Scientific Steering Committee

Minutes of the Meeting of 10 - 11 December 1998

1. Welcome, apologies, introductory remarks

Prof.Dr.Pascal welcomed the participants, especially Prof.Dr.T.Hardy, new chairman of the Scientific Committee Plants. Apologies were received from Prof.Dr.I.Knudsen, Prof.Dr.R.Kroes and Prof.Dr.A.Osterhaus (for 11.12.98). The list of participants is attached as annex 1.

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 22-23 October 1998.

The draft minutes of the meeting of 22-23 October 1998 were approved without changes.

4. Work plan for the SSC

The SSC members discussed the heavy workload resulting from their membership in the SSC and, for the chairmen, in a SC. They underlined that the members of all scientific committees experience similar workloads. This workload results, inter alia, in delays in the preparation of scientific reports and opinions. The members made clear that the personal investment in the work of the scientific committees has to be combined with a full time, often leading job in their respective home institutions, and that this sometimes leads to conflicting situations in their day-to-day professional life. It was brought to the attention of the committee that some members spend up to 30% of their working hours for SSC-related activities. Such an commitment is unbearable, in particular for independent experts without institutional support.

The SSC also made clear that they are well aware that the secretariats of all SCs (including the one of the SSC) are overloaded because too many questions need to be addressed at the same time with short delays. It therefore cannot be expected that the secretariats could provide any additional support without increase in resources. The request for additional resources was supported by the information that similar committees at national or international level have normally more resources at their disposal. Examples for additional support which could be provided from scientific secretariats included compilation of literature and preparation of literature reviews, and drafting of working documents and of detailed minutes of working group meetings as basis of scientific reports and draft opinions.

The SSC considered the present system needed to be revised. Reference was made to the statements of Commissioner Fischler at the recent BSE-conference in Brussels with regard to an agency and interest was expressed to be involved, as SSC, in discussions on this or similar reflections as to the future scientific advise system of the European Commission. A discussion with the Commission on this issue was felt to be urgently needed.

It was proposed that the Commission, would write to the hierarchical superiors of the members. In that letter the situation should be explained and the enormous amount of work already realised by the Scientific Committees be acknowledged. The essential position of the Scientific Committees in Consumer protection policy making at European level should be stressed and concrete statements as to the future development of the workload of the members should be made. If possible an approximate date should be

indicated as from when it is expected that the workload will decrease or additional resources could be made available for supporting the scientific committees.

The Commission expressed its sympathy with the position of the members of the scientific committees and in particular the SSC. It agreed that sustainable solutions have to be found within the next 8 to 12 months and invited members to participate in a brainstorming on possible solutions. A letter to the hierarchical superiors was promised.

4.1. Progress on multidisciplinary matters:

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

Prof.Dr.W.Klein, rapporteur of the Working Group reported on the meeting of 9 December 1998. The issues to be covered by the mandate of this WG (chairman: Prof.G.Pascal) are:

- How to deal with uncertainties and with emerging hazards in risk assessment, including factors perceived by the public or part of the scientific world as a hazard but not yet "officially" recognised as such. (e.g.: long term dispersion of GMOs in the environment, possibly at continental scale, over large distances; potential for cross-fertilisation of GMOs, allergies linked to GMOs, …).
- How to deal with factors perceived by the public as a risk, without necessarily being one.
- How to link the above with the application of the precautionary principle.
- How to communicate to the general public the mechanism and the process of the establishment of a scientific opinion, indicating also the uncertainties, the possible non-availability of hard scientific evidence, the assumptions made, the building of consensus, etc.

Risk assessment of GMOs will be taken as a case study. 3 steps will be followed:

a) Listing of already identifiable major gaps (missing criteria) in the risk assessment, on the basis of the 1998 experience of the SC-Plants with 12 GMO Dossiers.

b) Inventory of ongoing (national or EU funded) research in the field of risk assessment (with special emphasis on environmental aspects).

c) Proposal of amendments to the check- lists of criteria for risk assessment and to the content of application dossiers.

In the discussion it was mentioned that the SC-Plants is presently finalising an opinion entitled: "Guidance document to facilitate notifiers in the preparation of Plant GMO dossiers for consideration by the Scientific Committee on Plants". The opinion should be adopted on 18.12.98 by the SC-Plants. It is meant to be a helpful guidance to industry for the preparation of application dossiers but not a binding regulation. The opinion will be presented to the SSC at its next meeting.

Reference was made to a UK committee currently preparing a paper on the issue at stake and the secretariat was asked to get a copy of that paper as input to the work of the working group.

As a general orientation it was stated that the SSC should clearly demonstrate its open-mindness and ability to cope with uncertainties, if necessary by identifying research needs to close the most important gaps in knowledge.

The importance of defining the precautionary principle and its application in case of emerging hazards was underlined and the relevance of taking account of the sustainability concept was mentioned.

b. Harmonisation of risk assessment procedures (progress report)

No further progress on this subject has been made. The chairmen of the working group (Prof.Bridges and Prof.Kroes) have not yet received the information paper on risk assessment methodologies currently applied in the different Scientific Committees which should have been submitted before the end of November. As a meeting is planned for the end of January 1999, the papers should be submitted to the secretariat before January the 15th at the latest.

c. Resistance to antimicrobials (progress report)

Prof.Dr.K.Jones, chairman of the working group, reported that the group finished a first draft scientific report. It is based on more than 150 scientific publications. Four main sources of resistance against anti-microbials are addressed: human clinical medicine (including in hospitals), veterinary clinical medicine, animal feed additives and plant protection products. However, the draft needs further discussion and editing. Once this will have been done, an orientation document will be distilled from it and discussed by the SSC at its meeting of 21-22 January 1999. A final opinion can be expected for April 1999.

Remark:

The SSC discussed also the proposed ban by the EC of 4 anti-microbials. (Bacitracine Zinc, Virginiamycine, Tylosine, Spiramycine – for the last 3 ones, a scientific opinion prepared by SCAN, is available). (The proposed ban was discussed on 1 and 11 December 1998 in the Permanent Committee for Animal Nutrition; it is planned to be discussed by the Council on 14 and 15 December 1998.)

The proposal was discussed and it was recognised that, whereas the Scientific Committees concentrate on risk assessment, the Commission can take other aspects in consideration, such as socio-economical ones, when deciding on risk management.

The SSC felt nevertheless that the scientific advice available on these substances offered a more balanced view of arguments pro and contra a possible ban. If this would be confirmed, the SSC would feel that this posed an ethical problem of the use of scientific evidence in decision making. In order to verify the matter, the chairman of the SCAN was asked to carry out a detailed comparison of the content of the SCAN opinions with the Commission's press release and the recitals of the Decision Proposal. . He should report on his findings at the next SSC-meeting. The chairmen of all committees where also asked to report on similar experiences, if existing.

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, reported on the activities of the Group since last meeting. He pointed to the list of pending questions, which should be addressed in 1999, as well as to the tentative planning for the adoption of opinions. Both documents where handed out to the SSC-members.

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

This question is of an horizontal nature and extremely complex as it is not limited to TSEs but also covers conventional infectious agents and toxic and undesirable substances. The Working Group installed by the TSE/BSE *ad hoc* Group has been intensively working on the issue since June 1998. However, according as progress is made and draft reports are submitted to the SSC, the mandate is further broadened. Now it includes also rendering and disposal of non-mammalian animals and products, the risks associated with various ways of disposal (incineration, burning for fuel, burial, landfill, bio-gas production, composting) and the risks that may result from the possible (if any) "silent" presence of TSE infectivity in animal species that are considered free of TSE (e.g., fish).

An opinion is therefore not expected before March 1999.

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

A draft scientific report will be discussed by the WG on 15 December. If adopted, a draft opinion may be available for adoption in January 1999.

