Minutes of the Scientific Steering Committee Meeting of 21-22 January 1999

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

Prof.Dr.Pascal welcomed the participants. Apologies were received from (for 21 &nd 22.01.99) Prof.Dr.A.Osterhaus and Prof.Dr.M.Wierup, (for 21.01.99) Prof.Dr.Bridges and (for 22.01.99) Prof.Dr.R.Kroes. The list of participants is attached as annex 1.

No member had to declare an interest in any of the point of the agenda which would have endangered his independence.

2. Approval of the agenda

The draft agenda was approved without changes. It is attached as annex 2.

3. Approval of the minutes of the meeting of 10-11 December 1998.

The draft minutes of the meeting of 10-11 December 1998 were approved with minor changes, including an annex to the minutes containing the working document of the SSC concerning the compatibility of the OIE-proposal for a BSE-chapter in the code and the various relevant SSC positions.

4. Work plan for the SSC

4.1. Progress on multidisciplinary matters:

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

No progress was made, as the meeting initially scheduled for 19 January had to be postponed until 17 February 1999.

b. Report on the opinion adopted on 18.12.98 by the SC-Plants on "Guidance document to facilitate notifiers in the preparation of Plant GMO dossiers for consideration by the Scientific Committee on Plants".

Prof.Dr.A.Hardy presented the document. He insisted on the fact that this opinion is intended to be a "guidance" document, not a binding "guideline". It is largely based on the Scientific Committee's 1998 experience, during which 10 GMO notifications were assessed [1]. It will be subject to permanent updates, according as new experience is acquired and according as comments become available. It should also be noted that this document is complementary to the opinions on the assessment of novel foods adopted in 1997 by the Scientific Committee for Food.

The SSC welcomed the document of the SC-Plants as and discussed it briefly in view of future updates and within the more general context of risk assessment procedures.

The SSC considered that, as a matter of priority, a series of "harmonised guidelines for GMO risk assessment" needs to be developed, covering all the possible uses and destinations and fate of GMOs and GMO derived products. These should cover (possibly propose an optimal harmonisation and integration of) the methods, guidances and guidelines which are (1) presently used in the various EU Scientific Committees evaluating GMOs according to their expected use (as food or feed, intentional or accidental, to be locally cultivated or only as imported product), (2) imposed by the EU legislation as part of existing Guidelines to notifiers of new GMOs, (3) applied in Member states, third countries or international institutions.

Such document would be unique and the first in its kind and would eventually serve as the basis for updating EU

legislation and, possibly, of the WHO Codex Alimentarius.

Mr.O.Rohte (DGIII) agreed to provide the SSC with relevant documentation on risk assessment methods with respect to GMOs used as food, which may be available in DG III (e.g., inventories of existing methods in Member States and Third Countries).

The working group "Harmonisation of risk assessment procedures" was asked to assess whether it would be possible to develop such guidelines [2], as a case study within its present mandate.

c. *Harmonisation of risk assessment procedures*

No progress was made. The secretariat of the SSC reminded the Committee of the discussions at the last SSC and stressed that, so far, the contributions from only 3 Scientific Committees (SC-F, SC-TEE, SC-CNFP) had been received. Taking into account the importance of the exercise, the chairmen of the other 5 Committees were urged to send in their contributions to the chairman of the Working Group. A draft document, for discussion by the working group, will then be prepared.

The mandate should be enlarged in order to respond to the above mentioned case study on harmonised risk assessment procedures for GMOs.

d. *Resistance to antimicrobials*

The rapporteur presented the comprehensive preliminary draft report. He mentioned that it was the aim to have the guidance from the Committee on the orientations taken by the Working Group (WG) and that the document is still subject of substantial scientific debate in the WG. Furthermore, he explained that the draft report addresses 4 major areas (i.e. human medicine, veterinary medicine, animal husbandry and plant health) and stressed that it still requires considerable additional work, including editorial changes to achieve the required length and balance.

