

Minutes of the Scientific Steering Committee Meeting of 16-17 September 1999

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

Prof.Dr.Pascal welcomed the participants. He apologised Prof.I.Knudsen and Prof.V.Silano (for 16 and 17 September) and Prof. M.Gibney and Prof.K.Jones (for 17 September). The list of participants is attached as annex 1.

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

2. Approval of the agenda

An updated version of the draft agenda was approved. It is attached as annex 2.

3. Approval of the minutes of the meeting of 22-23 July 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".

Prof.W.Klein, chairman of the Working Group, reported that the structure of the report has been finalised. The different contributions will be merged according to the following orientations:

- introduction/context : this present report will focus on a specific case study :GMOs. However, it should be highlighted that the problem of "emerging health issues" is a permanent and intrinsic task of a Scientific Committee: need to identify and address health issues in an evolving scientific environment, need to question its own scientific process in particular in relation with dealing with certainties, uncertainties.
- First chapter : actual practice and problems that have been identified
- Second chapter :new questions : theoretical risks, need of a proactive approach in relation with the second generation of GMOs.

In the margin of the discussions on the above subject and following an exchange of views, the SSC decided to establish a permanently updated list of "possibly emerging health issues" in order to discuss priorities. According to these priorities, a process allowing to seek scientific data on these priority points should be found in the framework of a preventive approach.

b. Harmonisation of risk assessment procedures.

The Working Group on "Harmonisation of risk assessment procedures" met on 15 September 1999. Members were presented with a draft discussion paper prepared by Prof. J. Bridges. This paper consists of two parts: in the first one, the procedures in current use for risk assessment are outlined and some key issues which need to be taken into account in harmonising and moving forward the risk assessment process identified. In the second one, recommendations are made on priorities for the activities of the Working Group.

The group discussed the draft discussion paper and made several proposals for amendments which will be incorporated in a revised version of the document. In particular, a diagram illustrating the risk cycle (risk analysis) has been sketched and discussed. This draft diagram, presented to the SSC, is reproduced in Annexe 3.

The following action plan was agreed upon:

- To assemble, by the end of October, a list of lead documents for each of the issues under consideration.
- To have an agreed set of definitions.
- To draft a set of guidelines to improve understanding and develop harmonisation in the way risk assessments are presented.
- To develop a strategy for introducing quantitative risk assessment in a transparent manner across the various Scientific Committees.
- To develop a guideline on the procedures to ensure effective and efficient dialogue between risk assessors and risk managers.

The next meeting of the Working Group will take place on 8 December 1999.

5. Multidisciplinary matters relating to TSE/BSE

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

Prof.A.Osterhaus, provided on behalf of Prof.Gibney a summary report on the recent activities of the ad-hoc group.

- **P.Willeberg**, member of the ad-hoc group will be nominated as Chief Veterinary Officer of Denmark.. Prof.Willeberg is member of the TSE/BSE ad-hoc group representing the Scientific Committee for Veterinary Measures related to Public Health. As he is resigning from that SC he automatically has to resign as member of the TSE/BSE ad-hoc group.
- The draft opinion on **Intra-Species Recycling** was discussed, revised in detail and be transferred to the SSC.
- Two working groups are going to be established.
 - **WG-“Safety of Blood”** (aiming mainly but not only on bovine blood which is still allowed to be fed to bovines, e.g. as blood meal).
 - **WG-“Origin of BSE”** (Task: to list and scientifically discuss all different theories on this issue and identify the most plausible.).
- The draft opinion on **Human Exposure Risk** was not discussed. It will be transferred to the SSC before 22/10/99.
- **Prof. Sheila Gore**, Epidemiologist, University of Cambridge, UK; and **Prof. Aguzzi**, neuropathologist and Prion Specialist, Univ. Zurich, will be invited as additional members of the ad-hoc group.
- A discussion on the importance of the minimal molecular weight of **hydrolysed proteins** lead to the conclusion that in fact the limit of 10.000 kDaltons could be a critical size below which it is most probably safe. This needs to be formalised. The Commission announced to formulate a concrete question to the SSC on this matter.
- Details on some of the items are given under the subsequent points of these minutes.

5.2. Reports on specific issues

a. Intra-species recycling of animal waste .

Prof.Osterhaus presented the updated draft opinion prepared by the TSE/BSE ad hoc Group at its meeting of 9 September 1999. The new draft takes into account the suggestions made by the SSC at its meeting of 22-23 July 1999. A detailed discussion was held and, after having introduced modifications in the draft text, the SSC adopted the opinion as attached in annex 4.