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

The SSC was informed that new and recent information on the inactivation of TSE agents during the process became available, requiring an additional discussion within the working group. An opinion is now expected for January 1999.

b.4. Safety of gelatine (updated opinion and report from the TSE/BSE ad hoc Group)

The SSC agreed that bovine hides from healthy animals, can be considered as safe for the production of gelatine. The Gelatine opinion of 27.03.98 was therefore amended and put in line with the Opinion on the Safety of Hydrolysed Proteins adopted on 23.10.98. (The original gelatine opinion requested that hides should be derived from animals fit for human consumption, that had undergone a pre- and a post-mortem inspection. As long as no validated post-mortem tests for BSE infectivity are available, the condition of a post-mortem inspection does not add any additional safety. Moreover, hides can not be traced back to the individual animals in a slaughtered batch.).

The opinion will be made available on Internet in January 1999, when also the final opinion on the above heat/pressure will have been adopted and integrated in an updated overall Opinion on the Safety of gelatine (with respect to BSE).

b.5. Update of the opinion on the safety of tallow, adopted on 27.03.98.

Minor changes were introduced in the scientific report attached to the opinion. The opinion itself remains unchanged. The new report will be made available on internet.

b.6. " Appropriate heat treatment of animal meal" progress report and preliminary results of the validation study carried out by the Joint Research Centre.

The results of a validation study of an analytical method for the proof of the appropriate heat treatment of animal meal according to the decision 96/449 EEC has

been presented by C. von Holst (Joint Research Centre of the European Commission Ispra, Italy). Animal meal is an important ingredient of compound feed for non-ruminants. However, specific conditions for the production of the animal meal have to be fulfilled since the causative agent of BSE is supposed to be inactivated if the animal material is treated for 20 minutes at 133^0C and 3 bar.

A commercially available Enzyme Linked Immuno Sorbent Assay (ELISA) test kit for the identification of pork in cooked meat has been used in this study. The general applicability of this kit to the specific purpose of the control of the proper heat treatment of animal meal bases on the fact that animal meal is a mixture produced from animal species like cows pigs, poultry and sheep. Therefore the result of the analysis of an animal meal sample using the ELISA kit is expected to be positive. However, it was demonstrated that the response of this test depends strongly on the temperature of the heat treatment of the pork (Hoffman et al. 1995) which is indicated by a significant lost of sensitivity of the test if the heat treatment took place at 133^0C. Therefore a negative response of the analysis confirms a proper heat treatment of the animal meal.

In the current validation study the participants were provided with four animal meal samples produced in an animal waste rendering plant employing different temperatures of the sterilisation process.

21 laboratories from 12 European countries participated in the validation study and delivered results on time thus demonstrating that the method can be employed in all Member States of the EU.

The results confirms a low variability of the data (standard deviation is about 20 %). Moreover the outstanding sensitivity of the kit allows for an unambiguous differentiation of animal meals produced under slight different conditions of the production.

Therefore it can be concluded that ELISA method may be a reliable method for the surveillance of the appropriate heat treatment of animal meals.

The SSC will re-discuss the results once it has received the complete version of final report.

b.7. Progress report and schedule of the Working Group on Human Exposure Risk.

The WG-HER has embarked on the assessment of the potential risks resulting from the consumption of bovine derived foodstuff such as beef or other directly eaten bovine tissues, meat products that could contain mechanically recovered meat, gelatine, or tallow.

The WG-HER first tried to carry out a detailed analysis of the production and consumption of these foodstuffs but had to recognise that it would be impossible/unrealistic to carry out such an exercise for all Member States. The required data on production methods and on consumption patterns are not available.

The WG-HER has therefore decided to try to prepare a set of realistic scenarios describing the distribution of one normally processed bovine via different foodstuffs to human consumers of the food. It became clear that batch size of products is a key variable for spreading material from one animal over a large number of servings and hence persons. If BSE-infective material would enter such a batch, rather large numbers of persons could be exposed to small or extremely small doses of the BSE-agent.

In view of these preliminary reflections the SSC underlined the need to address the significance of such low-level exposure with regard to human health and invited the WG-HER to cover this aspect in the draft pre-opinion scheduled for the next meeting of the SSC.

b.8. Handbook for the assessment of geographical BSE risk (possible pre-opinion, open for comments until 15 January 1999).

Following a request of the chairman, the secretariat presented the principles underlying the proposed methodology for the assessment of the geographical BSE-risk as described in the "Handbook". This presentation was regarded to contribute significantly to the clarity of the whole exercise and the secretariat was asked to integrate it into the pre-opinion on a method for the assessment of the geographical BSE-risk.

On condition that this was done, and other remarks of the SSC also been taken appropriately into account, the SSC agreed that the preliminary-opinion (see annex 4) on a method to assess the geographical BSE-Risk of countries or regions", including the detailed "handbook for the assessment of the geographical BSE risk" will be

- send out to the Member States, and
- put on the Internet

for comments until 15 January 1999.

The comments received will be discussed at the next meeting of the SSC (21/22 January) and a final opinion, including a final version of the "handbook" should be adopted at the February 1999 meeting of the SSC, taking due account of the comments received.

b.9 Comparison of the draft proposal for a revised OIE Code on BSE and the existing SSC opinions: compatibility and conflict.

A discussion document on the comparison between the draft revised OIE Code on BSE and the 1998 opinions of the SSC, was discussed and partly revised. The secretariat was asked to finalise the document in accordance to the remarks made by the SSC. This finalised version should be adopted by written procedure (response from members requested for 18.12.98 at the latest) and will be attached as an annex to the minutes of the present meeting (see Annax 6). It will be sent to the OIE-secretariat for information and comments. At its January meeting the SSC will decide on the use to be made from this document, taking due account of the comments received from the OIE secretariat.

b.10. Schedule for the assessment of the geographical BSE-risk and the preparation of an opinion on the BSE-status of Member States and Third Countries.

The indicative schedule provided in annex 5 was proposed by the secretariat and accepted by the SSC.

b.11 Discussion on criteria determining BSE-status categories, taking account of the geographical BSE-risk, the human exposure risk and the OIE recommendations.

Some SSC members expressed their concern regarding the demand that the SSC should determine the BSE-Status of countries because the allocating a BSE-Status has to take account other than scientific aspects and is hence more policy than science. According to them, this would be the responsibility of the Commission. The

SSC should only be involved in the methodological aspects and, at most, provide a classification solely based on the propagation and incident risk.

General concern was expressed as to taking into account of the human exposure risk for the status determination but a general scheme, included into the opinion on a method for the assessment of the geographical BSE-risk was accepted by the SSC. In the context of the discussion it was stated that the geographical BSE-risk represents the animal side of the issue. The BSE-Status of a country should, however, also take into account the importance of geographical BSE-Risk for the human side. Hence the Human Exposure Risk has to be integrated into the status allocation.

The TSE/BSE ad-hoc group, respectively the WG-"Sourcing" should work along this line and report at the next meeting of the SSC.

c. The EU conference on food security: lessons from the BSE crisis (report of the conference held in Brussels on 30 November and 1 December 1998).

Mr Rateau (DGXXIV) thanked all the members of the SSC for their attendance at the Conference on Food Security which took place on 30 November and 1 December and in particular Prof. Pascal, Dr. James and Dr. Gibney for their active participation as speakers at the conference.

The conference turned out to be a good success with a large participation of people. In particular, the organisation of the debates between the different groups of interest worked very well.

Furthermore, Mr Rateau underlined that this event could be considered as a positive response of the Commission to the demand made by the EP to make the point on the results of all the work that has been realised to date concerning the BSE problem and the food security in general.

