Summary minutes of the meeting of 19-20 February 1998

1. Welcome, apologies, introductory remarks

Prof.G.Pascal, chairman, opened the meeting at 10h00. He welcomed the participants and provided apologise of Prof. A.M.S. Silva Fernandez, Prof.V.Silano and Mr.B.Carsin (Director of DGXXIV.B) who could not participate in the meeting. Prof.M.Vanbelle could not be present after 13h00 of 19 February 1998, other members had announced to arrive around lunch time of the first meeting day. The list of participants is given as annex 1.

2. Approval of the agenda

The following items were added to the agenda:

- Presentation of the opinion on the safety of slaughtering practices and methods, adopted on 17 February 1998 by the Scientific Committee Veterinary Measures relating to Public Health.

- Presentation of the opinion on Phthalate migration from soft PVC toys and child-care articles expressed on 9 February 1998 by the Scientific Committee Toxicity, Ecotoxicity and Environment.

- Discussion and possible adoption of an opinion on the revised version of the UK Date Based Export Scheme and the UK proposal on compulsory slaughter of the offspring of BSE-cases, submitted on 27.01.98 by the UK Government to the European Commission.

The revised agenda is attached as annex 2.

3. Approval of the minutes of the meeting of 22-23 January 1998

The draft minutes of the meeting of 22-23.01.98 were adopted with some changes. The main change concerned section on the safety of tallow, meat and bone meal, and gelatine. The following paragraph, common to all 3 items, should be added:

"The Scientific Steering Committee also decided that it would, in order to provide the Commission with two alternative choices, eventually submit to the Commission both the proposed approach to reduce the risk of infectivity in the final product (e.g., resulting from remaining protein impurities in tallow or gelatine) to the lowest possible level as well as the detailed (quantitative) risk analysis."

4. Multidisciplinary matters

4.1. Priority matters related to Transmissible Spongiform Encephalopathies

Preliminary remark: it was foreseen that the introduction of the draft reports and opinions and their in depth discussion would be done as separate. In reality, the discussions followed the introductions immediately. The report hereafter covers thus both items 4.1. and 4.7 of the agenda.

(a) Briefing on the follow-up given to the opinion on geographical sourcing adopted on 22-23.01.98, defining the BSE risk for specified geographical areas.

Based on the opinion of 22-23 January of the SSC, the Commission has finally decided to include an element of regionalisation into its proposal for a SRM-Decision. Members States and other countries may request derogation, based on a complete documentation that should allow to establish its epidemiological status with regard to TSEs and in particular BSE. This documentation has to be established in accordance to the 8 factors established in the January opinion of the SSC.

(b) Introduction, discussion and possible adoption of a report and opinion on the preliminary application of the "List of factors contributing to the incident and propagation risks in a geographical area" (SSC opinion of 22-23 January 1998) to EU countries that submitted an application to be considered BSE free.

The SSC was requested to adopt at its current meeting an opinion on a definitive list of information that should be provided by any country requesting derogation from the proposed SRM-Decision.

A draft list was presented, based on the list in the January opinion of the SSC and amended by some explanatory remarks requested, inter alia, by the Working Groups "Sourcing" and "Modelling" of the SSC. After addition of one paragraph, clarifying that the SSC is well aware of the ideal case character of the requested information, the opinion was finally adopted (see annex 3, pp 6-10).

In the course of the discussion, the SSC recognised the need to embark on a consistent framework for the assessment of the BSE risk, with particular emphasis on the risk for the consumer. A group of members worked in parallel to the plenary meeting and prepared a short paper which was finally adopted by the plenary as a preliminary opinion of the SSC (see annex 3, pp 2-4). It was agreed that this paper should be seen as a first step towards a consistent framework for detailed opinion concerning, for example, the question of the geographical risk or the safety of tallow, gelatine or MBM.

(c) Introduction, discussion and possible adoption of reports and opinions on the safety of tallow, meat and bone meal and gelatine.

Prof.Vanbelle, chairman of the responsible working groups presented the draft reports and opinions, which where discussed in detail and finally adopted as preliminary opinions (annex 3, pp 11-62).

