

# Summary minutes of the meeting of 22-23 January 1998

## **Preliminary note:**

Mrs.E.Bonino, Commissioner in charge of Consumer Policy, visited the Scientific Committee on Thursday 22 January, 17h00. The main issues in the address she made were:

The importance of the work of the Scientific Committees, as an essential support for decision making;

The importance of the Scientific Committees respecting the principles of transparency and independence, as part of the way to re-assure the confidence of the society in the consumer policy.

As the scientific opinions are part of the decision making process, they should be based as much as possible on considerations of practicability and realism. (Mrs. Bonino underlined that she is well aware of the fact that a "zero risk level" does not exist in any human activity. Therefore the opinions should target for the lowest realistically possible and practicable risk level. They should possibly be completed with explanatory notes to facilitate their exploitation and with an indication of the degree of risk resulting from an option presented in an opinion as part of the justification of a decision.).

Mrs.Bonino expressed her gratitude for the large amount of work realised so far and in such a short period. She recognised that the SSC was working under strong pressure and had to respect very short deadlines. She finally congratulated all members for the quality of the work so far and for the co-ordinating role it had played in a number of dossiers.

Prof.G.Pascal, chairman of the Scientific Steering Committee thanked the Commissioner on behalf of all members and introduced a short exchange of ideas between the Commissioner and the SSC members. The main issues discussed where: the time pressure imposed on the Committee; the relations with the press; the possibility to produce future opinions in a more interactive way with the general public; and the fact that scientific opinions should present balanced scientific views and therefore are not necessarily presented in the most adequate format for political decision making.

Some of the elements of the preceding exchange of view were further discussed during the remaining part of the meeting and are, where appropriate, summarised in the minutes hereafter.

## **1. Welcome, apologies, introductory remarks**

Prof.G.Pascal, chairman, opened the meeting at 14h00. He welcomed the participants and apologised Dr.Knudsen who could not attend on 22 January 1998 due to long standing commitments but would join on 23 January. The list of participants is given as annex 1.

## **2. Approval of the agenda**

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

## **3. Approval of the minutes of the meeting of 8-9 December 1997**

The draft minutes of the meeting of 8-9.12.97 were adopted with minor changes.

## **4. Multidisciplinary matters**

### **4.1. Priority matters related to Transmissible Spongiform Encephalopathies**

#### **a) Briefing on the follow-up given to the opinion on Specified Risk Materials adopted on 8-9.12.97.**

- The secretariat of the SSC reported on the follow up given by the Commission to the opinion on Specified Risk Materials adopted on 8-9.12.97. The SSC was informed that the Commission has postponed its SRM-Decision until 01/04/98 and embarked on an in-depth analysis of all consequences of the opinion of the SSC. It was also made clear that pending opinions of the SSC, in particular the ones on Gelatine and Tallow are very important in that context.
- A number of typing errors and ambiguities in the text of the SRM opinion were mentioned. A re-edited version presented by, Prof. James (rapporteur), was adopted (annex 3).
- In the context of the public reaction to the SRM opinion, the question of communication with the press was raised. As a mean to avoid misinterpretation the participants discussed how the SSC members in general, and the chairpersons and rapporteurs of an opinion in particular, could in future be associated with the process of informing the press. It was agreed that this issue requires further discussion in the future. As a first step the contents of press releases and/or of summary reports, should be adopted by the SSC before it could be made public, if necessary immediately after a meeting, and all SSC-members should receive a copy of the final version at the moment it is published. Prof. Pascal expressed his willingness to stay longer after a meeting to possibly further finalise these texts and attend, if required, meetings with the press. Prof.Gibney further suggested that the SSC should release a general statement to inform the public on its mandate, on the relative uncertainty that goes along with a number of scientific issues because of the limits in data availability, research results, etc. This suggestion was generally accepted, but no further discussion was held on how to implement it.

Prof.Gibney repeated his previously made proposal to release "Interim SSC Opinions" and to allow for feed-back before finalising the text. In his view, such a procedure could significantly improve the quality of the final versions, to be adopted.

It was further stressed that adopting opinions within too short deadlines was not a good practice as it could affect the quality of the opinions. However, it was understood that urgencies exist and that providing sufficient time for finding answers would without any doubt ask for a change in mentality as it was not yet a common practice in Europe.