It has been stated by Ms Bonino at the conference that it is important to continue in making efforts in the field of security and research. In addition, since the pressure and the interest on BSE is getting lower, it is likely that at present the Commission will follow other subjects with as much attention as for the BSE related matters.

d. New issues:

The Scientific Steering Committee was informed about an article which appeared in the American Journal of Pathology (Vol.153, N°5, November 1998) on *Human keratinocytes expressing cellular prion-related proteins in Vitro and during inflammatory skin diseases*. However, for the time being the SSC sees no reason to change its opinion regarding the safety of hides and skins. The presence of prion-like proteins in skin cells is a known fact and their increase in concentration in inflammated skin tissues is normal. The paper will be sent for possible further comments to the Scientific Committees medicinal Products and Medical Devises, to the SC-Cosmetic and Non-Food Products and to the TSE/BSE ad hoc Group. They will, if necessary, report back to the SSC.

6. Organisational matters

The proposed meeting days of the SSC until September 2000 were presented and agreed upon. They are attached as annex 5.

7. Co-ordination: 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 (22-23 September 1998). A summary of their reports is given in annex 3.

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

Mr.O.Rohte (DGIII) informed the SSC on the recent developments in the context of the scientific co-operation in food.

9. Any other business:

- Letter from the University of Leuven (B)

  A letter was received from a PhD researcher of the University of Leuven (B), asking (amongst others) whether SSC members could be interviewed on the role of scientific advice in the legislative process on consumer protection matters. Whilst the SSC was sympathetic to the subject, the members nevertheless stressed that their workload did not permit them to attend to such individual requests, which are numerous. Therefore, the SSC secretariat was invited to provide the PhD student with the relevant information. In addition, each individual SSC member could decide for himself whether he would contribute to the study. Prof.Dr.M.Gibney declared that he accepted to give an interview and to discuss with the student, at a suitable moment (e.g. in the margin of a meeting in Brussels).

- SEAC's note on Dorsal Root Ganglia

  The November 1998 Report to Ministers of the UK Spongiform Encephalopathy Advisory Committee (SEAC), providing a review of infectivity in bone marrow and dorsal root ganglia in cattle infected with BSE, was provided to the SSC members. The report was not discussed. It should be taken into account by the Working Groups "Safety of Products", which also handles the questions of safety of bones.

The meeting ended on Friday 11 December 1998, at 13h00.

The next meeting will be held in Brussels, on 21 and 22 January 1999.

Annex 1: List of participants of the Scientific Steering Committee meeting of 10-11(morning) December 1998

List of presence

Members of the SSC:

- Prof. Georges Bories
- Prof. W.Bridges (not present on 10 December 1998 morning)
- 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)
- Prof. Albert Osterhaus (not present on 11 December 1998 morning)
- Prof. Gérard Pascal
- Prof. Marcel Vanbelle
- Prof. Martin Wierup

Participants from the Commission:

DG III: M. Mieschendahl, O. Rothe

DG VI P. Colombo, T. Chalus, J. Pérez-Lanzac

DG XI V. Matzeit

CCR Von Holst

DG XXIV: B.Carsin, J.J. Rateau, W. De Klerck, C. Cox, C.Diez, F. Drion, J.Kreysa, M. Lauridsen, G.Morrison, W. Schuller, E. Thevenard, A. Van Elst, R. Vanhoorde, J. Vergnettes, P.Vossen, M. Walsh, M. Zampaglione

Stagiaires: S. Gonçalves, N. Huyghe, H. Vanhoutte

Annex 2: agenda of the Scientific Steering Committee Meeting of 10 - 11 December 1998

1. Welcome, apologies, introductory remarks
2. Approval of the agenda
3. Approval of the minutes of the meeting of 22-23 October 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". (Progress report)

b. Harmonisation of risk assessment procedures (progress report)

c. Resistance to antimicrobials (Orientation report for discussion and adoption)

4.2. Multidisciplinary matters relating to TSE/BSE

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

b. Reports on specific issues:

Production systems and products.

b.1. 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 disposal of potentially BSE infected materials and animals (Progress report)

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

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

b.4. Safety of gelatine (updated opinion and report from the TSE/BSE ad hoc Group)

b.5. Update of the opinion on the safety of tallow, adopted on 27.03.98.

b.6. "Appropriate heat treatment of animal meal" progress report and preliminary results of the validation study carried out by the Joint Research Centre.

Human exposure risk.

b.7. Progress report and schedule of the Working Group on Human Exposure Risk.

Geographical risk.

b.8. Handbook for the assessment of geographical BSE risk (possible pre-opinion, open for comments until 15 January 1999).

b.9 Comparison of the draft proposal for a revised OIE Code on BSE and the existing SSC opinions: compatibility and conflict. Adoption of a first report on the comparison and decision on approaches to address conflicts.

b.10. Schedule for the assessment of the geographical BSE-risk and the preparation of an opinion on the BSE-status of Member States and Third Countries.

b.11 Discussion on criteria determining BSE-status categories, taking account of the geographical BSE-risk, the human exposure risk and the OIE recommendations.

c. The EU conference on food security: lessons from the BSE crisis (report of the conference held in Brussels on 30 November and 1 December 1998).

d. New issues:

Possible implications of the publication "*Human Keratinocytes Express Cellular Prion-Related Proteins in Vitro and during Inflammatory Skin Diseases*".

6. Organisational matters
7. Co-ordination: reports of the Chairmen of the 8 Scientific Committees
8. Information by the Commission services on matters related to consumer health
9. Any other business:
   - Letter from the University of Leuven (B)
   - SEAC's note on Dorsal Root Ganglia

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 on Plants

At its meeting on 10 November 1998 members of the Committee elected Professor Tony Hardy as the new Chairman.

1 Plenary

The Committee discussed in depth the progression of several draft opinions which are planned for adoption at the next Plenary on 18 December:

- a guidance document to help notifiers in the preparation of GMO dossiers, in the light of the Committee's experience of the dossiers examined to date.
- an opinion on the relationship between the elimination or strong reduction in the use of plant protection products in the cultivation of fruits and vegetables and the presence of mycotoxins and heavy metals (a working group subsequently met 9 December to finalise the draft).

The committee discussed the follow up action from earlier adopted opinions:

- Opinion on data requirements for microorganisms (adopted 2 October) - this was presented at an international workshop in Stockholm 24-28 October organised by the Swedish Authorities at the request of the EC, to revise the draft data requirements for risk assessments on micro-organisms under 91/414/EEC.
- Opinion on GM high amylopectin potato cultivars *apriori* and *apropos* notified by Avebe (C/NL/96/10) adopted 2 October. This opinion concluded that insufficient risk assessment had been carried out on specific genes (particularly the amikacin resistance gene) or gene elements (some of unknown function) that the Committee was unable to fully assess the safety under 90/220/EEC. Regretfully due to claims of confidentiality by the notifier, Avebe, the Commission was unable to publish the full opinion on the internet but only a truncated version of paragraph headings but no supporting text.

2. Plant protection Products Active Substances

Isoxaflutole — The working group on environmental risk assessment will meet on 17 December to finalise a draft which will be combined with a toxicological evaluation for possible adoption at Plenary on 18 December.

Aldicarb — The working group will meet on 17 December to complete work on various draft contributions to an opinion on environmental risk assessment. A working group on residues has met on 11 November to further their evaluation of the probabilistic risk assessment of dietary exposure. A draft contribution on operator exposure is in progress and the draft opinion will be finalised for adoption at Plenary on 18 December.

Flurtamone — The environmental working group is working on draft opinions on the fate of metabolites and beneficial organisms, will meet again on 17 December to finalise an opinion for adoption at Plenary on 18 December.

Spiroxamine — The environmental working group is assessing aquatic toxicology, will meet on 17 December to finalise its draft which will be combined with a draft response

on risks to operators. A draft opinion will be considered for adoption at Plenary on 18 December.

Azimsulphuron The environmental working group is assessing aquatic toxicology, will meet on 17 December to finalise its draft opinion to be combined with one on risks to operators and considered for adoption at Plenary on 18 December.