The presentation of the report itself included the questions of the amounts of antimicrobials used, the basis of resistance, the prevalence of antimicrobial resistance in pathogens from humans, animals and plants and its impact on health and productivity, the relationship of resistance to use, options for control and containment of antimicrobial resistance, areas for further research. Special attention was given to orientations for possible actions.

The SSC welcomed the work that was done and recognised the multidisciplinary approach. Some members suggested a different sequential presentation of the report, whereas others referred to the need for further development of the interrelationship of different uses of antimicrobials and of the importance of food hygiene. Several members recommended that the environmental aspects should be dealt with in a separate chapter and not combined with plant health uses (an SSC member promised a contribution on this aspect). It was also suggested to simplify the report by transferring technical details into annexes.

In view of the sensitivity of the issue, attention was drawn to the immature nature of the document which therefore should be kept fully confidential. Members were reminded that they should not divulge any detail of the internal discussions.

The rapporteur invited the SSC members to communicate any comment / suggestion in writing to him by 29 January at the latest. The next working group meeting is scheduled for 16 February. The rapporteur will provide a feedback at the next plenary report on that meeting but no written report will be distributed.

4.2. Multidisciplinary matters relating to TSE/BSE

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

Prof.Dr.M.Gibney, chairman of the TSE/BSE *ad hoc* Group, provided a summary report on the activities of the Group since last meeting. For most issues presented by Prof.Gibney, the corresponding details are provided in Section (b)

hereafter.

In addition, the following information was provided:

a.1. Recent comments from Prof.Dr.M.Pocchiari [3] on the SSC-opinion on cross-contamination with mammalian meat-and-bone meal and recent suggestions by Prof.Dr.H.Diringer on the LD_{50} values to be used for assessing the risk of transmission of BSE by various tissues [4]. A working group ("WG-LD50") was created by the TSE/BSE ad-hoc group. It shall *"address, in a TSE context, the definition, meaning and applicability/use/application of the LD_{50} concept, as well as the possible implications for humans or animals exposed to a given level of residual BSE/TSE-infectivity*". The SSC agreed to this WG.

a.2. The TSE/BSE *ad hoc* Group proposes that a 1/2 - 1 day informal seminar on prion-related diseases would be organised for members of the SSC, the TSE/BSE ad hoc Group and its major Working Groups, around the following subjects:

- Recent advances in the molecular biology of prion-related diseases

- Recent advances in the neuropathology of prion-related diseases.

The SSC agreed to this idea and suggested that such a seminar could be organised in the context of a regular SSC meeting.

The TSE/BSE ad hoc Group was invited to propose a date, a programme and the scientists who should be invited to make presentations at this seminar. It was suggested that selected experts from the veterinary (TSE) field as well as some of the scientists who made presentations during the EMEA Seminar of 19-20.01.99 on blood safety, should be invited as well. The TSE/BSE ad-hoc group will discuss this at its meeting of 11/2/99 in order to allow the proposal to be discussed at the next meeting of the SSC (18-19 February 1999).

Remark: see also section 4.2.b.6 in these minutes.

a.3. Preliminary report on JRC's validation study of an appropriate heat treatment of animal meals by using the ELISA technique.

The complete report is not yet available. However, referring to the presentation provided by the JRC to the SSC at its December meeting, the SSC discussed the Europe-wide validity of the results as an operational tool for verifying the heat treatment because commercially available animal meals do not always contain porcine protein. This will be further discussed when the report is available. The usefulness of the results as a tool for experimental verification of the temperatures reached during processing, will then also be assessed.

b. *Reports on specific issues*:

b.1. "Fallen stock": The risk of infectious agents or non conventional transmissible agents entering the human food or animal feed chains via raw material from fallen stock, exotic/zoo animals, fur animals, dead animals, condemned materials, dead fish sick animals and laboratory animals and including the environmental aspects of disposal of potentially BSE infected materials and animals

The SSC secretariat reported on the progress made by the Working Group since its meeting of 15 December 1999 and confirmed that a draft opinion may be ready for discussion by the SSC at its meeting of March 1999.

b.2. Intra-species recycling of animals waste.