As preliminary opinions they should be open until 16 March 1998 for possible comments. The TSE/BSE ad hoc group would than analyse the comments and prepare draft final opinions to be adopted at the next meeting of the Scientific Steering Committee. At the same meeting the TSE/BSE ad-hoc group should report on the comments received.

The SSC underlined the fact that these opinions follow the approach to reduce the risk of infectivity of tallow, meat and bone meal, and gelatine to the lowest possible level.

In addition to this approach the SSC requested the Working Groups to carry out more detailed risk analyses. These analyses should aim to assess the exact level of the human exposure risk depending upon:

- type of final product and infectivity reduction capacity of the production procedure;

- the geographical origin of the raw material, taking account of the incidence and propagation components of the geographical risk, as specified in the opinion of 22-23 January 1998 of the SSC;

- the type of raw material, including the age of the animals;

- the removal or not of specified risk materials.

The SSC stated its awareness of the fact that this assessment requires data that are not always available. Results of experiments on and justified estimates of the capacity to reduce infectivity of the various steps of the production process, from sourcing to marketing, have to be used, even if some experiments are still ongoing or only in a planning phase.

The SSC, however, confirmed its commitment made on 22-23 January 1998 that it would, in order to provide the Commission with two alternative choices, eventually submit to the Commission both the proposed approach to reduce the risk of infectivity in the final product (e.g., resulting from remaining protein impurities in tallow or gelatine) to the lowest possible level as well as the detailed (quantitative) risk analysis.

(e) Introduction, discussion and possible adoption of a report and opinion on the revised versions of the UK Date Based

Export Scheme and of the proposal on compulsory slaughter of the offspring of BSE-cases.

Prof.M.Wierup, rapporteur of the working group that evaluated the original proposals and the revised versions submitted by the UK in response to the Opinion of 8-9 December 1997, presented the draft opinion. The draft opinion was adopted with minor changes. The full text is given in annex 3, pp 63-64.

4.2 Genetically Modified Organisms: state of affairs of the 4 opinions adopted on 10 February 1998 regarding (1) genetically modified, insect-resistant maize, notified by the MONSANTO Company; (2) the placing on the market of glufosinate tolerant corn (*Zea mays*) transformation event T25" by the AGREVO Company; (3) genetically modified maize, notified by the NOVARTIS Company; (4) glufosinate tolerant rape seed notified by AGREVO Company.

The chairman congratulated the SC-Plants for having succeeded in handling the 4 large dossiers within such a short period and having prepared the 4 opinions earlier than expected.

The issue was raised that the reports introducing the overall safety assessments (the opinions), also addressed issues related to the possible consequences for human health of the use of these plants.

Two clarifications appeared to be needed:

- on the treatment of the aspects related to human health resulting from the possible use of GMOs as food or for human nutrition purposes, and

- on the treatment of questions related to novel feeds in attendance of the adoption of a Directive regulating the putting on the market of novel feeds.

The following approach, which basically is a clarification of the approach already adopted during the meetings of 9-10 December 1997 and 22-23 January 1998, was agreed upon:

i. Questions related to the placing on the market of GMOs according to Directive 90/220, but excluding the aspects related to human consumption, are handled by the Scientific Committee on Plants, completed with scientists from the SCs Animal Nutrition and Food.

ii. According to the Novel Food Regulation, advice regarding the safety of the use of the GMO as food or for human nutrition purposes, should be prepared by the SC-Food (leading committee) in co-operation with the SC-Plants.

iii. For the time being, and awaiting a Directive on Novel Feeds, the questions addressed to the SC-Animal Nutrition and related to the use of GMOs as or for animal nutrition should be handled in close collaboration with the SC-Food and SC-Plants.

A comment was made on the press release on the opinion of 10 February 1998 of the Scientific Committee on Plants regarding the genetically modified, glufosinate-tolerant rapeseed, notified by the AGREVO Company. It was felt that the press release was not clearly enough specifying that this opinion is clearly limited to the import of seed with the aim of processing and excludes the possible cultivation of the cultivar. This gave the impression that the seeds were approved regardless of the use that would be made of it.