3. Genetically Modified Plants

Male sterile chicory from Bejo-Zaden (C/NL/94/25-A) - there had been no response from the notifier asked questions to clarify in relation to the Committee's draft opinion. There has since been a response, the GMO working group will meet 17 December to finalise its draft opinion for adoption at Plenary on 18 December.

Modified starch potato from Amylogene (C/SE/96/3501) - though referred to the Committee, the dossier has not yet been released by DGXI.

Glufosinate ammonium tolerant Bt maize from Dekalb (C/NL/97/17) - though referred to the Committee, the dossier has not been released by DGXI.

Scientific Committee Cosmetic and non-Food Products

Prof. Kemper, the chairman, reported on the topics dealt with since the last SSC meeting.

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

1. *Alternatives to animal testing* : within this framework, opinions were adopted on (i)guidelines on the use of human volunteers in the testing of potential cutaneous irritant cosmetic ingredients or mixtures of ingredients, (ii) on in vitro methods to assess photo-toxicity in the safety evaluation of cosmetic ingredients or mixtures of ingredients and on (iii) in vitro methods to assess skin corrosivity in the safety evaluation of cosmetic ingredients or mixtures of ingredients.

   COLIPA data on in vitro / in vivo dermal absorption / percutaneous penetration were received, based on which the WP prepared a draft opinion on the in vitro assessment of percutaneous absorption of cosmetics ingredients.

2. *Hair Dyes* : an opinion on hydroquinone as a skin depigmenting agent was adopted, saying that the substance may not be use for this purpose in cosmetic formulations.

   A overview of pending files on hair dyes was presented and a request for a mandate (= work programme) for the safety evaluation of these substances was made to the Commission.

3. *Preservatives, Colorants & Fragrances* : draft opinions were discussed on carbamide peroxide and on acrylamide. As a result of these discussions, letters were sent to the respective industry asking to answer the questing raised by the Committee.

   The adoption of an opinion on Benzylhemiformal was postponed as it was found that the mutagenicity data needed further consideration.

   An opinion was adopted on Benzalkonium chloride, bromide and saccharinate.

   A working document was approved on fragrance allergy, and in particular on the size of the problem in epidemiological terms and on the importance of some fragrance ingredients identification on skin care products. In this framework, a letter was sent to EFFA to ask for information on the substances subject to IFRA restriction, and in particular the original data concerning their cutaneous toxicology (cutaneous safety).

4. *Inventory* : a draft first update of the inventory, as prepared by the cosmetic industry, was received. Based on this document, the Committee will adopt an opinion.

5. *UV filters* : draft opinions were approved by the WP on 3 UV filters.

Scientific Committee for Medicinal Products and medical Devises

At the last meeting of the SCMPMD on 9 December 1998 several subject were discussed such as:

- Draft Report on « Authorised colouring agents for use in medicinal products ».
- Draft Guidelines on the concept of « Clinical Superiority » regarding legislation on orphan medicinal products.
- Information on « Antimicrobial Resistance ».
- Information on « Medical Devices ».
- Dates of next Plenary Meetings for 1999.

In 1999 with the work already started in 1998 but not yet finalised, would continue. In addition, several news subjects are already on the agenda for discussion during 1999.

<u>Annex 4</u>: Pre-opinion on a method for the assessment of the geographical BSE risk.

(This annex has been distributed separately)

Annex 5:

Planned dates of SSC meetings in the period January 1999 to October 2000 as adopted by the SSC

1999

21/22 January 1999

18/19 February 1999

18/19 March 1999

22/23 April 1999

27/28 May 1999

24/25 June 1999

22/23 July 1999

16/17 September 1999

28/29 October 1999

9/10 December 1999

2000

20/21 January 2000

2/3 March 2000

13/14 April 2000

25/26 May 2000

6/7 July 2000

14/15 September 2000

26/27 October 2000

Annex 6:

DISCUSSION DOCUMENT ON THE CORRESPONDENCE BETWEEN THE DRAFT OIE CODE ON BSE (SEPTEMBER 1998) AND THE SSC OPINIONS REGARDING BSE (NOVEMBER 1997 – OCTOBER 1998)

PREPARED BY SCIENTIFIC STEERING COMMITTEE

AT ITS MEETING OF 10-11 DECEMBER 1998

INTRODUCTION

1. The Scientific Steering Committee (SSC) has adopted in 1997 and 1998 scientific opinions on 19 BSE-related issues (See Annex 1). In addition, the Scientific Committee on Veterinary Measures related to Public Health, adopted in 1998 an opinion on Pneumatic stunning as a practice for slaughtering ruminants.

   In addressing these issues, the SSC frequently came to the conclusion that safe sourcing is a key-element in any risk management strategy. However, with regard to the source, the SSC defined conditions which, in its view, would have to be met for products to be safe.

2. Recently, a new draft Chapter of the Animal Health Code on bovine spongiform encephalopathy of the International Office of Epizootics (OIE) became available. It addresses many of the same issues as those treated by the SSC and also differentiates conditions for safe products in relation to the source of the raw material.

   The SSC felt that it would be worthwhile to prepare a discussion paper on the convergence of its opinions with those of the OIE.

   The SSC secretariat prepared as a working document a schematic comparison of the draft revised OIE Code and the SSC opinions. This comparison is attached as Annex 2.The members of the SSC were asked to comment on the compatibility of the two approaches and to propose solutions in case of conflict.

REPORT

1. Regarding geographical risk criteria and the geographical BSE risk assessment

Criteria for assessing the geographical risk

There exists a large correspondence between the geographical BSE risk criteria listed in Article 3.2.13.1 of the draft revised OIE Code on BSE, and the ones listed in the SSC opinion of 23.01.98 *defining the BSE risk for specified geographical areas* and of 20.02.98 *on BSE risk*. However the SSC opinions are more detailed and complete. Also, a detailed pre-opinion on BSE risk assessment, including a methodological approach and a handbook,

has been adopted on 10-11 December. The OIE criteria are considered to be general enough to implicitly embrace all SSC criteria.

On the geographical BSE status categories:

The SSC notes that the draft revised OIE Code introduces the fact that the evaluation of the BSE status of a country or zone cannot be based only on incidence figures, but should be based in the first place on risk assessment and the evaluation of risk management measures with respect to the propagation and incident risks. This was also published in the SSC opinions of 23.01.98 *defining the BSE risk for specified geographical areas* and of 27.03.98 *on BSE Risk.*

For the time being the SSC has the following comments:

a. The draft revised OIE code proposes that the following periods are sufficiently long to have resulted in an appropriate risk reduction:

   - 8 years for the implementation of an MBM feed ban;
   - 7 years for the introduction of on-going education programmes, a compulsory notification and an investigation system of all cattle showing clinical signs compatible with BSE, a BSE surveillance and monitoring system, record keeping and laboratory examination of brains or tissues collected within the framework of the surveillance system,.

   The SSC agrees with the above values.

   However, regarding the other risk management measures, the OIE code is less precise and is limited to the statement that "*a risk analysis, as described in point 1 of Article 3.2.13.1, has been conducted which demonstrates that appropriate measures have been taken to manage any risk identified*". The SSC prefers to be as explicit as possible on all aspects of risk management.

b. In the evaluation of the BSE status of countries, the quality of identification and tracing systems, the BSE related culling, the existence of an SRM ban and scrapie-related measures should all be taken into account.