A draft scientific report has still not been adopted by the WG. It is now expected that a draft will be available for discussion by the SSC at its meeting of 18-19 March 1999.

b.3. Safety of gelatine: the heat/pressure/time process as a possible alternative.

Following the new and recent information on the inactivation of TSE agents during the process which became recently available, additional discussions were held within the working group (on 15.12.98). Following discussion of the WG's report, a draft opinion was prepared by the TSE/BSE ad hoc Group at its meeting of 15.01.99. This draft was discussed by the SSC, amended and eventually adopted. It is attached as annex 4.

b.4. Safety of gelatine (update of the opinion of 26-27 March 1998)

The opinions on the safety of hydrolysed proteins (adopted on 23-24.10.98) and on the possible use of the "133°C/20'/3 bars" production standard (see previous section) contain a number of conclusions which have also implications for the opinion on the Safety of gelatine, adopted on 26-27 March 1998. The latter opinion needs therefore to be updated to take into account also the use of hides from healthy animals and the possible use of the "133°C/20'/3 bars" production standard.

The opinion also needs minor updates so as to include the final report on the INVERESK inactivation study, which became only available after the adoption.

An updated draft opinion will be discussed during the next meeting.

b.5 Human exposure risk (HER).

The Working Group did not meet since the last SSC meeting. However, discussion between the WG-members continued, particularly addressing the question of how to address the issue of the importance of very small levels of human exposure to BSE. The work of the "WG-LD $_{50}$" (see section 4.2.a.1.) will be useful in this context.

A second issue addressed in the meantime was the fate of bovine tissue after slaughter. Prof.Gibney had contacted the Irish rendering industry and had a first meeting with them. Presenting them with a theoretical scheme, developed with the help of the Irish veterinary service, he had a fruitful exchange and looks forward to receive detailed information from them. For future meetings a member of the secretariat might be invited.

Prof.Gibney. underlined that the proposed work on the HER may not be able to develop an assessment of the real risk resulting from human exposure to (very small) doses of BSE-agent but that it will probably be able to evaluate the relative benefit of risk reduction measures with regard to the resulting HER.

b.6. Preliminary discussion on the Lancet paper (1999; **353**: 183-189): Hill *et al*, *Investigation of variant Creutzfeldt-Jacob disease and other human prion diseases with tonsil biopsy samples*.

The paper was distributed to all members and a preliminary discussion was held. The Scientific Committee Medicinal Products and Medical Devices was invited urgently to review the article and to evaluate whether an update of its recent opinion on the safety of blood is needed.

The SSC agreed also that a further exchange of views on the topic should be organised in the framework of the above mentioned informal seminar (see section 4.2.a.2. on prion related diseases). This exchange of views should not be limited to the Hill *et al* paper as such, but may cover a broader context (e.g., the sensitivity of the laboratory tests for the detection of TSE infection, detection limits and % risks for false results; design of statistical samples for the screening of human or animal populations, the risk of introduction of the PrP^{Sc} in the hospital environment, etc.) It was therefore suggested that selected experts from the veterinary (TSE) field as well as some of the scientists who made presentations during the EMEA Seminar of 19-20.01.99 on prion diseases, should be invited as well/

b.7. Handbook for the assessment of geographical BSE risk (presentation of the comments received until 15 January 1999).

The SSC secretariat reported that only 8 comments were received following the publication on internet of the pre-opinion in December. These comments will be integrated into the pre-opinion and a final version be prepared by the WG-Sourcing (meeting on 26/1/99) and the TSE/BSE ad-hoc group (meeting on 11/2/99) for adoption as final opinion

by the SSC on 18/19 February 1999.

b.8. Preliminary report on the completeness of applications received from Members States and Third Countries for evaluation of their BSE status.