The Scientific Steering Committee therefore explicitly confirmed that the opinion regarding the genetically modified, glufosinate-tolerant rapeseed notified by the AGREVO Company, adopted on 10 February 1998, only covered the import of seed with the aim of processing it and excluded the possible cultivation of the cultivar. It also confirmed that the 4 opinions on GMOs adopted 1998 by the Scientific Committee on Plants on 10 February did not cover their possible use as food or for human nutrition purposes.

The SSC finally confirmed its wish that press releases should be carefully prepared and, if possible, adopted by the concerned SC before the end of a meeting.

The SSC also expressed its wish that the SSC members should be immediately informed of the adoption of any opinion of the Scientific Committees. The SSC members could than get the complete text from the INTERNET and inform the chairman and the secretariat of the relevant Scientific Committee of possible fundamental objections or criticisms. If necessary, these can then be discussed by the Scientific Committee(s) in question.

4.3. Possible link between Johne's and Crohn's disease: state of affairs.

A working group has been set up by the Scientific Committee Animal Health and Animal Welfare (SCAHAW). It held its first meeting on 17 February 1998. The group realised the complexity of the question and several meetings of the group will be necessary to prepare an opinion for adoption by the plenary SCAHAW.

4.4. Bovine Somatotropine: state of affairs.

The Scientific Committee on Veterinary Measures relating to Public Health (SCVMPH) has set-up a working group, which will hold its first meeting on 25.03.98. It is expected that a draft opinion will be available for possible adoption in June or July.

4.5. Hormones in meat: follow-up given to the briefing and preliminary discussion held on 22-23 January 1998.

Dr.Reichenbach, Director General of DG XXIV of the Commission, provided the SSC with an up-date on the state of affairs:

On 13.02.98, the World Trade Organisation (WTO) adopted the report of the WTO Appellate Body on EC measures concerning hormones used as growth promoters in meat production. This ruling significantly modifies the earlier report of the Panel on a number of important points, as the Appellate body concluded that:

(a) the SPS requirement to base a given measure on risk assessment, means that it must be "significantly warranted or reasonably supported by" a risk assessment. This is especially relevant for WTO members who act cautiously and wish to achieve a level of sanitary protection higher than that recommended by international standards.

(b) the Panel's finding that risk assessment must be quantitative in nature and must establish a minimum magnitude of risk, can be rejected. The imposition of such a quantitative requirement was indeed found to have no basis in the SPS agreement.

(c) a risk assessment does not have to come to a monolithic conclusion reflecting the main stream of scientific opinion. The body states: "Equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources".

(d) the scientific evidence presented by the Community was relevant and showed that the hormones concerned have a carcinogenic potential.

(e) a risk assessment can include the risks arising from a failure to comply with the requirements of good veterinary practice in the administration of hormones for growth promotion purposes, as well as risks arising from difficulties of control, inspection and enforcement of requirements of good veterinary practice. According to the Appellate Body, it does also include "risk in human societies, as they actually exist, in other words, the actual potential for adverse effects on human health in real world where people live and work and die".

The Appellate Body thus considered the evidence presented by the EC in the Panel proceedings relevant. This evidence included a number of recent studies on the carcinogenicity and genotoxicity of hormones and their metabolites. According to the Appelllate Body, the only shortcoming in the EC scientific evidence was that it did not appear to be sufficiently specific. It was not focused enough on the "carcinogenic and genotoxic potential of the residues of these hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes."

On 13 March 1998, the EC will inform the WTO Panel how it wants to conform with the Panel judgement. On 28.03.98, the EC, USA and Canada are expected to agree on a delay for its implementation.

Presently, all necessary information (on carcinogenic and genotoxic effects) is being collected and additional research is being considered.

An EC group composed of all concerned Directorate Generals and of the Secretariat General has been established.

The Scientific Steering Committee will be requested to evaluate the conclusions of this group.

For the time being, the SCVMPH will be kept informed and will follow exactly what is going on, but it will not take any action.

The Scientific Steering Committee finally stressed that risk assessments should be carried out for each of the 6 hormones in question (3 natural and 3 synthetic ones), and should not be conducted for the set of 6 hormones as a whole.

4.6. Presentation of the opinion on Phthalate migration from soft PVC toys and child-care articles expressed on 9 February 1998 by the Scientific Committee Toxicity, Ecotoxicity and Environment.