   Of equal importance is the time dimension. Given the long delay between exposure/infection and outbreak, it is important to know the dates of introduction or important changes in BSE-related risk management measures such as feed bans, SRM bans, rendering standards, TSE surveillance network and culling strategies. This will also permit the degree of compliance with the different criteria in all the submitted dossiers, including a time dynamic to be estimated.

c. The SSC considers that, in the BSE status evaluation process, the weight to be givento (the non compliance with) a given risk factor or a management measure, will depend upon the presence or absence of other risk factors or the full enforcement or not of other measures. For example, compliance with a "safe" rendering standard should be evaluated against other information on feeding practices, BSE incidence (and quality of the surveillance system), SRM bans, etc. In certain cases a "high risk" factor in a given country could be negligible in another if that country enforced a number of other appropriate risk management measures.

d. All appropriate measures to manage any risk identified, should have been implemented and enforced for a sufficient period of time (number of years) to result in a significant risk reduction. This period of time may vary according to the risk factor. *For example*, if cannot be guaranteed that MBM is/was not fed to ruminants, MBM-related measures

(feeding, imports, rendering, etc.) may need to be in force for at least 8 years (8 years corresponds with the upper end of the BSE incubation period).

e. The SSC notes that whereas its opinions have placed a negligible emphasis on reported incidence of BSE in assessing geographic risk, the draft revised OIE Code attributes some weight to BSE incidence rates as a criterion for putting countries or zones in a given BSE status category and has included it within its BSE status criteria.

The SSC agrees that, if an appropriate and reliable surveillance system is in place, incidence numbers can be an indicator of the BSE risk from the cattle stock of a country and as such should be taken into account. However, most animals are slaughtered before signs of illnesses may develop. For BSE, pre-clinical prevalence in the live cattle population is unknown. Incidence figures can thus not be the major criterion for the assessment of the BSE status of a country. The future risk also depends heavily on the measures taken to limit any possibility of propagating BSE from one generation to the next.

The SSC accepts that, given the limited knowledge on (the historical evolution of) BSE epidemics in countries other than the UK, the identification of incidence threshold values, as a criterion for attributing a preliminary view of the BSE risk in a country, must be based on reasonable estimates derived from the little evidence that is available. The OIE thresholds of 1 and even 200 animals per 1,000,000 animals above 24 months old over the past 12 months, might be acceptable subject to quantitative information becoming available on the risk of human exposure to the BSE agent via meat products and derived products such as gelatine and tallow. The categorisation of countries under the OIE system can, however, be affected substantially by any one of a number of attributes of a country ranging from such general issues as education of staff to the conduct of surveillance systems. These vague criteria, open to selective interpretation, substantially limit the rigour of any strict evaluation.

The incident and propagation risks determine the geographic risk from cattle within the administrative region but many other factors, e.g., the handling of SRMs and food processing, imports and exports; etc., determine the risk of human exposure within any one country. The SSC therefore considers it insufficient to depend on reported incidence figures alone in evaluating the true risk of BSE exposure in a population.

Furthermore, the SSC believes that single point estimates of BSE prevalence is not in itself sufficient. The criterion of incidence should be qualified to indicate whether the incidence over recent years has been significantly and consistently increasing or decreasing. This historic perspective should reflect the efficacy of risk management measures that were enforced in previous years or the effects of an inappropriate risk assessment and management policy.

An example, simply for illustrative purposes in this discussion document of an "incidence evolution" criterion completing the "incidence rate" criterion, is the following:

<u>For countries or zones with a low BSE risk:</u>

If the present BSE incidence rate, calculated over the past 12 months, is greater than or equal to one case per million and less than or equal to two hundred cases per million within the cattle population over 24 months of age in a country or zone, and if the incidence in a previous year was above two hundred, it should have ~~been~~ significantly and consistently decreased for a number of consecutive years.

[By "significantly" is meant that the average annual decrease was at least 1/3 of a previous year's number. This ratio is based on the following reasoning, which is also in line with the UK experience:

The average incubation period of BSE is 5 years. This means that approximately 5 (average range: 4-6) years are needed, for a complete set of risk management measures to become fully effective and visible in a reduced incidence. For example, starting from an incidence of 1000 cases, an average decrease of 1/3 per year would during the subsequent (additional) 5 years, result in the following incidence figures: 667, 444, 296, 198, 132 (overall reduction: 87%).

For countries or zones with a high BSE risk:

Countries where the BSE incidence rate, calculated over the past 12 months, has been greater than or equal to one case per million, and less than or equal to two hundred cases per million within the cattle population over 24 months of age in a country or zone, and where the incidence has significantly increased since the previous year, should also be considered as high risk countries. An increase by 40 cases per million is considered to be significant."

[The basis of choosing the figure of 40 cases is the following: as an increasing incidence rate implies inappropriate or not (yet) fully effective risk management measures, or may point to improvements in the surveillance system (which previously was inadequate), and because the incubation period is several years, one cannot exclude that within 5 years, the incidence rate would be above 200.]

2. Regarding Specified Risk materials

The SSC agrees with the OIE principle on the introduction of SRMs lists modulated according to the BSE status of a country or zone. This was expressed in its opinions of 9.12.97 on Specified Risk Materials and of 26-27 March 1998 on the safety of gelatine: "*Unless otherwise specified, the wording "Specified risk materials" refers to all tissues listed in the opinion of the Scientific Steering Committee (SSC) adopted on 9 December 1997. However, the SSC intends to consider the possibility of making a selection of specified risk materials on the basis of the results of a risk assessment, which takes into account the geographical origin of the animals, their species and their age"*.

The SSC will consider the modulated SRM lists proposed by the OIE.

However, given the uncertainty of infectivity of bovine bone marrow and given the risk of cross-contamination with spinal cord and with brain material, the SSC wishes to reserve its opinion with respect to bones obtained under conditions other than the ones specified in schemes such as the UK Date Based Export Scheme (See SSC opinion of 22-23.10.98 on *The safety of bones produced as by-product of the Date Based Export Scheme*).

3. Regarding the safety of products

The SSC notes that there is a high degree of correspondence between the draft OIE criteria and the SSC opinions for certain products to be considered as safe.The SSC raises a number of discussion points which result from the detailed table presented in annex 2:

Gelatine and collagen: The OIE draft lists the same conditions for both products. The SSC wishes to verify which conditions are valid for collagen and whether the conditions it has recommended for gelatine, are also valid for collagen.

Greaves: The SSC has no specific opinion on greaves, but considers that the same conditions as set out in its opinion on meat-and-bone meal, should be applicable.

Organic fertilisers from bovine material: The SSC confirms its opinions of 24-25.09.98 and of 22-23.10.98, implying that for MBM-like organic fertilisers, bovine raw material should be excluded in high risk countries.

Tallow and dicalcium phosphate: The OIE draft text implicitly assumes that "protein-free" tallow and dicalcium phosphate "with no trace of protein or fat" can exist. The SSC opinions on the contrary implicitly state that protein-free tallow or dicalcium phosphate with no traces of protein or fat, do not exist. Regarding the maximum level of impurities in tallow of 0.15% in weight, the SSC points out that its opinion of 26-27 March 1998 refers to insoluble impurities.

Cross-contamination: The SSC considers that the assessment of this risk should be part over the overall risk identification exercise.

Clearance of TSE infectivity during production. The SSC wishes to draw attention to its scientific opinion on the safety of gelatine which explained that the cumulative (TSE infectivity inactivation) effect of different sequential treatments in one production process still needs to be confirmed. Therefore, the total level of inactivation realised during a production process is not necessarily equal to the sum of the inactivations realised during subsequent process steps.