The secretariat reported on the first step in the geographical BSE-risk assessment, the data analysis exercise, which took place from 11-15 January. 21 country dossiers have been treated, i.e. 11 MS (except GR, IRL, NL and PT) and 10 third countries. For each of these a report was prepared which, after final approval of the independent experts, will be transmitted to the countries together with a request to provide the additional information deemed necessary.

The SSC appreciated the good co-operation of the MS who all sent a country expert. Together with the independent experts invited by the Commission these country-experts where able to clarify many issues immediately. They also where in general very helpful for the establishment of a standardised data-set (see annex 2 of the handbook).

b.9. Correspondence between the Draft OIE Code on BSE (September 1998) and the SSC opinions regarding BSE (November 1997 - October 1998). - complementarity and differences.

Immediately following the discussions held at the December meeting, the SSC secretariat prepared an updated draft Discussion Document on the correspondence between the Draft OIE Code on BSE (September 1998) and the SSC opinions regarding BSE (November 1997 - October 1998). The update was circulated for written comments until 18 December 1999 and sent on 19.01.99 to the OIE for information and possible comments.

It is attached as Annex to the minutes of 10-11 December 1998. Depending upon the possible comments received from OIE, the document may be amended at the SSC meeting of February 1999.

b.10 Further discussion on criteria determining BSE-status categories, taking account of the geographical BSE-risk, the human exposure risk and the OIE recommendations.

The secretariat had prepared a discussion paper which proposed to address the relationship between geographical BSE-risk and the BSE-Status as follows:

Ignoring all other aspects, the BSE-Status would be equivalent to the geographical BSE-risk. However, factors like import of potentially BSE-contaminated materials or significant improvements of surveillance and monitoring could justify to allocate a better or worse BSE-Status as would be derived from the geographical BSE-risk alone.

As regards to a definition of a BSE-Status it can be found that currently no exact definition is available, neither from the OIE nor from the SSC itself. As a first step towards such a definition it was outlined that a BSE-Status is an indicator based on which risk management measures can be identified which are necessary to ensure an "acceptable" overall risk level, be it for exports or internal consumption.

The SSC agreed to this approach and requested the WG-sourcing, and the TSE/BSE ad-hoc group to discuss the issue along this line and to prepare for the next meeting a substantial discussion document.

5. Organisational matters: No organisational matters were discussed.

6. Co-ordination:

a. Recombinant Bovine Somatotropine (BST)

A short progress report was given. It was recalled that two separate working groups with multidisciplinary expertise are addressing respectively the public health aspects and the animal health and animal welfare aspects. Co-ordination between both working groups is ensured in so far as some members participate in both working groups and through a joint meeting of the respective rapporteurs. Work is at an advanced stage and the two draft reports are being submitted to the SCVPH and the SCAHAW for discussion in plenary with a view to their adoption in March.

Since the two aspects are felt to be very distinct and not overlapping the two committees proposed to the SSC to accept a separate adoption of two opinions by the SCVPH (addressing veterinary public health aspects) and the SCAHAW (addressing the animal health and animal welfare aspects).

The SSC endorsed this procedural change, but some members requested that they are kept informed on the orientations taken on this important issue. It was underlined that the intention is not to comment on the content of the two reports .

It was agreed that the chairpersons of the SCVPH and SCAHAW will provide a feedback on progress at the next plenary. SSC members requested to be provided with a copy of the opinions immediately following their adoption in order that they are aware of what will appear on the internet.

b. reports of the Chairmen of the 8 Scientific Committees.

The chairmen of Scientific Committees reported on the activities of their committees since the last SSC meeting (10-11 December 1998). A summary of their reports is given in annex 3.

A general point mentioned was the need to increase the capacity of the secretariats to provide scientific support to the committees. This would only be possible by additional staff in the secretariats.

