

# Scientific Steering Committee, Minutes of the Meeting of 24-25 September 1998

## 1. Welcome, apologies, introductory remarks

The chairman welcomed the participants and provided apologies of Prof. Dr.A.Osterhaus. He also welcomed and introduced Dr.W.Schuller, newly appointed Head of DG XXIV Unit B1 - Monitoring and dissemination of scientific opinions which co-ordinates the activities of the Scientific Steering Committee. The complete list of participants is given in annex 1.

## 2. Approval of the agenda

The agenda was approved with minor changes.

## 3. Approval of the minutes of the meeting of 16 July 1998

The minutes were approved, after introduction of changes. The SSC members stated that they were very pleased with the short reports on the activities of the various Scientific Committees, which were attached as an annex.

## 4. Work plan for the SSC

### 4.1. Progress on multidisciplinary matters:

a. Genetically Modified Organisms: Reflection on the possible need to broaden risk evaluation exercises so as to include possible potential hazards not yet recognised.

Prof. G.Pascal introduced the reflection documents on the above subject, prepared by him, Professor Klein and Professor James. A "drafting group" was created who will draft a mandate proposal for a working group on the subject. The drafting group will be presided by Prof.Pascal and Profs.Klein, James, Bories, Silva Fernandes and Knudsen are members.

A preliminary discussion was held on the orientation of this mandate.

b. harmonisation of working procedures (discussion of the reports by K.Bridges and R.Kroes and adoption of a draft mandate for a working group, including on the definitions of "reasonable" and "negligible risk")

Professor R.Kroes briefed the SSC on the first working group meeting that was held on 23 September 1998. The draft mandate prepared by this group was accepted by the SSC. It is attached as Annex 4.

The chairman of the working group, Professor R.Kroes, will now prepare a note to the chairpersons of all Scientific Committees and request them for information on currently applied risk-assessment procedures and nomination of a contact person for that purpose. The Working Group will then analyse the responses and meet with contact persons to discuss them. The objective is to identify and present before end January 1999 the common grounds and approaches for risk assessment used in the various Committees.

It was agreed that "reasonable and negligible risk" can not yet be defined as such. It would require significant efforts (e.g. for inventory of commonly used definitions, risk levels regarded to be acceptable, tolerable etc.) and hence time.

c. Resistance to antimicrobials

Prof.K.Jones briefed the SSC members of the progress made by the Working Group. The present planning is to finalise

in the coming months a first working document providing general indications on the issue of antimicrobial resistance and to submit a draft opinion to the SSC by April 1999.

#### **4.2. Multidisciplinary matters relating to TSE/BSE**

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

M.Gibney, chairman of the TSE/BSE *ad hoc* Group, reported on an ongoing discussion about the working relationship between the SSC, the TSE/BSE ad-hoc group and the Working Groups.

This question was also addressed at several other occasions during the meeting and finally it was agreed that a WG-report may be reviewed and modified by the TSE/BSE ad-hoc group as felt necessary but that the modified version would then be the sole-responsibility of the ad-hoc group. Equally the SSC could modify the text again. This does not preclude the possibility that a WG-report may be taken over without modification. However, in any case the opinion would make reference to the WG-report and could acknowledge the members of the WG.

Another general point addressed by the TSE/BSE ad-hoc group was the question of minority opinions. The SSC clarified that only minority opinions of SSC members could appear in opinions of the SSC, with an individual acknowledgement of the member, if requested. Hence a minority opinion of an expert could only appear if an SSC-member took it over, otherwise the majority opinion of a WG counts.

The current case of an existing minority opinion on the TSE infectivity clearance of infected meat-and-bone meal by rendering at "1"33°C / 20 minutes / 3 bars" was discussed. (See also annex 9: *Updated Scientific Report on the safety of meat-and-bone meal derived from mammalian animals fed to non-ruminant food-producing farm animals.*) It was decided that the existence of a minority opinion should be mentioned in the opinion but neither a name nor the detailed content of this minority opinion should be given because no SSC-member shares that point of view.

It was agreed that the Commission would further look into the issue and prepare guidelines.

Prof. Gibney finally informed the SSC on organisational matters of the ad-hoc group, including the fact that currently 24 questions are in front of the group and hence the SSC of which 19 are scheduled for before the end of the year. The workload, therefore, continues to be extremely high.