On behalf of Prof.Bridges, chairman of the Scientific Committee on Toxicity, Ecotoxicity and Environment (CSTEE), who was absent and not replaced by his vice chairman, the secretary of the Committee presented the Opinion on Phthalate migration from soft PVC toys and child-care articles, expressed on 9 February 1998.

In its analysis of 6 phthalates (DINP, DNOP, DEHP, DIDP, BBP, DBP), the SCTEE applied a worst case scenario of human exposure risk by toys and childcare products, because there are currently no elements to model alternative scenarios.

The SSC commented on this use of a worst case scenario, that the opinion should be considered as very precautious. However, it agreed that this precautionary attitude might be balanced (justified) by the fact that children in reality may be exposed to several more sources of phthalates other than in toys and childcare products.

The SSC noted that, although the scientific opinions on phthalates adopted in 1996 by the Scientific Committee for Foods were considered by the CSTEE, the reference values for Non Observable Adverse Effect levels (NOAELs), applied for certain phthalates, as well as the applied safety factors were not strictly the same, because new data on carcinogenicity and reprotoxicity had been made available since then.

The SSC suggested that these different NOAEL values and safety factors should be explained and justified in order to avoid some uncertainties in the opinion of 9 February 1998. It also recommended an assessment of the total risk resulting from accumulated exposures to all possible sources (e.g., toys, the environment, food products, etc.). The Scientific Committees for Food and for Cosmetic Products and Non Food Products should be associated to that work.

The Secretary of the CSTEE announced that the CSTEE had already agreed to a new meeting of the 'Phthalates in toys' working group, probably on 20 March 1998. Members of the Scientific Committees for Food and for Cosmetic Products and Non Food Products will be invited.

In the light of its discussion on the opinion established by the SCTEE, the SSC expressed that it felt the need to actively start co-ordinating the activities of the scientific committees, in particular with regard to uniformity of risk assessment practices. An introductory discussion on this issue should be held during the next SSC meeting of 26-27 March 1998.

4.7. Discussion and possible adoption of opinions on the safety of tallow; meat and bone meal, and gelatine; a preliminary categorisation of EU regions (countries) with regard to their incident and propagation risks; and the revised version of the UK Date Based Export Scheme and of the proposal on compulsory slaughter of the offspring of BSE-cases.

See paragraph 4.1.(a) to (d) of these summary minutes.

4.8 Other matters related to TSE/BSE:

(a) Possible transmission of CJD via infected human blood and risk quantification for CJD transmission via substances of human origin;

This question was attributed to the Scientific Committee for Medicinal Products and Medical Devises. This Committee received also the mandate to monitor the present activities of the UK Spongiform Encephalopathy Advisory Committee (SEAC), which has commissioned a risk analysis study, and of the Scientific Committee for Proprietary Medicinal Products (CPMP) of the European Agency for the Evaluation of Medicinal Products (EMEA), which is preparing an position statement on New Variant CJD and plasma-derived medicinal products.

(b) Attribution to the TSE/BSE ad hoc group and/or to the appropriate scientific committee of new questions.

No new attributions were done.

(c) Presentation of the opinion on the safety of slaughtering practices and methods, adopted on 17 February 1998 by the Scientific Committee Veterinary Measures relating to Public Health.

The report and opinion were presented by Prof.A.Osterhaus, chairman of the SCVMPH. They were noted by the SSC without further discussion.

5. Organisation of the Scientific Steering Committee

This item was referred to the next meeting of the SSC.

6. Co-ordination matters

6.1. Reports by the chairpersons of the 8 Scientific Committees

(a) The Scientific Committee Animal Nutrition (SCAN).

Prof.Bories, chairman of SCAN, reported that two plenary sessions had been held since November and several working groups have been formed. Major items on the present agenda relate to the Directive on Additives in Animal Nutrition and the issue of antimicrobial resistance.

A short discussion was held on the possible effects of feed additives on the quality of food and on the environment, especially if they were released, be it in very small amounts. The SSC agreed that, for the handling of scientific questions related to such effects, the SC Food and the SC Toxicity, Ecotoxicity and Environment should be involved.