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

The representative Directorate General VI informed the meeting of DG VI's ongoing activities related to the exploitation of the SSC opinions adopted in the course of 1998. Presently, a draft Commission Decision on hydrolysed proteins was being discussed by the Standing Committee for Animal Nutrition. The Draft Decision related to gelatine, and including the exploitation of the SSC's opinion of 26-27 March 1998, was still not adopted, awaiting an additional opinion on the safety of gelatine produced by applying a heat/pressure/time process. (See also above section 4.2.b.3.). The SSC was also informed that the procedure for the co-decision by Parliament and Council on a *Regulation laying down rules for the prevention and control of certain transmissible spongiform encephalopathies*, was following its course. The representative finally stressed that, in order to enable the Commission to update its legislation with respect to the disposal or possible recycling of condemned materials, the SSC's opinion on "fallen stock" (see section 4.2.b.1.) was now urgently needed.

8. Any other business.

- Participation of industry representatives in working group meetings

This suggestion was discussed and in principle endorsed. However, it should be clear that the industry representatives should only contribute to the fact-finding aspects but not participate in the decision making and conclusion drawing. Careful consideration and decision on a case-by-case basis was recommended by the SSC.

- Participation of members of scientific committees in industry meetings

Members were reminded that no restrictions exist with regard to the participation in meetings organised by industry etc. However, they where requested to act prudently, in particular while opinions on sensitive issues are still pending. In no case a member participating in such a meeting should allow the impression to arise that he/she speaks on behalf of the committee.

- Improving contacts to other scientific advice bodies.

The Commission asked the members to provide the secretariat with addresses and any other available information on scientific committees or similar bodies providing advice to national governments or to international organisations (WHO, FAO, OIE, ...)

The meeting ended on Friday 22 January 1998, at 13h00.

The next meeting will be held in Brussels, on 18-19 February 1999.

***Annex 1*: List of participants of the Scientific Steering Committee meeting of 21-22 January 1999**

List of presence

***Members of the SSC*:**

Prof. Georges Bories, Prof. W.Bridges (not present on 21 January 1999), Prof. F.Garrido Abellán, Prof. Michael J. Gibney, Prof. Anthony Hardy, Prof. Philip James, Prof. Keith H.Jones, Prof. Fritz H.Kemper, Prof. Werner Klein, Prof. Ib Knudsen (not present), Prof. Robert Kroes (not present on 22 January morning), Prof. Albert Osterhaus (not present), Prof. Gérard Pascal, Prof. Marcel Vanbelle, Prof. Martin Wierup (not present)

***Participants from the Commission*:**

DG III: M. Mieschendahl, O. Rothe, **DG V** H. Buchow, **DG VI** P. Colombo, T. Chalus, **DG XI** V. Matzeit, **DG XII** A. Fabre; **DG XXIV**: B.Carsin, S. Clarke, T. Daskaleros, W. De Klerck, M. de Sola, C.Diez, J.Kreysa, M. Lauridsen, G.Morrison, H. Reichenbach, A. Sanabria, J. Savio, W. Schuller, A. Somogyi, R. Vanhoorde, J. Vergnettes, P.Vossen, P. Wagstaffe, Stagiaires: S. Gonçalves

Annex 2*: *agenda of the Scientific Steering Committee Meeting of 21-22 January 1999

1. Welcome, apologies, introductory remarks, declarations of interest

2. Approval of the agenda

3. Approval of the minutes of the meeting of 10-11 December 1998

4. Work plan for the SSC

4.1. Progress on multidisciplinary matters:

a. "Considerations for the evolution of scientific advice to address emerging health issues" (Second progress report)

b. Report on the opinion adopted on 18.12.98 by the SC-Plants on "Guidance document to facilitate notifiers in the preparation of Plant GMO dossiers for consideration by the Scientific Committee on Plants".

c. Harmonisation of risk assessment procedures (progress report)

d. Resistance to antimicrobials (discussion of the progress report)

4.2. Multidisciplinary matters relating to TSE/BSE

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

b. Reports on specific issues:

Production systems and products.

b.1. "Fallen stock": The risk of infectious agents or non conventional transmissible agents entering the human food or animal feed chains via raw material from fallen stock, including environmental aspects of disposal of potentially BSE infected materials and animals (progress report).