<u>Annex 1</u>: list of BSE-related opinions adopted by the Scientific Steering Committee since November 1998

Date of adoption	Title of the opinion
9 December 1997	1. Listing of Specified Risk Materials: a scheme for assessing relative risks to man
9 December 1997	2. Report on the UK Date Based Export Scheme and the UK proposal on Compulsory Slaughter of the Offspring of BSE Cases
22-23 January 1998	3. Opinion of the Scientific Steering Committee ondefining the BSE risk for specified geographical areas
19-20 February 1998	4. 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
19-20 February 1998	5. Final Opinion on the contents of a "Complete dossier of the epidemiological status with respect to TSEs".
26-27 March 1998	6. Opinion on BSE risk
26-27 March 1998	7. Opinion on the Safety of Gelatine
26-27 March 1998	8. Opinion on the Safety of Tallow
26-27 March 1998	9. Opinion on the Safety of Meat and Bone Meal
25-26 June 1998	10. The safety of dicalcium phosphate precipitated from ruminant bones and used as an animal feed.
25-26 June 1998	11. Possible links between BSE and organophosphates used as pesticides against ecto- and endoparaistes in cattle.
24-25 September 1998	12. Opinion on the risk of infection of sheep and goats with Bovine Spongiform Encephalopathy agent.
24-25 September 1998	13. Report and Opinion on mammalian derived meat and bone meal forming a cross-contaminant of animal feedstuffs.
24-25 September 1998	14. Opinion on the safety of organic fertilisers.
24-25 September 1998	15. Updated Scientific Report presented on 24-25 September to the Scientific Steering Committee on the safety of meat and bone meal derived from mammalian animals fed to non-ruminant food-producing farm animals,
22-23 October 1998	16. The safety of hydrolysed proteins produced from bovine hides.
22-23 October 1998	17. The safety of bones produced as by-product of the Date Based Export Scheme.
22-23 October 1998	18. Evaluation of an alternative process 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.
10-11 December 1998	19. Opinion on a method for the assessment of the geographical BSE risk.

Annex 2: Comparison between the draft revised OIE Code on BSE (draft version September 1998) and the SSC opinions (updated, 25.11.98)

1. Equivalency between the OIE and SSC geographical sourcing and geographical BSE Status categories

Domain	Draft revised OIE Code (September 1998)		SSC Opinions	
	Content	Article	Opinion content	Date
1.1. BSE status assessment criteria:		3.2.13.1		23.01.98 19.02.98
1. Potential factors for BSE occurrence and their historic perspective:				
a) meat-and-bone meal and greaves consumption	• listed		• listed, but SSC opinion does not mention greaves;	
b) imports of meat-and-bone meal	• listed		• listed, but SSC opinion provides details;	
c) imports of animals or embryos	• listed		• listed, but SSC opinion provides details;	
d) epidemiological situation all TSE	• listed		• not named as such but implicit; focus on BSE and scrapie;	
e) Population structure	• listed		• listed, but SSC opinion provides details;	
f) origin animal waste, rendering, methods of feed production	• listed		• listed, but SSC opinion provides details;	
1. education programmes	• listed		• listed	
2. compulsory notification	• listed		• listed	
3. surveillance system + keeping records	• listed, limited to BSE		• all TSE, but "*with particular reference to BSE and scrapie*".	
4. Laboratory analysis	• listed		• listed	

Domain	Draft revised OIE Code (September 1998)		SSC Opinions	
1.2. Geographical risk categories		**3.2.13.2.**	**Used in opinions, but definitions pending**	**pending**
• Category: BSE free country or zone.	• Completely defined *		• BSE free *or negligible* risk country or region. Compatible with OIE as far as risk criteria compatible.	
• Category: Country (or zone) that is provisionally free of BSE.	• Completely defined *		• not existing; +/- equivalent to lower risk (not defined).	
• Category: Country or zone with low incidence of BSE	• Completely defined *		• not existing; +/- equivalent to lower risk (not defined).	
• Category: Country or zone with high incidence of BSE	• Completely defined *		• not existing: +/- equivalent to high risk (not defined).	
• Category: lower risk	• not existing		• existing but not defined	
• Category: high risk	• not existing		• existing but not defined	
• Category: status unknown	• not existing		• existing and, in practice, defined as country that can not submit evidence or elements to permit status evaluation and therefore should be considered a high risk country.	

Domain	Draft revised OIE Code (September 1998)		SSC Opinions	
1.3. Geographical risk categories		**3.2.13.2.**		**pending**
• Category: BSE free country or zone.	The country/zone has carried out risk analysis and taken measures to manage any risk. And either: 1. There has been no BSE case, and: Complies > 7 years with the above listed criteria 2-5, *or* Compul. notification (>7 years) and MBM+greaves ban (>8years) or: 2. All BSE cases are imported and offspring (24 months) slaughtered & destroyed; and: Complies since at least 7 years with the above listed criteria 2-5, *or* Compulsory notification (> 7 years) and MBM+greaves (>8 years). or: 3. Last BSE case > 7 years ago. Complies since at least 7 years with the above listed criteria 2-5 *and* MBM+greaves ban (>8 years).		• Opinion pending	23.01.98
• Category: BSE provisionally free country or zone	The country/zone has carried out risk analysis and taken measures to manage any risk. And either: 1. There has been no BSE case, and: Complies since < 7 years with the above listed criteria 2-5, *or* Compul. notification (<7 years) and MBM+ greaves ban (>8years) or: 2. All BSE cases are imported and offspring (24 months) slaughtered & destroyed; and: Complies since < 7 years with the	3.2.13.2.	• Opinion pending	23.01.98

	above listed criteria 2-5, *or* Compul. notification (< 7 years) and MBM+ greaves ban (> 8 years) or: 3. Last BSE case > 7 years ago. Complies with the above listed criteria 2-5 *and* MBM + greaves feed ban, but: - criteria 2-5 applied since < 7 years or: - MBM and greaves ban < 8 years or: 4. There has been indigenous BSE, but: - criteria 2-5 applied since > 7 years - offspring (24 months) destroyed - incidence: < 1/1.000.000 (adult population > 24 months)			
• Category: Country or zone with low incidence of BSE	EITHER: 1. The country/zones complies with risk analysis criteria; Incidence >= 1/1.000.000 and <= 200/1.000.000 (adult population > 24 months); or: 2. The country/zones does not comply with all risk analysis and other status assessment criteria; Incidence < 1/1.000.000 [< = ???] (adult population > 24 months); or: 3. The country/zones does not comply with all risk analysis and other status assessment criteria and compulsory notification not complied with; Incidence is 0/1.000.000	3.2.13.2.	• Opinion pending • Incidence alone not considered to be sufficient criterion; propagation and incident risks are at least is equally important.	23.01.98
• Category: Country or zone with high incidence of BSE	EITHER: 1. Incidence >200/1.000.000 (adult population > 24 months)	3.2.13.2.	• Opinion pending • Incidence alone not considered to be sufficient criterion; propagation and	23.01.98

	The country/zones complies with risk analysis criteria; or: 2. Incidence >=2/1.000.000 and <= 200/1.000.000 (adult population > 24 months) The country/zones does not comply with all risk analysis criteria;		incident risks are at least is equally important.	
• Category: status unknown	• not existing		• existing and, in practice, defined as country that can not submit evidence or elements to permit status evaluation.	23.03.98 + all subsequent opinions

2. Equivalency between the OIE and SSC: Specified risk materials

2.1. The Specified Risk Materials:	OIE [OIE Code covers bovines only]	3.12.13.14	SSC [For bovines:]	
• SRMs: maximum list	Applicable to high incidence countries: • Brains, eyes, spinal cord, tonsils, thymus, spleen, intestines, dorsal root ganglia, trigeminal ganglia, bones • Obvious nervous and lymphatic tissues visible during deboning of fresh meat for export • Age > 6 months	3.2.13.14	Applicable to all countries except if BSE free/negligible risk, until geo- risk known: • Brain, Eyes, Dura mater, Pituitary, Skull, Spinal cord, Dorsal root ganglia, Vertebral column, Spleen, Ileum, Tonsils, Lung (*for lungs: contamination from brain via blood when animals are killed by pithing or stunning).* • Obvious nervous and lymphatic tissues in fresh meat deboned for export from high risk countries • *trigeminal ganglia not listed* • Age > 12 months, except for ileum and spleen where the age limit is 0 months • modulation of list possible as soon as the results of a risk assessment are available , which takes into account the geographical origin, species and age of the animals.	9.12.97 SC-VMPH 17.02.98 9.12.97 27.03.98 (gelatine)
• SRMs: intermediate list	Applicable to low incidence countries but ***only if*** cattle were born before date of enforcement of ruminant MBM ban ***and if*** age > 6 months. Otherwise: no SRMS [?] • Brains, eyes, spinal cord, distal ileum • Protein products derived from above • Ruminant-derived MBM may contain these SRMs ***if not*** used for the preparation of food, feed, cosmetics, pharmaceutical or medical devices ***and if*** produced in validated plants respecting processing parameters	3.2.13.14 3.2.13.13	• Principle as such of "intermediate list" is implicitly accepted, but not defined; above maximum list could be modulated on the basis of "the results of a risk assessment, which takes into account the geographical origin of the animals, their species and their age". • However, also for uses of MBM other than as feed (organic fertilisers), the SSC opinion still recommends SRM removal	27.03.98 (gelatine) 24.09.98