Regarding the handling of questions related to novel feeds, addressed to the SCAN, the SSC confirmed that, awaiting a Directive on Novel Feeds, the questions related to the use of GMOs as or for animal nutrition should be handled in close collaboration with the SC-Food and SC-Plants.

(b) The Scientific Committee Medicinal Products and Medical Devises (SC-MPMD).

Prof.K.Jones, chairman, reported on the activities of the Committee. The main items presently on the agenda, include:

- analysis of the draft opinions on the safety of tallow and of gelatine prepared in the framework of the TSE/BSE ad hoc group;

- the provision of guidance on good manufacturing practices for starting products;

- definition of the notions "equivalence" and "superiority" of a medicinal product;

- safety of colouring agents;

- guidelines on specified risk materials in medicinal products and medical devices;

- the equivalence of alternative products for materials from bovine origin;

- the risk of transmission of Creutzfeldt-Jacob Disease via blood and blood products.

On all these issues, working groups had been established.

(c) The Scientific Committee Animal Health and Animal Welfare (SC-AHAW).

Dr.Garrido, chairman, reported on the activities of the Committee since the last SSC meeting: No plenary session took place but several working group meetings had been held. These working group meetings covered the following questions:

- emergency vaccination against Foot and Mouth Disease;

- developments in research and diagnosis of Swine Vesicular Disease;

- criteria for funding of eradication programmes of scrapie;

- the possible link between Johne's disease in animals and Crohn's disease in man;

- the definition of Newcastle Disease.

On the latter question, an opinion was expected to be ready for adoption at the plenary meeting of March 1998.

(d) The Scientific Committee Cosmetic Products and Non Food Products (SC-CPNFP).

Prof.F.Kemper, chairman, reported that the plenary meeting of January 1998 has adopted opinions on 15 products out of the long list of specific substances which require an opinion.

He stressed that, for the treatment of questions related to non-food products, a collaboration with the Scientific Committee for Medicinal Products and Medical Devices needs to be established.

Prof.Kemper finally elaborated briefly on the issue of alternatives for conventional animal experiments, which is a priority on the agenda of the SC-CPNFP.

(e) The Scientific Committee for Food (SCF).

Prof.I.Kundsen, chairman, reported on the plenary session of the SCF of January 1998 and on the themes covered by the various working groups that have been set up.

He also presented the long list of pending questions for the SCF. This list includes:

- food additives,

- contaminants,

- materials in contact with food,

- novel foods and derived products,

- antimicrobial resistance

- baby and infant nutrition,

- dietetic foods,

- intake and exposure modelling,

- chemically derived flavouring substances,

- dietary copper in calve feed,

- evaluation of dossiers on Food Irradiation,

- pesticides in baby food, etc.

He stressed that the capacity of the SC-F to address all these questions was not large enough. For example, the list of flavouring substances to be evaluated within the coming 6 years consists of 2.500 substances.

Prof.Knudsen informed the SSC that the SCF had agreed that it would not re-address question in detail that had already been treated by another international Scientific Committee (for example the Joint FAO/WHO Meeting on Pesticide Residues). Given the long list of pending questions and the corresponding workload, it would limit itself to a scientific evaluation of the consequences of such opinion. The Scientific Steering Committee endorsed this approach.

He further elaborated on the "principles and terminology of risk analysis" which were presently being defined by the Codex. This activity should eventually result in the development of a risk assessment approach itself.

The SCF also intends to make an inventory of existing intake and exposure models, to assess how they possibly complement each other and to look into the possibility of streamlining all these models.

The Scientific Steering Committee agreed that both domains (risk assessment models; intake and exposure models) were of general interest for all Scientific Committees. A harmonisation of methods in both fields and across the various Scientific Committees would be advisable.

It further agreed that this exercise should not be limited to these two fields, but that it should be extended to the general principles and methods to be followed when carrying risk assessments. Examples, mentioned with regard to harmonisation needs, included standard and reference values used in toxicological evaluations.