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

The Secretariat reported that, for administrative reasons, the elaboration of an overall view on the various opinions on the safety of ruminant-derived products will be delayed and a final document is unlikely to be available in the immediate future.

c. Human exposure risk.

This item will be discussed with priority at the next SSC meeting (28-29 October 1999).

d. Assessment of the geographical BSE risk and BSE-status categories:

The commission informed the SSC on the recent developments, in particular the option to use the recently evaluated post-mortem BSE-tests for a pre-scribed screening in order to establish the actual BSE-situation in Member States (obligatory) and Third Countries (voluntary).

The qualitative risk assessment currently underway shall be somewhat delayed, attending the screening exercise. However, in order to bring the reports into a usable form, a final review meeting shall take place in December or early January with the aim to harmonise the terminology employed in the different reports.

The SSC agreed that the tests do indeed allow mass screening for clinical BSE-cases, but not necessarily for pre-clinical cases. The incidence could be much better established as at current (see Swiss, UK) but the screening would not provide information on the propagation risk. A qualitative analysis would be needed whenever cases would be found in order to interpret this finding.

The SSC therefore recommended to continue the qualitative risk assessment and to reflect on a way to inform the countries of the results, for example on a bilateral basis. This information could be limited to listing the strong and the weak points in the BSE/cattle system of a country and the resulting propagation risk. This would provide the countries with the scientific advice necessary to appropriately manage their BSE-risk, even if no formal opinion on the geographical BSE-risk of specific countries would be issued by the SSC.

e. Quantitative risk assessment: progress report

The SSC secretariat briefed the participants on the results of the contractual study on the quantitative risk assessment of ruminant derived gelatine and tallow which was carried out by an external contractor. The study results and the corresponding software (a spreadsheet) will be discussed on 20 September by a small group of experts, composed of some members of the SSC, the TSE/BSE ad hoc Group, the Working Group “Products” and technical representatives of the gelatine, tallow, tallow

derivatives and rendering industry. A final version of the spread-sheet model, will be made available to the SSC in October or November.

f. BSE surveillance in Switzerland; survey of OTMS cattle in the UK.

The SSC members were provided with a summary account of the results of the intensified and targeted BSE surveillance programme in Switzerland, using diagnostic tests and applied to fallen (cattle) stock and emergency slaughtered cows of about two years of age or older. The SSC was also provided with a copy of the UK MAFF's preliminary results of the survey of BSE incidence in OTMS cattle.

Both documents were briefly discussed.

The secretariat of the SSC was requested to contact the UK authorities with the question to provide the SSC with additional details on (1) the results per class of age and date of birth and (2) the nature of the difficulties encountered when applying diagnostic tests in this survey.

The SSC noted that the information on the BSE-OTMS was outdated by several months and expressed its wish to be kept informed in quasi-real time about the (further) results of this and similar surveys, according as they become available. The permanent monitoring of the BSE epidemic is indeed part of the SSC activities. The SSC noted that it is regularly invited to prepare scientific opinions within the shortest possible delay and that in such cases information can be made available within a matter of days. If confidentiality of MS information would be at stake, the SSC confirmed once more that such information would be kept confidential, like it has been the case in the past.

g. Handling and storage of possibly BSE contaminated materials.

Prof. Bridges, chairman of the Scientific Committee for Toxicity, Ecotoxicity and the Environment reported on problems that emerged recently in several EU countries with the storage of possibly BSE contaminated cadavers and materials such as MMBM. He signalled also that the SSC had mentioned in its opinion on "Fallen stock" (adopted, 24-25 June 1999) that an additional opinion on safe handling and storage of possibly contaminated materials was needed. He proposed that the Scientific Steering Committee would address the following question (preliminary formulation): "What are considered to be the acceptable standards for storage of suspected BSE contaminated materials and what precautions should be introduced to ensure proper protection of workers in storage areas?".

It was agreed that Prof. Bridges will chair a working group. Its membership still needs to be determined. Prof. Bridges will also prepare the first draft report that will serve as the starting point for the WG discussions.

It needs to be discussed whether this WG would directly report to the SSC (via its TSE/BSE *ad hoc* Group) or to the Scientific Committee for Toxicity, Ecotoxicity, or to both.

Directorate General XXIV announced that it would contact DGs III (Industry), VI (Agriculture), XI (Environment), XII (Research) and the Joint Research Centre whether they would like to be associated with this activity and, if so, to provide the SSC secretariat with possible comments and contributions.

The adoption of an opinion is tentatively scheduled for January 2000.