• SRMs: minimum list	• Applicable to countries (or zones) considered provisionally free of BSE where BSE has been reported but ***only if*** cattle were born before date of effective enforcement of ruminant MBM ban AND IF age > 30 months [?] • Brain and spinal cord • Protein products derived from above • However, ruminant-derived MBM may contain these SRMs IF NOT used for the preparation of food, feed, cosmetics, pharmaceutical or medical devices AND IF produced in validated plants respecting processing parameters	3.2.13.14 3.2.13.13	• Principle as such of "minimum list" is implicitly accepted, but defined as such; but could be modulated on the basis of "the results of a risk assessment, which takes into account the geographical origin of the animals, their species and their age". • However, also for uses of MBM other than as feed (organic fertilisers), the SSC opinion still recommends SRM removal.	27.03.98 (gelatine) 24.09.98
• SRMs: zero list	• Applicable to: - countries (or zones) considered free of BSE and - in countries or zones provisionally free of BSE but where no BSE has been reported	3.2.13.14 3.2.13.13	• Applicable to BSE free or negligible risk countries.	All opinions

2.2. Specified Risk Materials in specific products:	**OIE [Bovine SRMs only:]**		**OIE [Bovine SRMs only:]**	
• Hides and skins	• NOT an SRM, regardless of status of country of origin	3.2.13.3.	• Not an SRM, if cross-contamination can be excluded	26.03.98 (gelatine)
• Semen	• NOT an "SRM", regardless of status of country of origin	3.2.13.3	• The 1996 Opinion of the ScVC (Scientific Veterinary Committee) is under revision • (Safe according to ScVC in 1996)	26.04.96 (ScVC)
• Bovine embryos/ova	• Are an "SRM", unless very strict conditions are respected	3.2.13.10, - 11 - 12	• Under study • (The 1996 Opinion of the Scientific Veterinary Committee was not conclusive)	26.04.96 (ScVC)
• Milk and milk products	• Not an "SRM"	3.2.13.3	• Idem as OIE, but Working Group Human Exposure Risk monitors	MDSC: 09.97
• Food, feed, cosmetics, pharmaceuticals or medical devices in general • In fresh, deboned meat and meat products	<u>For high incidence countries</u>: • Brains, eyes, spinal cord, tonsils, thymus, spleen, intestines, dorsal root ganglia, trigeminal ganglia, bones • Age > 6 months <u>For low incidence countries</u> • Brains, eyes, spinal cord, distal ileum and protein products derived therefrom • Cattle born before ruminant feed ban • Age > 6 months <u>For BSE provisionally free where no BSE has been reported</u>: • Brains and spinal cord and protein products derived therefrom • Cattle born before ruminant feed ban • Age > 30 months	3.2.13.14 3.2.13.7, 3.2.13.8 3.2.13.9	• Removal of SRMs depends upon the product, its end use and the origin of the raw material.	

• In meat and bone meal and greaves	Ruminant-derived animal feed fed to ruminants: • In high incidence countries: the whole animal is a SRM • In countries or zones not free from BSE: the whole animal is a SRM • In BSE free countries: no SRM restrictions For all other uses, including feed for non-ruminants and fertilisers: • no SRM restrictions, but respect processing parameters	3.2.13.13	Ruminant derived, as feed for non-ruminant food producing farm animals • In high risk countries: the whole animal is a SRM • In lower risk countries: SRMs to be removed • In BSE free/negligible risk countries: no SRM restrictions As feed for other animals: • Opinions pending on fur animals and on intra-species recyecling	27.03.98
• In organic fertilisers	• Not mentioned as such, but implicit: no SRMs provided appropriate and validated processing	3.2.13.13	• SRM removal as for MBM for food producing farm animals • ***Bovine*** raw material excluded in high incidence countries.	24.09.98
• In hydrolysed proteins from hides an skins	• Safe, *IF* hides and skins obtained from healthy animals	3.2.13.3.	• Safe as a fertiliser and as feed, also in high risk countries, if the hides/skins are from healthy animals AND if sourcing and process conditions respected.	23.10.98
• In collagen	• As for gelatine	3.2.13.15	• Not covered by an SSC opinion	
• In Gelatine	Gelatine from hides and bones: • Hides / skins are safe Gelatine from bones: • No SRMs: in BSE-free or provisionally free countries; • in high incidence countries: all bones excluded; • in low incidence countries: Skulls and vertebrae (excluding tail vertebrae) and appropriate processing needed.	3.2.13.15	Gelatine from hides and bones: • Hides and skins are safe, provided cross-contamination can be excluded Gelatine from bones: • BSE free/negligl. risk countries: No SRMs • in high risk countries: all bones excluded, except under UK DBES conditions; elsewhere: SSC list of SRMs, if end-use implies any human or animal consumption • for industrial use: no SRMs, except if ingestion or exposure risk	27.03.98 23.10.98

• In dicalcium phosphate	• No SRMs, *IF* no trace of protein or fat in final product	3.2.13.3.	For use as an animal feed: • Safety depends upon geographical source, removal of SRMs, production process conditions and weight of residual protein; • In high risk countries: exclude ruminants + appropriate production process	25.06.98
• In tallow	• in BSE free-countries: no SRMs Otherwise: • IF protein-free (=maximum level of impurities of 0.15% in weight): no SRMs • in low incidence countries: - Brains, eyes, spinal cord, distal ileum: if prepared by fat melting; - Skull and vertebral column: if prepared from defatted bones • in "BSE provisonally free " countries: - Brains, spinal cord: if prepared by fat melting; - Skull and vertebral column: if prepared from defatted bones • No tallow from bovine material from high incidence countries	3.2.13.16	• No SRMs: - in BSE free-/negliglible risk countries, except if derived from animals not fit for human consumption for use as animal feed. - For industrial use, *but* appropriate purification (=maximum level of insoluble impurities of 0.15% in weight) *and*: fit for human consumption *or* 133°C/20'/3 bars • *Otherwise*, remove SRMs • The opinion implicitly states that protein-free tallow does not exist.	27.03.98 24.09.98

• In Tallow derivatives:	• If protein-free raw material (=maximum level of impurities of 0.15% in weight): no SRMs Otherwise (i.e;, >0.15% impurities) • For BSE free or provisionally free countries or zones: no SRMs • For low incidence countries or zones: - no SRMs, but only if appropriate processing conditions. • For high risk countries: production not authorised for cosmetics and for pharmaceutical products	3.2.13.16	• No SRMs, if appropriate processing conditions and independently from country of origin; • If inappropriate processing conditions: as for tallow • Authorised also for high risk countries	27.03.98 (SSC) 23.09.98 (SCC)

