- 4) Opinion on the safety assessment of phospholipids obtained from egg yolk as food produced using a new process.** This opinion was prepared by the working group on Novel Foods in application of Article 11 of Regulation (EC) 258/97 (obligatory consultation of the SCF on matters relating to public health).
- 5) Opinion on Stevia Rebaudiana Bertoni plants and leaves.** This opinion was prepared by the working group on Novel Foods in application of Article 11 of Regulation (EC) 258/97 (obligatory consultation of the SCF on matters relating to public health).
- 6) Opinion on an additional list of monomers and additives for food contact materials.** The opinion was prepared by the working group on food additives.
- 7) Interim statement on chromium and the use of chromium for gelatin production in relation to the request for the opinion of the SCF on the adequacy of a proposed specification for gelatin in terms of protection of consumer health.**

A number of new requests submitted to the SCF for a scientific opinion was assigned to the relevant working groups:

- nitrate (working group on contaminants)
- fusarium toxins (working group on contaminants)
- phytosterol esters in yellow fat spreads (working group on novel foods)
- green hearted chicory (working group on novel foods)
- Radicchio rosso (working group on novel foods)
- evaluation programme for chemically identified flavouring substances (task force on flavourings)

- cyclamate (working group on food additives)
- aspartame acesulfame salt (working group on food additives)
- acesulfame K (working group on food additives).

Scientific Committee on Plants

The SCP met on 16 July. The Committee examined draft opinions on the relationship between pesticide usage and mycotoxin content of plants, guidance documents on environment effects of plant protection products, guidance documents on genetically modified micro-organisms and the possible adverse effects of Bt modified maize on butterflies. These opinions are expected to be adopted at the next meeting of the Committee on 24 September.

Scientific Committee on Animal Nutrition

SCAN working groups on enzymes and micro-organisms met in order to progress on the assessment of the numerous products submitted to their evaluation. The SCAN plenary dedicated the main part of its meeting to the revision of the existing guidelines. These revised guidelines will be the basis for the establishment of dossiers submitted by industry for products seeking an EU approval in the future (september 2000).

Scientific Committee Veterinary Measures relating to Public Health

The working group of the Scientific Committee on Animal health and Animal Welfare met on 16 July to continue its work on the Animal Welfare Aspects of the Rearing of Chickens for meat production (broilers).

The draft opinion of the Committee on Classical Swine Fever in Wild Boar was put into written procedure on 13 July 1998. The procedure will close on 10 August.

Scientific Committee on Animal Health and Animal Welfare

The Working group on the *Welfare of Broilers* (Chairman Prof. Per Jensen) met on 16. July. Much of the data collection is now complete and a working document is prepared. A few more meetings will be required for completion.

The Report on *Classical Swine Fever in Wild Boar* (Rapp. Prof. Moenning), already approved by the Sub-committee, was examined in detail by the Committee on Animal Health and Animal Welfare during the plenary on 23 June. Considering the several amendments to the draft report, it was decided that the document would be amended, sent out by electronic mail for possible approval by means of the written procedure. The deadline of this procedure is the 10 August. At the moment (27.7.99) over 70% of the members sent a positive answer. Therefore, the report can be considered as adopted.

Scientific Committee for Toxicity, Ecotoxicity and the Environment

A. Since the June 99 SSC plenary meeting the CSTE held its 10th plenary meeting in Oslo. The choice of venue was determined for reasons of convenience as some CSTE members were already in place to participate in EUROTOX 99, the European Congress of Toxicology. The 10th plenary meeting was the first attended by the three newly appointed members of the CSTE. The committee is now 18 strong.

In terms of progress made on the opinions submitted to the CSTE still pending adoption the situation is the following:

B. On the subject '*Terrestrial environment*' - '*Available scientific approaches to assess the potential effects and risks of chemicals on terrestrial ecosystems*' the activities will restart as soon as a date for a working group meeting is agreed.

C. On the subject '*Selection of a Community wide mineral oil marking system - Safety of the preferred product*'. A few azo dyes have been identified as substances on which information is necessary to address the opinion request. Data

was requested from the European Chemicals Bureau but no satisfactory answer was obtained so far. The data will be sought after from other sources. As soon as it is available the WG chairperson will prepare a draft opinion.