Regarding antimicrobial resistance, it was made clear that the importance of this issue was not limited to the SCF, but that it also concerns the SCMPMD, SCAN, SCTEE and other Scientific Committees. The SSC therefore considered that the issue of antimicrobial resistance was a priority item to be co-ordinated. The SSC felt that it should decide how and where the question itself of antimicrobial resistance should be handled. Possible options discussed where (a) one leading Scientific Committee enlarged with scientists from other Committees, or (b) a working group composed of members from several SCs, directly reporting to the SSC.

(f) Scientific Committee Veterinary Measures relating to Public Health (SC-VMPH).

Prof.A.Osterhaus, chairman, presented an overview of the activities of the SC-VMPH and elaborated on the opinion on the safety of slaughtering practices and methods, adopted by the SCVMPH on 17 February 1998 (see point 4.8.c of these minutes).

(g) Scientific Committees on Plants and on Toxicity, Ecotoxicity and Environment

Due to the absence of the chairmen of these two Committees, the respective Secretaries had to report on their activities.

The SCPlants focussed mainly on the opinions on Genetically Modified Plants (see above).

The SCTEE created the following working groups:

- **'Tin , Arsenic and Cadmium'** (first meeting: 16 March 98). Source: Opinion request from DG III to comment on a report commissioned to WS Watkins International Ltd. on the purported risks of these chemicals to human health and the environment.

- **'Pentachlorophenol'** (first meeting: 30 March 98). Source: Same as above in respect of this chemical but consultant is the firm 'Environmental Resources Management'.

- **'Water framework directive'** (first meeting: 10 March 98). Source: Opinion requested following interservice consultation carried out by DG XI on the upcoming changes to be proposed by the Commission on the Directive.

- **'Endocrine disrupters'** (first meeting: 20 March 98). Source: DG XXIV following an initiative of the CSTEE.

6.2. Allocation of multidisciplinary matters which do not concern TSEs to scientific committees.

- The safety of devices emitting electromagnetic waves such as portable telephones.

It was noted that a number of Member States and research bodies did already conduct studies to assess the safety of such devices. As a first step, an inventory would therefore be made of the existing publications and ongoing research on the basis of which Prof. Klein accepted to prepare an initial report presenting the state of affairs. Prof Kemper, Prof.Kroes, Prof. Knudsen and the SSC secretariat agreed to send to Prof.Klein any scientific and technical material they had already on this issue. If necessary, the issue would then further be taken up by the Scientific Committee Toxicity, Ecotoxicity and Environment (CSTEE) which would become the leading committee. When treating the question, this committee should be reinforced with scientists, including epidemiologists, from the SC-Medicinal Products and Medical devises and possibly from the Scientific Committee Cosmetic Products and Non Food Products.

7. Information by the Commission services

This item was not addressed

8. Any other business

- **Request from ECPI for a SSC member to participate in the 4-5.06.98 conference on Practical Strategies for Finding the TSE Solution**: The SSC accepted the principle that the committee should participate in this initiative and unanimously proposed Prof.K.Jones to represent the Scientific Steering Committee. Prof. Jones accepted.

- **Proposal of the Danish Renderers to include a specialised expert into the working group "Safety of MBM and Fur Animals":** The SSC expressed its opinion that the Scientific Committees should identify members of working groups. It is not up to external bodies to propose possible additional members. The procedure for the identification and appointment of members of Woking Groups should be described in the rules of procedure of the Scientific Committees. These should also specify the conditions of such membership regarding neutrality and independence.

- The SSC asked the Secretariat to prepare, as an internal document and for their own management, an "action plan", listing the actions agreed upon during a meeting as well as persons, Scientific Committees or services to whom the action was conferred. Where relevant, a time schedule should be added.

The other items of the agenda were referred to a next meeting .

The meeting ended on Friday 20 February at 17h30.