3. Equivalency between the OIE and SSC: Safety of products

3. Safety of products.	**OIE**	**3.2.13.3**	**SSC**	
• Food, feed, cosmetics, pharmaceuticals or medical devices in general	Safety depends upon removal of SRMs as indicated in Section 4, safe sourcing; appropriate production processes.	3.2.13.14	Safety depends upon removal of SRMs safe sourcing; appropriate production processes, end-use	27.03.98
• Hides and skins	• safe, regardless of country of origin		• safe *IF* cross-contamination excluded	27.03.98
• Semen	• Safe, regardless of country of origin	3.2.13.3	• The 1996 Opinion of the ScVC (Scientific Veterinary Committee) is under revision • (Safe according to ScVC in 1996)	26.04.96 (ScVC)
• Bovine embryos/ova	• Safe if strict conditions are respected • Conditions vary according to geographical risk category (See relevant OIE articles)	3.2.13.10, - 11 - 12	• Under study • (The 1996 Opinion of the Scientific Veterinary Committee was not conclusive)	26.04.96 (ScVC)
• milk and milk products	• safe	3.2.13.3	• safe (update pending)	SVC: 1996 SSC: 9.97
• Ruminant derived meat-and-bone meal or greaves	• no trade of MBM or feedingstuffs containing it from high incidence countries, for any use • no trade of MBM or feedingstuffs containing it from countries with BSE, for use as feed for ruminants; • for other uses, including as feed for non-ruminants and as a fertiliser: appropriate processing is sufficient	3.2.13.13	Safe as feed for non-ruminant food producing farm animals, if: • High risk countries: No meat and bone meal from ruminant animals for mammalian animals • Lower risk countries: fit for human consumption; SRMs excluded; 133°C/20'/3 bars; avoid cross-contamination; • BSE free/negligible .risk countries: fit for human consumption; 133°C/20'/3 bars; avoid cross-contamination. • Batch and continuous not necessarily equivalent	26.03.98 24.09.98
• cross-contamination of MBM	• not listed	-	• feedstuffs to be condemned if cross-contamination content exceeds the detection level (currently 0.5%)	24.09.98

• Organic fertilisers	• Not listed as such, but implicitly: safe provided the appropriate processing parameters are applied (and such has been validated)	3.2.13.13	• Safety depends upon geographical source, removal of SRMs and production process conditions. • Excluded in high incidence countries	24.09.98
• Hydrolysed proteins from hides an skins	• Not listed as such, but implicitly: Safe, *IF* hides and skins derived from healthy animals	3.2.13.3.	• Safe, *IF* hides and skins derived from healthy animals. Safety further depends upon geographical source, removal of SRMs and production process conditions.	23.10.98
• tallow	• safe if protein-free (<0.15% impurities) • if not protein-free: - material from high incidence countries excluded; - safe if from BSE free or provisionally country or zone - In low incidence countries: ° if prepared by fat melting: SRMs excluded ° if prepared from defatted bones: skulls and vertebral columns excluded + appropriate production process or equivalent clearance = 5 $\log_{10}$ LD50/g	3.2.13.3 + 3.2.13.16	• safe for human or animal consumption if: - < 0.15% insoluble impurities *and*: - animal fit for human consumption; and: - SRMs removed in high and lower risk countries; *and:* - if rendering mixture of tissues in high risk countries: 133ºC/20'/3bar (except for discrete adipose tissues); • if for ruminant feed and from animals not fit for human consumption: SRMs removed *and* 133ºC/20'/3 bar *and* < 0.15% insoluble impurities. • if for non-ruminant feed and from animals not fit for human consumption: SRMs removed ***and*** 133ºC/20'/3bar (preferably) or <0.15% insoluble impurities. [but exclusive use as non-ruminant feed is probably not controllable) • if for industrial use: 133ºC/20'/3bar and appropriate purification; • Implicit to SSC opinion: "protein-free tallow" does not exist • opinion pending on fat from bones;	27.03.98 24.09.98

• Tallow derivatives	• raw material was protein-free tallow, or: • from BSE free or provisionally free country or zone or: • in low incidence countries: hydrolysis, transesterification or saponification using high temperature and pressure • material from high incidence countries excluded in cosmetics and in pharmaceutical products	3.2.13.16	• hydrolysis transesterification or saponification using high temperature and pressure, regardless of origin of material and quality of raw tallow • THE SSC AND SCC OPINIONS ALLOW PRODUCTION IN HIGH RISK COUNTRIES AND FROM SRMs IF APPROPRIATE PROCESSING	SSC: 27.03.98 SCC: 23.09.98
• Gelatine and collagen from hides and skins	• safe	3.2.13.3	• Safe, but only if no risk for cross-contamination • Collagen not covered by this opinion	27.03.98
• Gelatine and collagen from bones	• safe if raw material from BSE free or provisionally free country or zone: • bones from high incidence countries excluded; • bones from low incidence countries: SRMs (skulls and vertebrae) excluded; • appropriate production process or equivalent clearance = 5 $\log_{10}$ LD50/g	3.2.13.15	• Opinion does not cover collagen • Gelatine is safe if: - as for OIE, *AND*: - if end-use is human (consumption, pharmaceutical, cosmetic, etc.): from animals fit for human consumption; - end-use pharmaceutical or parenteral: extra conditions imposed; - industrial/technical use: appropriate production process in all cases; protection of workers in high risk countries. - Separated production lines in high risk countries.	27.03.98
• Dicalcium phosphate	• safe (if no trace of protein or fat)	3.2.13.3	• Opinion specifies criteria of SRM removal if from high or low risk country • No traces of impurities (fat, proteins) is considered as not realistic.	26.06.98

4. Equivalency between the OIE and SSC: Import of cattle

Domain	Draft revised OIE Code (September 1998)		SSC Opinions	
4. Import of cattle				
• Category: BSE free country or zone.	• Free		• no opinion, but: free (extrapolation from various opinions on tallow, gelatine, etc.)	
• Category: BSE provisionally free country or zone	• list criteria given • when importing: certificate required	3.2.13.4	• no opinion pending	
• Category: Country or zone with low incidence of BSE	• list criteria given • when importing: certificate required	3.2.13.4	• no opinion pending	
• Category: Country or zone with high incidence of BSE	• list criteria given • when importing: certificate required	3.2.13.5	• no opinion pending	

5. Equivalency between the OIE and SSC Import of fresh deboned meat and meat products

Domain	Draft revised OIE Code (September 1998)		SSC Opinions	
5. Import of fresh deboned meat and meat products				
• Category: BSE free country or zone.	• free		• no opinion pending, but: free (extrapolation from various opinions on tallow, MBM, gelatine, DBES, etc.)	
• Category: BSE provisionally free country or zone	• list criteria given • when importing: certificate required	3.2.13.6	• no opinion pending	
• Category: Country or zone with low incidence of BSE	• list criteria given • when importing: certificate required	3.2.13.6	• no opinion pending	
• Category: Country or zone with high incidence of BSE	• list criteria given: - deboned meat and products derived from deboned meat do not contain SRMs of maximum list, nor obvious nervous and lymphatic tissues - tracing back to the establishments - ante mortem inspection - permanent identification system of the cattle to dam and herd of origin - ruminant feed ban effectively enforced. - All BSE cases and their offspring (24 months) slaughtered & destroyed - animals are not progeny of BSE suspect or confirmed cases and: > were born after enforcement of feed ban, OR: > born, raised and remained in herds with no BSE for > 7 years • when importing: certificate required	3.2.13.8	• Two opinions: - Export Certified Herd Scheme - Date Based Export Scheme • criteria largely compatible with OIE, but: - animal at least 6 months old and younger than 30 months; - Dam to survive for at least 6 months; • inspection and control are crucial - but no details given. • 24 months is compatible with MDSC opinion on maternal risk enhancement • the bone is not an SRM which should be destroyed, but could be used fro, for example, gelatine, under the same conditions as in lower risk countries Opinion on "Closed herds": pending	ScVC: 09.97 SSC: 9.12.97+ 20.02.98+ 17.04.98 MDSC: 09.97 SSC: 23.10.98