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 (22-23 July). (See annex 5)

b Revision of the work programme of the 5th Framework Programme for R&TD (DGXII)

Mr.R.Gerold (Director, DGXII.B.10, DGXII-Research), reported on the state of advancement of the 5th Framework Programme (5th FWP). He also announced that a revision of the work programme of the 5th FWP was now being prepared and should be finalised before the end of this year. He highlighted the importance of the recommendations for research made in the opinions of the various Scientific Committees.

With respect to the latter, the SSC supported the DGXXIV proposal that the SSC-secretariat would prepare a table summarising the research recommendations made in the SSC opinions adopted since December 1997 and forward it to DGXII.

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

Mr. Rohte of DGIII/E/1 reported on the progress made in the field of International Scientific Co-operation and on the additional studies that will be launched in the near future.

9. Any other business:

No other business were discussed

The meeting ended on Friday 17 September 1999, at 11h45.

The next meeting will be held in Brussels, on 28 October 1999, starting at 9:00.

Annex 1: List of participants of the Scientific Steering Committee meeting of 16-17 September 1999

List of presence

Members of the SSC:

- Prof. Georges Bories
- Prof. James W. Bridges
- Prof. Fulgencio Garrido Abellán
- Prof. Michael Gibney (not present on 17 September 1999)
- Prof. Anthony R. Hardy
- Prof. Philip T. James
- Prof. Keith H. Jones (not present on 17 September 1999)
- Prof. Fritz H. Kemper
- Prof. Werner Klein
- Prof. Robert Kroes
- Prof. Albert Osterhaus
- Prof. Gérard Pascal
- Prof. Marcel Vanbelle
- Prof. Martin Wierup

Apologies: Prof. Ib Knudsen, Prof. Vittorio Silano

Mrs. N. Verdière, Secretary to the Chairman of the SSC, participated as an observer.

Participants from the Commission:

DG III: O. Rohte

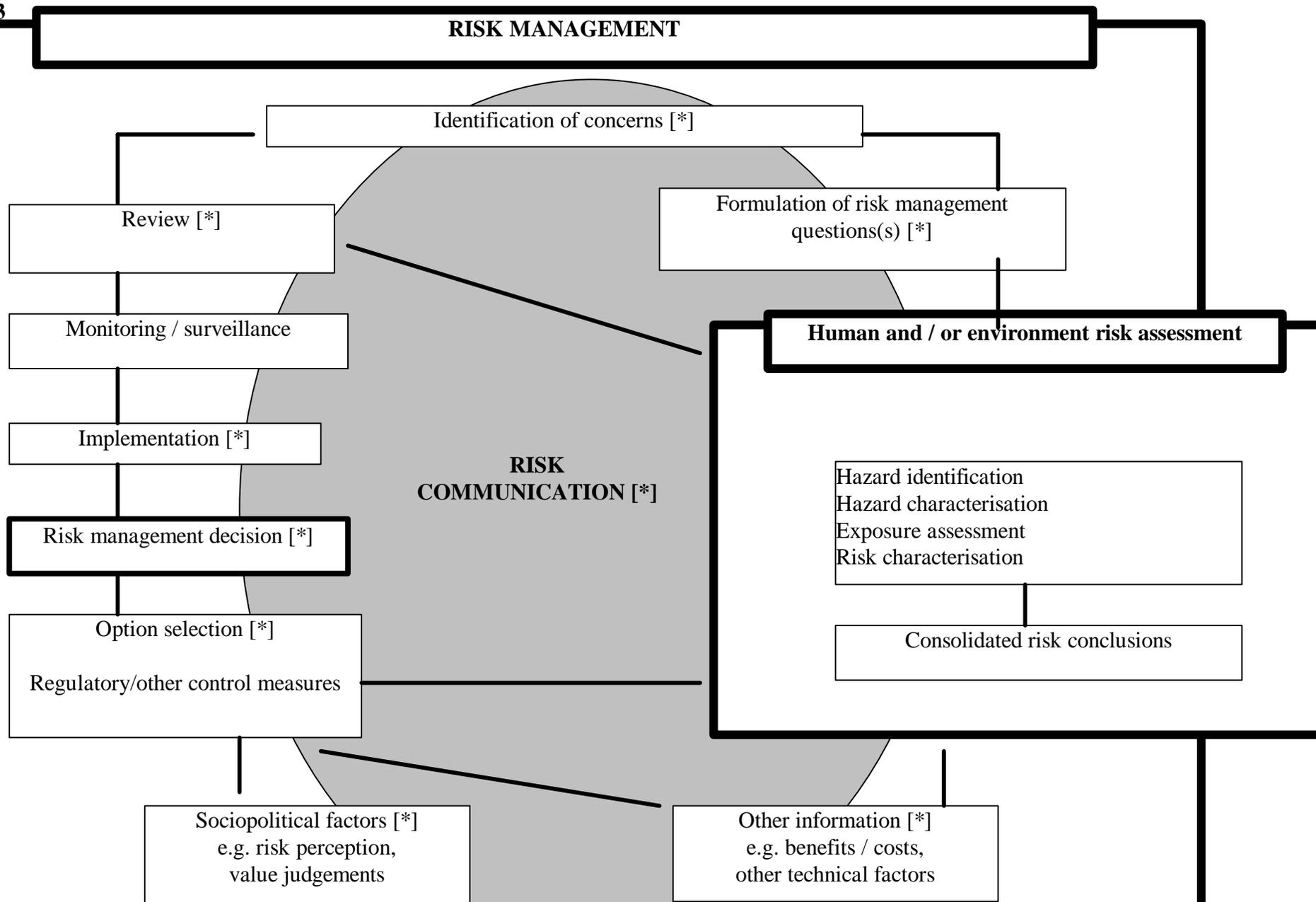
DGXII: R. Gerold, L. Breslin (on 16 September only)