All members agreed that these points were most important and therefore asked for their further discussion as part of the discussions on the internal rules of procedure.

- The secretariat briefed the participants also on a meeting that was held on 18.12.97 between DGXXIV and the (UK) National Farmers Union, to clarify a number of elements of the opinion. At that meeting the NFU explained its unease with the idea that sheep and goat are suspect to the SRM list as cattle – which seemed to indicate that the SSC saw them to be carrier of BSE in the same way. This point was clarified and also the re-edited version prepared by Prof.James takes account of this misunderstanding.

#### **b) Briefing on the follow-up given to the opinion on the UK Date Based Export Scheme adopted on 8-9.12.97.**

- The SSC secretariat briefed the meeting on the preliminary contacts between the UK Government and Commission services on the exploitation in legislative terms of the opinion on the UK Date Based Export Scheme adopted on 8-9.12.97. The matter would now further be followed by Directorate General VI –Agriculture.
- The secretariat briefed the participants also on a meeting which was held on 18.12.97 between DGXXIV and the (UK) National Farmers Union, to clarify a number of elements of the opinion.
- Prof.M.Wierup (rapporteur) informed the meeting about an ambiguity in the text, resulting from the fact that the final version had to be edited quite rapidly during the last meeting. He presented a re-edited version, which was adopted without changes. This version is attached as annex 4.
- Regarding the requests to the UK Government to provide (simulation) estimates of the number of animals that would be affected if the offspring cull was extended to the subsequent generations of BSE cases, the SSC secretariat informed the participants that the UK authorities in principle had agreed to provide this information and that the competent service would contact the SSC secretariat on this matter.

### **c) Introduction of the reports and draft opinions**

It was decided to address the pending opinions in two steps: (a) to introduce the draft reports on the first day of the meeting and (b) to hold an in-depth discussion on the second day.

- *Geographical sourcing of bovine, ovine and caprine material in relation to BSE risk; and criteria ("compliance matrix") for the evaluation of the TSE status of a country.*

Prof. Osterhaus, rapporteur, clarified that the discussion on both subjects had been combined into one mandate to "define the BSE risk for specified geographical areas". He introduced a first draft report on this subject, prepared by the Working Group Sourcing.

- *Safety of tallow*

Prof. Vanbelle, chairman and rapporteur for the working group "tallow" summarised the report and draft opinion prepared on this subject. He underlined that the report and the draft opinion were finalised on the basis of a written consultation held from mid-December 1997 to mid January 1998.

- *Safety of meat and bone meal;*

Prof. Vanbelle, chairman and rapporteur for the working group "MBM" presented the report and draft opinion prepared on this subject. Also this report and the draft opinion were finalised on the basis of a written consultation held from mid-December 1997 to mid January 1998.

- *Safety of gelatine*

Prof. Vanbelle, chairman and rapporteur for the working group "MBM" presented the report and draft opinion prepared on this subject.

### **4.2. Genetically Modified Organisms:**

#### **a) Three genetically modified maize varieties and on one genetically modified winter rape seed variety: state of affairs.**

Prof. Silva Fernandes, chairman of the Scientific Committee Plants, briefed the meeting on the work done so far by this Committee, together with 3 members of the Scientific Committee on Animal Nutrition and one member of the Scientific Committee Food. Up to now 4 subgroups have been formed and started to look into the files: (1) Biotechnology, (2) Toxicology & Residues, (3) Environment and (4) Food and Feed. Each sub-group will submit its report to the next plenary of the SC-Plants, scheduled for 9-10 February. A draft opinion will be discussed and it is expected that a final opinion may be adopted in February or March 1998.

#### **b) Further discussion on the attribution of the various GMO-linked questions depending upon the legislative frame in which they fit.**

The chairman introduced the "Interpretative document on the interplay between Regulation 258/97 on Novel Foods and Novel Food Ingredients and Directive 90/220 on the deliberate release into the environment of genetically modified organisms", distributed to all members during the meeting. It was proposed that the SC-Plants would be leading committee for all questions related to biotechnology and the evaluation of the security of genetically modified plants and that the Scientific Committee Food would be leading committee for all questions concerning the security of foodstuffs and all questions related to food in general. These attributions would respect the Regulation 258/97 on "Novel foods and Novel Food Ingredients" as well as the Directive 90/220 on the "Deliberate release into the environment of genetically modified organisms".