##### **b. Reports on specific issues:**

###### **b.1. BSE in sheep**

Dr.E.Vanopdenbosch, member of the TSE/BSE *ad hoc* Group and also chairman and rapporteur of the Working Group who worked on this subject since March 1998, presented the scientific report of the working group and the draft opinion prepared by the *ad hoc* group. A letter a member of the Working Group with comments on the report and draft opinion and which was received by the SSC secretariat on 21.09.98, was distributed to all SSC members. After amendments, an opinion on " *The risk of infection of sheep and goats with Bovine Spongiform Encephalopathy agent*" was adopted by the SSC. The complete text is given in annex 7.

###### **b.2. Meat-and-bone meal for fur animals, cross contamination with MBM of animal feedstuffs, safety of organic fertilisers and of hydrolysed proteins**

Prof.Dr.M.Vanbelle, also chairman and rapporteur of the enlarged Working Group who worked on these subjects since March 1998, presented the Working Group's four scientific reports and the draft opinions prepared by the *ad-hoc* group. A letter of 23.09.98 from a member of the Working Group with comments on the reports was distributed to all SSC members. The documents were extensively discussed. After amendments, the two following opinions were adopted:

- *Report and Scientific Opinion on mammalian derived meat and bone meal forming a cross-contaminant of animal feedstuffs*

- *Report and Scientific Opinion on the safety of organic fertilisers derived from mammalian animals*

The complete versions of these two reports and opinions are given in annexes 5 and 6

Regarding the draft opinion on the feeding of fur animals, the SSC considered that the opinion should focus on the question if fur animals could be fed with bovine derived feed stuff.

The issue of using fur animal carcasses as raw material for meat-and-bone meal or directly as a feed for fur animals should be further discussed in the pending opinions on

- *Intra-species recycling of animals, and*

- *The protection against 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 also, for example, exotic/zoo animals, fur animals, dead animals, condemned materials, sick animals and laboratory animals).*

The opinion on the *Safety of hydrolysed proteins* will be adopted by means of a written procedure following a revision of the text on the basis of the discussions held during the meeting. Prof. Gibney undertook to provide the necessary amendments. If no unanimity would be reached opinion would be referred back to the TSE/BSE *ad-hoc* Group and re-submitted at the SSC meeting of 22-23 October 1998.

An " *Updated scientific report on the safety of meat-and-bone meal derived from mammalian animals fed to non-ruminant food-producing farm animals*" was presented to the SSC. In view of the importance of this issue and the clarifications and additional explanations provided in the report in comparison to the opinion of the SSC on the issue of 26 March 98, the SSC welcomed the document and adopted it as such. It is attached to these minutes as Annex 8.

b.3. *Fallen stock, disposal, recycling waste, and environmental aspects of disposing of potentially infected materials.*

The WG met for a first time and a draft opinion can be expected for the SSC plenary of October or November.

b.4. *Progress report of the Working Group on Human Exposure Risk (HER).*

No meeting was held since last SSC; the next meeting of the WG is scheduled for 8 October 1998.

b.5. *Blood, blood products, implantables, sutures*

Prof. Jones reported on progress made by the Scientific Committee Medicinal Products and Medical Devices (SC-MPMD) on the issues of blood and blood products. Currently there were no indications of transmissibility of CJD and nvCJD via blood. However no opinion had yet been finalised. This is expected for the SC-MPMD plenary of October 1998.

On the issue of sutures, the Committee adopted on 16 September 1998 an *opinion and report on the equivalency of alternative products to intestines of animal origin for use as surgical sutures.*

b.6. *Up-date on the activities related the assessment of the TSE status of countries after the recent OIE-meetings.*

The Commission is currently preparing a proposal for a " *R egulation of the European Parliament and of the Council laying down rules for the prevention and control of certain transmissible spongiform encephalopathies.*" Specified risk materials, sourcing from geographical regions, individual animals or herds, and the safety of certain products, are key-issues in this proposal. The already available relevant opinions of the SSC have been taken into account and certain pending opinions will be integrated as soon as possible. However, the current timetable makes these opinions rather urgent.

The SSC secretariat informed the SSC of the new draft of Chapter 3.2.13 of the Animal Health Code of the International Office of Epizootics of the World Organisation for Health (OIE), concerning bovine spongiform encephalopathy. This draft specifies categories of countries with regard to their BSE-status. It needs verification whether its content can be

considered to be compatible with the numerous SSC opinions already adopted, which refer to the geographical sourcing of bovine material.