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

b.3. Safety of gelatine: the heat/pressure process as a possible alternative (for opinion).

Human exposure risk.

b.4. Progress report.

b.5. Preliminary discussion on the Lancet paper (1999; **353**: 183-189): Hill et al., *Investigation of variant Creutzfeldt-Jacob disease and other human prion diseases with tonsil biopsy samples*.

Geographical risk.

b.6. Handbook for the assessment of geographical BSE risk (presentation of the comments received until 15 January 1999).

b.7. Preliminary report on the completeness of applications received from Members States and Third Countries for evaluation of their BSE status.

b.8. Correspondence between the Draft OIE Code on BSE (September 1998) and the SSC opinions regarding BSE (November 1997 - October 1998). - complementarity and differences.

b.9. Further discussion on criteria determining BSE-status categories, taking account of the geographical BSE-risk, the human exposure risk and the OIE recommendations.

5. Organisational matters.

6. Co-ordination:

a. Recombinant Bovine Somatotropine (BST)

b. reports of the Chairmen of the 8 Scientific Committees.

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

8. Any other business.

- Entrance permits

- Participation of industry representatives in working group meetings

Annex 3

Reports from the secretariats of Scientific Committees on the major activities and milestones since the SSC meeting of 24-25 September 1998.

Scientific Committee Food

The SCF adopted at its 114 th plenary session which took place on 9/10 December 1998 four opinions. One opinion concerns riboflavin produced by fermentation using genetically modified *Bacillus subtilis*. This opinion refers only to its use as a colouring matter authorised for use in foodstuffs. It will be used to consider the modification of the existing specifications for riboflavin as colouring matter. The second opinion adopted concerns the safety of the use of one enzyme preparation (a urease from *Lactobacillus fermentum*) in the ageing of certain wines. The Committee also adopted an additional list of monomers and additives intended to be used for the manufacture of food packaging materials. This list (the third adopted in 1998) contains the assessment of 23 substances. The SCF also adopted an opinion on the microbiological aspects of a Spanish notification of a regulation on broths, consommés, soups and creams. Besides these four opinions, the SCF clarified a sentence included in its previous opinion on algal beta carotene of 1997 in a statement in the minutes of this plenary session.

At its 115 th Plenary meeting, taken place the 20/21 January 1999, the SCF adopted two opinions. One opinion concerns the safety of caffeine, taurine and glucuronolactone as constituents of certain so called "energy" drinks. The second opinion is an evaluation of the safety of the presence of the aromatic hydrocarbons benzene, ethylbenzene, toluene, xylene and styrene in foods.

Scientific Committee on Plants

The SCP held its tenth Plenary Meeting on the 18th December 1998 adopted five opinions, three on plant protection products and two on plant GMOs. The opinions were as follows:

Plant Protection Products:

- Opinion of the SCP regarding the inclusion of aldicarb in Annex 1 to Directive 91/414/EEC concerning the placing of plant protection products on the market.

- Opinion of the SCP regarding the inclusion of flurtamone in Annex 1 to Directive 91/414/EEC concerning the placing of plant protection products on the market.

- Opinion of the SCP regarding the inclusion of spiroxamine in Annex 1 to Directive 91/414/EEC concerning the placing of plant protection products on the market

Plant GMOs: The opinions relate to Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms. The two opinions are:

- Opinion of the SCP regarding chicory derived from genetically modified male sterile, glufosinate tolerant parental lines (RM3-3, RM3-4 and RM3-6) notified by Bejo Zaden (Notification C/NL/94/25-A)

- Guidance document to facilitate notifiers in the preparation of plant GMO dossiers for consideration by the SCP

The Committee is preparing draft opinions on two plant protection products isoxaflutole and azimsulfuron for possible adoption in February.