The SSC agreed with the proposals and confirmed its opinion of 21 November 1997, that for the pending cases on maize (3) and rape seed (1), the SC-Plants would be the leading Committee and the other concerned committees should contribute to its work by seconding members to the GMO-working group of the SC-Plants.

It was also proposed that, in order to further enhance the collaboration between the Scientific Committee Food and Scientific Committee Plants, always one member of each Committee should attend the meetings of the other Committee. A similar practice exists in the United Kingdom. Prof. Bridges proposed that a member of the Scientific Committee Toxicity, Ecotoxicity and Environment, would attend the meetings of the Scientific Committees Food and Plants. The chairpersons of the concerned Committees agreed with the above proposals. The details of implementation would be further discussed bilaterally by the chairmen.

#### **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)**

Prof. Garido, chairman of the Scientific Committee Animal Health and Animal Welfare (the leading Committee for this matter), informed the SSC that a first meeting on this subject was planned for 17 February 1998.

#### **4.4. Bovine Somatotropine: state of affairs.**

Professor Osterhaus, chairman of the Scientific Committee Veterinary Measures relating to Public Health (the leading Committee for this matter) informed that a joint working group had been installed including members of the SC-Animal Nutrition and SC-Animal Health and Welfare. A report was expected for July 1998.

#### **4.5. Hormones in meat: briefing and preliminary discussion on the decision of the World Trade Organisation (WTO); follow-up.**

The Commission informed the Committee about the conclusions in the report of the WTO Appellate Body on EC measures with respect to the ban of hormones used as growth promoters. It was agreed that the most appropriate Committee to follow the developments in this matter was the Scientific Committee on Veterinary Measures relating to Public Health.

#### **4.6. In depth discussion and possible adoption of opinions**

##### *a) Definition of the BSE risk for specified geographical areas.*

The discussion was opened by Prof. M. Gibney, chairman of the Working Group "Sourcing" (WGS).

The general methodological approach, as outlined in the report, was welcomed and accepted by all members. The report itself was then discussed in detail, mainly with regard to:

- the availability of the data at a national or regional scale, needed to check the BSE status of a region (country) against the proposed list of criteria;
- the need to allow both for a model approach (if sufficient data and a satisfactory validated model are available) and for justified (using the same criteria) expert judgement if not all information is available as quantitative data;
- the need to correctly rank (attribute relative weights to) the criteria in order of importance and to identify the links, synergies or redundancies between (combinations of) them;
- the need to specify that the geographical risk is depending of a combination of the incident and propagation risk as defined by the WGS. The human exposure risk (probability that a human being is exposed to an infective dose of the BSE agent, within a given time period) is then an additional factor which has to be assessed when evaluating the safety of final products.

Various modifications to the proposed report were introduced. An opinion was finally adopted, consisting of an executive summary and a longer text was eventually adopted unanimously (see annex 5). A related draft press release was immediately prepared and verified with the rapporteur and chairman of the WGS and the chairman of the SSC.

The SSC also charged the TSE/BSE ad-hoc group to immediately apply the opinion to the Member States for which a dossier supporting their application to be considered free of BSE was already available. A first report, including the results of a preliminary assessment of the applications of these Member States, should be submitted to the SSC before its next meeting (19-20.02.98).

## **b) Safety of tallow**

The draft report and opinion, already introduced by Prof.M.Vanbelle, chairman and rapporteur of the Working Group on this subject, was discussed in detail, and various modifications were proposed.

The SSC agreed to the proposed approach to reduce the risk of infectivity in the remaining protein impurities to the lowest possible level. However, in addition to the more qualitative assessment presented in the report, the SSC requested a more detailed risk analysis, carried out in order to quantify the resulting human exposure. Prof.Osterhaus proposed an approach to which should take account of:

- type of final product and infectivity reduction capacity of the production procedure;
- the geographical origin of the raw material;
- the type of raw material, including the age of the animals;
- the removal or not of specified risk materials.

The basic idea should be to calculate a worst case scenario first and then develop a set of scenarios (model calculations) which would cater for more positive but realistic assumptions.