DG XXIV: B. Carsin, C. Diez, J.L. Jouve, G. Morrison, J.J. Rateau, A. Somogyi, P. Vossen, M. Granero, J. Vergnettes

Annex 2:

Agenda of the Scientific Steering Committee Meeting of 16-17 September 1999

1. Welcome, apologies, introductory remarks, declarations of interest
 2. Approval of the agenda
 3. Approval of the minutes of the meeting of 23-24 July 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)
 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
 - Human exposure risk.
 - c. Progress report
 - Geographical risk.
 - d. Assessment of the geographical BSE risk: and BSE-status categories: progress report.
 - Other issues:
 - e. Quantitative risk assessment: progress report.
 - f. BSE surveillance in Switzerland; survey of OTMS cattle in the UK.
 - g. Handling and storage of possibly BSE contaminated MBM.
 6. Organisational matters.
 7. Co-ordination:
 - reports of the Chairmen of the 8 Scientific Committees.
 - Revision of the work programme of the 5th Framework Programme for R&TD (DGXII)
 8. Information by the Commission services on matters related to consumer health.
 9. Any other business.
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[*] : likely to involve a range of stakeholders

FIGURE 1 : THE RISK CYCLE (Risk Analysis)

Annex 4:



INTRA-SPECIES RECYCLING

OPINION on :

**THE RISK BORN BY RECYCLING ANIMAL BY-PRODUCTS AS FEED
WITH REGARD TO PROPAGATING TSE IN NON-RUMINANT
FARMED ANIMALS.**

Adopted on 17 September 1999

(Distributed separately)

Annex 5: Reports from the secretariats of Scientific Committees on the major activities and milestones since the SSC meeting of 22-23 July 1999.

Scientific Committee for Food

The SCF has held in the period between 22 July and 17 September meetings of the Working Groups on Novel Foods, on Food Hygiene and Microbiology, on Food Contact Materials and also the Task Force on flavouring substances has met. No meeting of the Plenary have taken place.

Scientific Committee on Plants

The Scientific Committee on Plants had no meetings between 22 July and 16 September 1999.

Scientific Committee on Animal Nutrition

The SCAN plenary of September was dedicated to the Revision of the Guidelines for the assessment of additives in feedingstuffs.

Scientific Committee Veterinary Measures relating to Public Health

Scientific Committee on Animal Health and Animal Welfare

The Report on the Control of Classical Swine Fever in Wild Boar was adopted by written procedure the 10 August 99 and is already available on internet.

Between the 22 July 99 and the 17 September 99 the WGs on different questions on AH and AW continued their work by correspondence, the following reports are to be completed :

- welfare of broiler chickens,
- standards for forced ventilation for animal transport road vehicles,
- Bacterial Kidney Disease,
- the Adaptation of the Technical Annexes of Council Directive 64/432/EEC to take account of Scientific Developments regarding Tuberculosis, Brucellosis and Enzootic Bovine Leukosis.

Scientific Committee for Toxicity, Ecotoxicity and the Environment

A. Since the July 99 SSC plenary meeting no CSTE plenary took place. This interim period has been characterised by the unfortunate passing away of Prof. Philip Chambers, a CSTE member and one of its vice presidents. He was the longest serving member of any scientific committee of the Commission (he became a CSTE member – the scientific committee from which the current CSTE originated – in 1979.