Annex 1: List of participants of the Scientific Steering Committee meeting of 19-20 February 1998

List of presence

Members of the SSC:

- Prof. Georges Bories (from afternoon of 19.2.98 onwards)

- Prof. W.Bridges (19 February only)

- Prof. F.Garrido-Abellàn (from afternoon of 19.2.98 onwards)

- Prof. Michael J. Gibney (from afternoon of 19.2.98 onwards)

- Prof. Philip James

- Prof. Keith H.Jones

- Prof. Fritz H.Kemper

- Prof. Werner Klein

- Prof. Ib Knudsen

- Prof. Robert Kroes

- Prof. Albert Osterhaus,

- Prof. Gérard Pascal

- Prof. Marcel Vanbelle (morning of 19 February only)

- Prof. Martin Wierup

Participants from the Commission:

DGIII: O.Rohte (19 Feb.), L.Bansil, J-P. Feyaerts, P. Roza (20 Feb.),

DGVI: P.Colombo, J.Perez-Lanzac

DGXII: B.Hansen, X.Goenaga, M. Vidal, L. Matthiessen (20 Feb.)

DGXV: A.Matton

DGXXIV: H.Reichenbach, J.Costa-David, T. Daskaleros, C.Deckart, W.De Klerck, M.de Sola, C.Diez Ubierna, T. Emmerling, G. Evrard, J.Kreysa, M. Lauridsen, G.Morrison, J.Moynagh, J-J.Rateau, A.Sanabria, A.Van Elst, P.Vossen, M. Zampaglione.

Annex 2.

Agenda of the Scientific Steering Committee (SSC) meeting of 19-20 February 1998

1. Welcome, apologies, introductory remarks

2. Approval of the agenda

3. Approval of the minutes of the meeting of 22-23 January 1998

4. Multidisciplinary matters

4.1.. Priority matters related to Transmissible Spongiform Encephalopathies

a) Briefing on the follow-up given to the opinion on geographical sourcing adopted on 22-23.01.98, defining the BSE risk for specified geographical areas.

b) Introduction (without discussion) of the reports and draft opinions on

- The preliminary application of the "List of factors contributing to the incident and propagation risks in a geographical area" (SSC opinion of 22-23 January 1998) to EU countries that submitted an application to be considered BSE free;

- Safety of tallow;

- Safety of meat and bone meal;

- Safety of gelatine;

4.2. Genetically Modified Organisms:

- Three genetically modified maize varieties and on one genetically modified winter rape seed variety: state of affairs;

4.3. Possible link between Johne's and Crohn's disease: state of affairs (report by the chairman of the Scientific Committee Animal health and Animal Welfare)

4.4. Bovine Somatotropine: state of affairs (report by the chairman of the Scientific Committee on Veterinary Measures relating to Public Health).

4.5. Hormones in meat: follow-up given to the briefing and preliminary discussion held on 22-23 January 1998.

4.6. Presentation of the opinion on Phthalate migration from soft PVC toys and child-care articles expressed on 9 February 1998 by the Scientific Committee Toxicity, Ecotoxicity and Environment.

4.7. Discussion and possible adoption of opinions on:

- Safety of tallow;

- Safety of meat and bone meal;

- Safety of gelatine;

- A preliminary categorisation of EU regions (countries) with regard to their incident and propagation risks.

- the revised version of the UK Date Based Export Scheme and of the proposal on compulsory slaughter of the offspring of BSE-cases.

4.8. Other matters related to TSE/BSE:

- Possible transmission of CJD via infected human blood and risk quantification for CJD transmission via substances of human origin;

- Attribution to the TSE/BSE ad hoc group and/or to the appropriate scientific committee of new questions. (See the attached list of questions)

- Presentation of the opinion on the safety of slaughtering practices and methods, adopted on 17 February 1998 by the Scientific Committee Veterinary Measures relating to Public Health.

5. Organisation of the Scientific Steering Committee

5.1. TSE/BSE *ad hoc* group:

- Tasks and functioning of the ad-hoc group: report by the chairman of the TSE/BSE ad hoc group on the organisation and planning of its activities.

- Mandate and composition of the TSE/BSE *ad hoc* group.

5.2. Organisation of the Scientific Steering Committee

- Internal rules of procedure for the SSC; co-ordination aspects related to the internal rules of procedure for the scientific committees.

5.3. Introduction and short discussion on the relationship between risk assessment and risk management.

5.4. Introduction and short discussion on the definition of acceptable risk levels.

6. Co-ordination matters

6.1. Reports by the chairpersons of the 8 Scientific Committees;

6.2. Presentation of the opinion on Phthalate migration from soft PVC toys and child-care articles expressed on 9 February 1998 by the Scientific Committee Toxicity, Ecotoxicity and Environment.