It was understood that such a quantitative assessment would be critically dependent on results of experiments and justified estimates of reduction factors during the various steps of the production process, from sourcing to marketing. Even if it was clear to the SSC that such data are not always available, as some experiments are still ongoing or only in a planning phase, the SSC asked the Working Group "tallow" to make an effort to undertake this quantitative risk assessment. In doing so it should collaborate with recognised experts and institutions.

Due to the outstanding quantitative risk assessment, no final report and opinion were adopted. It was also felt prudent to await the final outcome of the "Sourcing" work, because the safety of tallow (and other products derived from animal material, such as meat and bone meal and gelatine) is critically dependent of the quality of the raw material used.

## **c) Safety of meat and bone meal**

Due to a lack of time, the draft report on the safety of meat and bone meal was not discussed in large detail. However, a number of the issues were raised and discussed in the context of the discussion on the safety of tallow.

## **d) Safety of gelatine**

As for tallow, the general approach taken by the WG-"Gelatine" was appreciated while an additional component of quantitative risk assessment was felt to be useful. The same factors as for tallow should be taken into account.

It was agreed that Prof.Vanbelle would prepare an updated draft version of the tallow, MBM and gelatine opinions, which would take into account the proposed amendments. These updated drafts would then be circulated before the next SSC meeting (19-20 February 1998) amongst all members of the SSC and the respective working group members. Final drafts would then be distributed before the next meeting of the SSC with a view to adopt them at that meeting.

The Scientific Steering Committee also decided that it would 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, in order to provide the Commission with two alternative choices.

With the exception of the visit of Commissioner Bonino to the SSC, which took place on the first day of the meeting, the other items of the agenda were referred to a next meeting .

The meeting ended on Friday 23 January at 18h00.

### **Annex 1: List of participants of the Scientific Steering Committee meeting of 22 and 23 January 1998**

List of presence

#### **Members of the MDSC/SSC :**

Prof. Georges Bories, Prof. W. Bridges, Prof. F. Garrido-Abellàn, Prof. Michael J. Gibney, Prof. Philip James, Prof. Keith H. Jones, Prof. Fritz H. Kemper, Prof. Werner Klein, Prof. Ib Knudsen (only Friday, 23 Jan.), Prof. Robert Kroes, Prof. Albert Osterhaus, Prof. Gérard Pascal, Prof. Vittorio Silano, Prof. Antonio M.S. Silva-Fernandes, Prof. Marcel Vanbelle, Prof. Martin Wierup

#### **Participants from the Commission :**

DG III : O. Rohte, L. Bansil, K. Howes, F. Campoli, Pilar Roza, F. Silva, K. Berend, S. Lorenz-Meyer (only 22 jan.)

DG V : P. Peters, A. Berlin (only 23 Jan.)

DG VI : P. Colombo, J. Perez-Lanzac, E. Siracusa (only 23 Jan.)

DG XII : B. Hansen, X. Goenaga, M. Vidal (only 22 Jan.)

DG XV : A. Matton (only 23 Jan.)

DG XXIV : H. Reichenbach (only 22 Jan.), H. Belvèze (only 23 Jan.), B. Carsin, J. Costa-David, J. David, C. Deckart, W. Deklarc, M. de Sola, C. Diez Ubierna, J. Kreysa, G. Morrison, J. Moynagh, K. Madsen, J.J. Rateau (only 22 Jan.), A. Sanabria, S. Van de Louw (only 22 Jan.), A. Van Elst, P. Vossen, R. Vanhoorde, M. Walsh (only 22 Jan.), U. Wissenbach (only 23 Jan.)

### **Annex 2. Agenda of the Scientific Steering Committee (SSC) meeting of 22-23 January 1998**

1. Welcome, apologies, introductory remarks
2. Approval of the agenda
3. Approval of the minutes of the meeting of 8-9 December 1998
4. Multidisciplinary matters
  - 4.1. Priority matters related to Transmissible Spongiform Encephalopathies
    - (a) Briefing on the follow-up given to the opinion on Specified Risk Materials adopted on 8-9.12.97.
    - (b) Briefing on the follow-up given to the opinion on the UK Date Based Export Scheme adopted on 8-9.12.97.
    - (c) Introduction (without discussion) of the reports and draft opinions on

- Geographical sourcing of bovine, ovine and caprine material in relation to BSE risk;
- Criteria ("compliance matrix") for the evaluation of the TSE status of a country;
- 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;
- Further discussion on the attribution of the various GMO-linked questions depending upon the legislative frame in which they fit.