Dossiers on two GM plants have now been released by the Commission (Modified starch potato by Amylogene and the herbicide tolerant and Bt resistant maize by Dekalb) and risk assessments are underway. An expert Working Group on Bt-resistance met on 13 January 1999 and a draft opinion is going forward for adoption in February.

Scientific Committee on Animal Nutrition (SCAN)

No plenary session were held since the last SSC meeting. However, SCAN's various working groups continued there discussions on the pending opinions under preparation.

Scientific Committee on Animal Health and Animal Welfare

The Scientific Committee on Animal Health and Animal Welfare has held the following meetings recently:

1. 15 December 1998 (Subcommittee on Animal Health): Special meeting on Foot and Mouth Disease;

2. 16 December 1998 (Scientific Committee on Animal Health and Animal Welfare): Plenary meeting. The Report on the welfare aspects of the Production of Foie Gras was adopted;

3. 08 January 1999: meeting of the Working Group on the welfare of chickens kept for meat production;

4. 13 January 1999 (Subcommittee on Animal Welfare): Special meeting on Welfare aspects of the use of BST;

5. 19 January 1999: meeting Working Group on Modification s to the technical annexes of Council Directive 64/432/EEC (tuberculosis, brucellosis and enzootuic bovine leukosis);

6. 21 January 1999: meeting Working Group on possible links between crohns disease in man and paratuberculosis in animals;

7. 22 January 1999: meeting Working Group on bacterial kidney disease in fish.

Scientific Committee Cosmetic and non-Food Products

One plenary meeting and a series of Working Parties took place, during which the following items were discussed :

1. *Alternatives to animal testing* : a special plenary meeting was organised on alternative methods to animal testing in the safety evaluation of cosmetic ingredients or mixtures of ingredients. The SCCNFP was asked by the Commission, in the framework of Council Directive 76/768/EEC on cosmetic products, to review the status of alternative methods and provide her with a report by the end of January 1999.

A series of meetings were organised during which matters were discussed with representatives of DG III, DG XI, DG XII, ECVAM as well as with representatives of the European Cosmetic Industry.

As a result, status report was prepared which was adopted during the 6 th Plenary Meeting of the SCCNFP of 20 January 1999.

2. *Hair Dyes* : the draft opinion on hydroquinone as a hair dye constituent was approved by the Working Party and addressed to the plenary for adoption.

The pending files remain a point of concern for the WP. To remedy the situation, a special task force was set up, who will go, in the first place, through all the 32 priority files identified during the previous WP meeting and will write a status report on each of them. The task force will meet for the first time from 1 to 4 February 99.

3. *Preservatives, Colorants & Fragrances* : draft opinions were approved on carbamide peroxide and on benzylhemiformal and addressed to the plenary for adoption.

The chemistry and toxicology of acrylamide/polyacrylamide was discussed with industry experts. An European review on the levels of acrylamide in the final cosmetic formulations will be done and discussions will resume on receipt of the document.

An attachment (1 st version) on the fragrance allergens document was presented, which lists 95 fragrances reported as allergens in clinical investigations and proposes criteria to classify fragrance ingredients for their allergenicity.

4. *Inventory* : the discussion on the revision of the present inventory is still on-going.

Scientific Committee for Toxicity, Ecotoxicity and the Environment

Since the SSC meeting of 10-11 December 1998, a series of CSTEE working group meetings and/or activities took place plus a CSTEE plenary meeting on the 18 th of January 1999.

A. During the January 1999 plenary meeting of the CSTEE the following opinions were adopted (with the indication of the legal framework and source of request):

1. ' ***Assessments of the risks to health and the Environment of Cadmium contained in certain products*** ' - Directive 76/769/EEC - DG III.