6.3. Allocation of multidisciplinary matters which do not concern TSEs to scientific committees:

- The safety of devices emitting electromagnetic waves such as portable telephones.

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

8. Any other business.

- Request from ECPI for a SSC member to participate in the 4-5.06.98 conference on Practical Strategies for Finding the TSE Solution.

- Request from the Danish Renderers related to the working group "Safety of MBM and Fur Animals".

UPDATE

Pending matters to be treated by the TSE/BSE (as of 19.02.98)

The SSC is requested to deliver or initiate scientific advice on:

(1) Safety of products (food and non-food) derived from animal material:

(a) Gelatine

(b) Feeding of MBM to fur animals

(c) Peptides and amino acids

(d) Bi-calcium phosphate

(e) Organic fertilisers

(2) TSE/BSE/Scrapie status of a country or region:

(a) Risk assessment method(s) and geographical aspects of the risk

(b) List of criteria ("compliance matrix") needed for the evaluation of the TSE status of a country.

(c) Request from Finland, to receive the status of scrapie- and BSE-free country;

(d) Request from Denmark, to receive the status of BSE-free country;

(e) Request from Sweden, to receive the status of BSE-free country;

(f) Request from Germany, to receive the status of BSE-free country;

(g) Claim from Canada to be BSE free;

(h) Request from Argentina, to receive the status of BSE-free country;

(i) Request from USA to re-assess application

(j) Request from Austria, to receive the status of BSE-free country;

(3) Semen and embryos: updated opinion

(4) Transmission of CJD via infected human blood; Risk quantification for CJD transmission via substances of human origin; (NOTE: not to be restricted to nv-CJD)

(5) Safety of bovine blood and blood products;

(6) Quantitative ranking of Specified risk materials according to their potential infectivity.

(7) Animal-derived rennet

(a) Need for carrying out a risk assessment and transmission studies

(8) Disposal of animals and animal tissues (SRM) assumed to carry a risk of being infected with BSE:

(a) plan proposed by UTG and submitted via the E.P.

(b) environmental impact of several possible methods of disposal

(c) the use of BSE infected cattle waste as combustible in power stations

(9) Maternal transmission

(a) Routes of infection

(b) Risk assessment for these routes

(c) Options to mitigate the risk from these routes

(10) Scrapie infectivity of peripheral nerves of sheep: implications in a BSE context

(11) The use of specified risk materials for the manufacture of implantable medical devises;

(12) Equivalency of alternative products for the use of intestine of animal origin for surgical sutures;

(13) the guarantees provided by 'closed herds' as compared to 'BSE free regions'.

(14) Culling strategies: should herds where a clinical case was detected, but where it is clear that the animal was infected in another herd, be culled?

(15) Organophosphates: review of the opinion of the MDSC of 1997

(16) Safety of slaughter practices and methods; risk to spread BSE infectivity through cross contamination of different tissues by using (pneumatic) stunners during the slaughtering process of cattle.

(17) Intraspecies recycling of fish, pig and poultry waste and meat and bone meal. (See letter N° 03690 of DGVI of 21.01.98)

(18) Monitoring of the research carried out by the Joint Research Centre on (a) the validation of a test to determine whether animal meal has received a correct heat treatment (20 minutes, 133°C) and (b) the detection of the presence of bovine mitochondrial DNA in feeding stuff containing less than 0.125% of bovine derived meat and bone meals.

Issues which might lead to questions in the near future

(1) Milk: review of the opinion of the Scientific Veterinary Committee of 1996 and of the MDSC of 1997

(2) Safety of Xenotransplants

(3) Evaluation of (so far) two methods for the post-mortem diagnosis of modified prions and of BSE infectivity.

(4) Acceptable minimum levels of cross-contamination in MBM.

(5) Protection against the risk of infectious agents or non conventional transmissible agents entering the human food or animal feed chains via raw material (for example as dead animals, condemned carcasses, sick animals, laboratory animals).

Annex 3 to the minutes of the Scientific Steering Committee of 19-20 February 1998.

(Distributed separately)

Opinions adopted by the Scientific Steering Committee at its meeting of 19-20 February 1998

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