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

#### 4.5. Hormones in meat: briefing and preliminary discussion on the decision of the World Trade Organisation (WTO); follow-up.

#### 4.6. Discussion and possible adoption of opinions on (first: brief introduction of the reports and draft opinions; second: in-depth discussion):

- Geographical sourcing of bovine, ovine and caprine material in relation to BSE risk;
- Criteria ("compliance matrix") for the evaluation of the TSE status of a country;
- Safety of tallow;
- Safety of meat and bone meal;
- Safety of gelatine.

#### 4.7. Other matters related to TSE/BSE:

- Possible transmission of nv-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 3 questions received from Directorate General III and related to
  - (a) the use of specified risk materials for the manufacture of implantable medical devices,
  - (b) equivalency of alternative products for the use of intestine of animal origin for surgical sutures, and
  - (c) guarantees provided by 'closed herds' as compared to 'BSE free regions'.

### 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. Relationship between risk assessment and risk management (introduction and short discussion)

## 6. Co-ordination matters

- reports by the chairpersons of the 8 Scientific Committees;

- allocation of multidisciplinary matters which do not concern TSEs to scientific committees.

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

## 8. Any other business

- Visit of Commissioner E.Bonino to the SSC (first day)

## **Attachment to the agenda of the meeting of the SSC on 22/23 January 1998**

### **Pending matters to be treated by the SSC (as of 20.01.98)**

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 (expected for 22-23.01.97)

(b) Feeding of MBM to fur animals (expected for 19-20.02.97)

(c) Peptides and amino acids (expected for 19-20.02.97)

(d) Bi-calcium phosphate (expected for 22-23.01.97)

(e) Organic fertilisers (expected for 19-20.02.97)

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

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

(b) Criteria ("compliance matrix") for the evaluation of the TSE status of a country.

(c) Requests from Finland, Denmark, Sweden, Germany, Argentina, to receive the status of a scrapie- and BSE-free country;

(d) Claim from Canada to be BSE free;

(3) Semen: updated opinion

(4) 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
- (5) Maternal transmission

Routes of infection, risk assessment for these routes, and options to mitigate the risk from these routes

- (6) Animal-derived rennet
- Need for carrying out a risk assessment and transmission studies
- (7) Scrapie infectivity of peripheral nerves of sheep: implications in a BSE context
- (8) Transmission of nv-CJD via infected human blood; Risk quantification for CJD transmission via substances of human origin;
- (9) Safety of bovine blood and blood products;
- (10) the use of specified risk materials for the manufacture of implantable medical devices;
- (11) equivalency of alternative products for the use of intestine of animal origin for surgical sutures;
- (12) the guarantees provided by 'closed herds' as compared to 'BSE free regions'.

#### **Issues which might lead to questions in the near future**

- (1) 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.
- (2) Organophosphates: update of the opinion of the MDSC of 1997
- (3) Milk: update of the opinion of the Scientific Veterinary Committee of 1996 and of the MDSC of 1997
- (4) Safety of Xenotransplants
- (5) Acceptable minimum levels of impurities in MBM

#### **Annex 3 to the minutes of the Scientific Steering Committee of 22-23 January 1998.**

##### **Listing of Specified Risk Materials: a scheme for assessing relative risks to man**

Opinion of the Scientific Steering Committee adopted on 9 December 1997

(Version adopted by the Scientific Steering Committee at its Third Plenary Session of 22-23 January 1998)

Remark: The reference to footnote N° 10 attached to "serum" in the table on page 2, should refer to footnote N° 11

#### **Annex 4 to the minutes of the Scientific Steering Committee of 22-23 January 1998.**

##### **Report on The UK Date Based Export Scheme and the UK proposal on Compulsory Slaughter of the Offspring of BSE Cases**

Opinion adopted by the Scientific Steering Committee at its Second Plenary Session of 8-9 December 1997

(Version adopted by the Scientific Steering Committee at its Third Plenary Session of 22-23 January 1998)

**Annex 5 to the minutes of the Scientific Steering Committee of 22-23 January 1998.**

**Opinion of the Scientific Steering Committee on defining the BSE risk for specified geographical areas**

Adopted during the meeting of 22-23 January 1998