2. ' ***Risk of cancer caused by textiles and leather goods coloured with azo-dyes*** ' - Directive 76/769/EEC - DG III.

B. The CSTEE also considered the latest draft report on the subject ' ***Endocrine disrupting chemicals*** '. Although the draft has now reached a sufficiently mature stage for an attempt to have been made to adopt it, it was considered

preferable to let the WG chairperson put some finishing touches into it in view of a final adoption at the next CSTEE plenary (4 th of March 1999).

C. Feedback was provided by the competent Commission services on the follow up given to the previous opinions adopted by the CSTEE on:

1. ' ***Assessments of the risks to health and the Environment of Tin organic compounds*** ' - Directive 76/769/EEC - DG III.

2. ' ***Assessment of the risks posed by Pentachlorophenol (PCP) through the exposure of man and the environment to Dioxins*** ' - Directive 76/769/EEC - DG III.

3. ***'Chrysotile asbestos and substitute fibres'*** - Directive 76/769/EEC - DG III.

4. ***'Phthalates migration from soft PVC toys and child-care articles - data made available since 16 th of June 1998'*** - General Product Safety Directive (92/59/EEC) - DG XXIV

Apart from the above the following took place during the plenary:

D. (i) A presentation by the competent Commission service (DG XI/D/3) of the upcoming consultation of the CSTEE on ***'Ground level ozone'*** , with a detailed explanation of the most recent developments on this topic.

(ii) The CSTEE were informed that, contrary to what had been indicated at the previous CSTEE plenary, no consultation on ' ***Polyvinylpyrrolidone in fish food*** ' (which had triggered the setting up of a joint SCAN/CSTEE working group to address this opinion request from DG VI), would see the light of day given that the company *'International Speciality products'* had withdrawn its request the use of the substance as a binder in fish feed under Directive 70/524.

(iii) In 'compensation' the CSTEE were informed that they would in principle be involved soon, in a manner similar to the one in (ii), (joint SCAN/CSTEE WG), in a consultation on the environmental impact of copper in feed additives.

E. (iv) A presentation took place of the definitive terms of reference for the consultation of the CSTEE on ' ***Substitutes of phthalates in teething rings and other child care articles intended to be put in the mouth*** '. The CSTEE were further informed that they would receive soon a substantial documentation package on citrates (the respective list was made available as a room document).

Scientific Committee for Medicinal Products and Medical Devises

The Scientific Committee on Medicinal Products and Medical Devices had a meeting in December 1998, and discussed several subjects such as "Clinical Superiority", "Medical Devices", etc. Comments on the corresponding draft reports were made. Other subjects as "Boric acid and Benzyl Alcohol in Medicinal Products" will be further discussed in future meetings, on the basis of draft reports to be prepared by the relevant Working Groups.

***Annex 4*:**

***Evaluation of the "133°/20'/3 bars heat/pressure conditions"* for the production of gelatine regarding its equivalency with commonly used industrial gelatine production processes in terms of its capacity of inactivating/eliminating possible TSE infectivity in the raw material.**

Report and Opinion adopted by the Scientific Steering Committee at its meeting of 21-22 January 1999 (This annex has been distributed separately)

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[1] On GMO-related subjects and questions, the Scientific Committee Plants is reinforced by 3 members of the Scientific Committee Animal Nutrition and by 1 member of the Scientific Committee for Food.

[2] The SSC noted that one of the issues to be addressed would be to identify the areas where no appropriate risk assessment methodology exists. Another issue is whether certain risk assessment principles may/should vary depending upon whether the end-use of the GMO or GMO-derived products is as a food or as a feed.

[3] Letter of 22.10.98, addressed to Prof.M.Vanbelle and commenting on the opinion of 24-25 September 1998.

[4] Suggested in the framework of the activities of the Working Group "Possible Vertical Transmission of BSE".