D. A paper prepared by one member on *'The use of measured exposure data in risk assessment'* was discussed at the Oslo plenary. In principle this will be followed up by means of a more detailed report. The working group chairperson will also follow up a number of related activities/opinion requests where the issue of modelling versus measured exposure data is at stake, one example being the new opinion request on the *'Water Framework Directive'*.

E. On the opinion request on *'Water framework directive'* a working group meeting will be organised soon.

F. Data obtained by the Commission requester service on the subject *'Toxicological characteristics and risks of certain citrates and adipates used as a substitute for phthalates as plasticisers in certain soft PVC products'* was submitted to the CSTEE and respective working group members and subsequently analysed by the respective chairperson. The interim conclusions were presented at the 10th CSTEE plenary. However we're still at a stage where the information available is considered scarce to allow for an informed opinion to be possible as defined by the terms of reference. Depending on how much information is made available till the next CSTEE plenary a WG meeting may or not take place in view of finalising a draft opinion for presentation at the September CSTEE plenary. Given the now long period since this opinion request was submitted, the request was made by the CSTEE secretariat that either an opinion be adopted or a statement be issued at the next plenary stating the reasons why this is not possible and what are the conclusions in terms of the known/unknown comparative risks between phthalates and the potential substitutes in the applications under consideration.

G. On the subject of phthalates migration, two reports have become recently available, one prepared by the Dutch 'TNO' and another by 'LGC' from the UK. These reports are an endorsement of the recommendation made by the CSTEE in its opinion on Phthalates in toys issued at its November 1998 plenary meeting. In it the CSTEE recommended that an inter-laboratory validation exercise should be carried out in order to confirm the conclusions of the so-called 'Dutch Consensus group' study. Those two reports aim to do that. An opinion request will be submitted soon to the CSTEE enquiring, in general terms, on how do they confirm the conclusions of the 'Dutch Consensus group study'. It is possible that the terms of reference may contain more detailed questions on specific aspects of the two reports. The importance of these reports is not negligible given that a significant debate is still taking place on whether a ban on phthalates in the articles under consideration (childcare articles for children under three years of age) will or not be adopted as a risk management measure.

H. A new opinion request was presented at the Oslo plenary by DG III on the subject *'Ready Biodegradability Test Methods of Surfactants in Detergents'*. The terms of reference have been sent to the CSTEE as well as backup documentation on the basis of which the CSTEE will deliver its opinion. This will focus on whether a proposed 'ready biodegradability test' constitutes an improvement in respect of the existing approach based on 'primary biodegradability'. A set of other related questions was also submitted.

I. On the subject *'Construction products in contact with drinking water'* feed back is still being waited from the responsible Commission requester service. It is expected that terms of reference will be submitted at the September plenary.

J. The upcoming submission of an opinion request on **'lead'** has been communicated to the CSTEE secretariat. At the time of writing the terms of reference have not been fully agreed by the Commission services as the request will likely focus on two aspects: (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. While the former is likely to be a 'standard' one, particularly where the CSTEE will presumably look at it on the basis of evidence submitted by the Danish authorities, the latter, given its wide focus, needs quite some fine tuning as the CSTEE cannot possibly answer in a period of about three months, all questions on all uses of lead in terms of all the hazards and risks posed by all lead compounds.

K. The next CSTEE plenary is confirmed for the 27th/28th of September 1999 in Brussels.

Scientific Committee for Cosmetics and Non-Food Products

A Working Party meeting took place during which the 1st update of the inventory and common nomenclature of ingredients employed in cosmetic products was discussed.

Revised documents on new entries and on corrections to be made to the existing entries were discussed with representatives from the cosmetic industry.

All parties recognised that the fulfilment of all requested modifications/corrections to the present version of the inventory would take several years, which is unacceptable. In order to put new entries into the Inventory and for reasons of labelling and thus an information of the consumer, an early publication of the 1st update becomes urgent.

Scientific Committee for Medicinal Products and Medical Devices

No meeting was held since the last SSC meeting