In terms of progress made on the opinions submitted to the CSTE still pending adoption or adopted 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*' a working group meeting will take place on the 20th of September and a draft report submitted to the September CSTE plenary.
- C.** On the subject '*Selection of a Community wide mineral oil marking system – Safety of the preferred product*'. An as thorough as possible data search was carried out by the CSTE secretariat. Data has been sent to the *rapporteur* and WG chairman who produced a

draft to be submitted to the September CSTEEN plenary. The prospects of it being adopted as an opinion are good.

- D. ***'The use of measured exposure data in risk assessment'*** - No major progress on this topic. Basically the WG chairman – *rapporteur* is gathering data and establishing the relevant links with other sc. committees and/or WG's activities in view of elaborating another paper. To such effect he participated namely in the most recent meeting of the WG on ***'Water framework directive'***. A more detailed report will be elaborated.
- E. On the opinion request on ***'Water framework directive'*** a working group meeting took place on the 31st of August. Progress made allowed for a draft to be prepared which will be presented at the September CSTEEN plenary.
- F. ***'Toxicological characteristics and risks of certain citrates and adipates used as a substitute for phthalates as plasticisers in certain soft PVC products' and 'TNO' and 'LGC' reports on validation attempts of the so-called 'Dutch consensus group study'*** - a meeting of the WG took place on the 27th of August 1999. A draft opinion on 'Phthalates substitutes' will also be submitted to the September 1999 plenary as well as drafts on the opinion request on the two reports prepared by LGC (UK) and TNO (NL) in view of attempting to validate a test method of phthalates migration from PVC.
- G. The CSTEEN adopted by written procedure on the 10th of September 1999 an opinion on ***"Request of the Federal Republic of Germany for a Article 100a(4) (Maastricht Treaty) for a derogation with regard to the classification of man made mineral fibres (MMMF)"***. This adoption was exceptional and the CSTEEN only accepted to collaborate given the imperative deadlines that the Commission services have to abide to to respond to the German authorities. Several CSTEEN members complained at the what some considered 'hasty' procedure and the matter will be discussed in the September plenary in view of possibly improve the system of adoption of opinions in this way
- H. ***"Ready Biodegradability Test Methods of Surfactants in Detergents"*** – a meeting of the WG took place on the 3rd of September 1999. A draft will be presented for discussion at the September 1999 CSTEEN plenary meeting.
- I. On the subject ***'Construction products in contact with drinking water'*** feed back is still being waited from the responsible Commission requester service. Initially it was expected that terms of reference would be submitted at the September plenary but apparently this will not be the case and a decision on that may have to be taken on the 5th of October 1999 by the relevant Commission service then since that is they are organising their 2nd meeting of regulators group for construction products in contact with drinking water (Council Directive 89/106/EEC).
- J. The opinion requests on ***'lead'*** have been submitted to the CSTEEN secretariat. At the time of writing, and in spite of the terms of reference having been agreed by the Commission services, there are still problems related with the scope of the general request on lead and the documentation to be submitted to the CSTEEN for it to answer the two questions. It is reminded that the consultation concerns 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.
- K. The next CSTEEN 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 entirely devoted to the fragrance labelling issue:

1. A re-styled document on the labelling of fragrance allergens was presented in which the mandate, a chapter on the background of the issue, the strategy and time schedule for tackling the problem were inserted. The document will be finalised according to the outcome of the discussion and put on the web side of the Committee for comments.
2. The position of DG XXIV was requested by DG III on a COLIPA proposal for a voluntary guideline on the labelling of fragrance allergens. As the SCCNFP is currently evaluating the scientific information available on the issue, DG XXIV found it logical to consult the committee on this proposal. At the same time, COLIPA was given the opportunity to present and discuss their position with the Working Party.

It was noted that there were considerable similarities between the SCCNFP draft opinion and the industry's proposal.

Scientific Committee for Medicinal Products and Medical Devices

A plenary meeting was held on 15.09.99. On the agenda were subjects such as: "Quality and safety of blood", Information on dioxine (FDA recommendation), "Xeno-transplantation", "Possible Implication of the problem of the Year 2000 (Y2K) for Medical Devices", "Development of Pharmaceutical Guidelines", "News information on possible risk of transmitting CJD via blood". A Working Group was created to draft a report on the latter subject.

The Working Group on "Quality and safety of blood" met on 17.9.99.

An additional meeting of the WG on "Possible Risk of Transmitting CJD via Blood", will be organised, to study the latest news on the subject.