#### b.7. Working Group Sourcing & Modelling (progress report; possible adoption of a handbook for the assessment of TSE-status dossiers).

Version 7 of the handbook was presented and discussed. On the basis of this discussion a new version will be prepared. SSC-Members will distribute this version as a confidential document to experts in the field, requesting comments to be sent to the SSC-secretariat before 12/10/98. On the basis of these comments the TSE/BSE will decide on 15/10/98 if a final version can be prepared and transferred to the SSC for adoption on 22/23 October 98, or if a specialised workshop is needed. In the latter case the method can hardly be adopted before November, 12/13.

#### b.8. Evaluation of diagnostic tests for TSE in bovines

The SSC was informed that the true negative samples are nearly all collected as well as about 50% of the true positive. The evaluation of the four tests retained will start soon.

#### b.9. Additional question from the Commission on the safety of tallow.

The Scientific Steering Committee was asked to express an opinion on the following question: "*Is it scientifically justified that tallow, derived from material non fit for human consumption and in order to obtain a safe product in terms of potential residual contamination with TSE infectivity, must be treated to "133°C/ 20' / 3 bars" or equivalent AND purified such that the maximum level of impurities does not exceed 0.15%?"*

The SSC expressed its un-ease with the fact that the question is posed now and not when the opinion was on the INTERNET (March 1998), open for comments. It discussed the matter and insisted on a combination of both conditions, if the tallow is fed to ruminants. If such can be excluded, one treatment alone could be sufficient, preferably the heat treatment. However, the SSC was sceptical as to the controllability of such a condition.

#### b.10. The identification of vCJD agent in the human appendix

The Scientific Steering Committee was invited to evaluate the possible implications resulting from the recent finding of TSE prions in the appendix of a person who developed nvCJD-symptoms eight month after his appendix was removed. The SSC should assess whether any action should be taken in the framework of the activities of the Scientific Committees; if so which ones. A copy of relevant press (*New Scientist*) and scientific (*The Lancet*) articles were provided to the SSC members.

The SSC saw no need to recommend immediate activities, given the fact that the Scientific Committee for Medicinal Products and Medical Devices is already following the issue, which was considered important for the investigation of the causes for nvCDJ. The SSC will be kept informed regularly.

## 6. Organisational matters

Reimbursements: Prof.Pascal stated that the reimbursements of travel indemnities and expenses are now going smooth. On behalf of the SSC he thanked DGXXIV and especially the SSC secretariat staff for the efforts made.

Publication of Scientific opinions: the SSC secretariat informed the SSC that the opinions and reports adopted since November 1997 by the Scientific Committees of the Commission, would only be made available on INTERNET and on CD-ROM. No hard copy would be printed anymore. Prof.Knudsen and other SSC members underlined, however, the usefulness of those opinions to be available also as printed publications.

## 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 (16

July 1998). A summary of their reports is given in annex 3.

The Committee was further briefed on the Scientific Committee for Toxicity, Ecotoxicity and Environment's activities related to Endocrine Disrupters.

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

Mr.O.Rohte reported on the activities of DG III in the field of Scientific Co-operation. He presented the status of Council Directive 93/5/EEC on assistance to the Commission and co-operation by the Member States in the scientific examination of questions relating to food. A status report and overview tables were distributed to all SSC members.

Mrs. P.Colombo reported on the ongoing DG VI activities related to the legislative exploitation of the SSC's opinions and the preparation of draft legislation proposals (see also above). These cover, amongst others, the safe production of tallow, meat-and-bone meal, hydrolysed proteins, dicalcium phosphate, etc., and the previously mentioned regulation of the European Parliament and of the Council laying down rules for the prevention and control of certain transmissible spongiform encephalopathies. For several of the legislative action DGVI is waiting for the opinions of the SSC.

## **9. Any other business.**

The SSC was informed of DGXXIV's internal reflection exercise which was presently going on regarding the possible introduction of additional obligatory consultation of the Scientific Committees. The Decision setting-up the SSC foresees that the Committee will assist the Commission in this exercise. The issue will be put on the agenda of one of the next SSC meetings

The meeting ended on 25 September at 17h00

[Annexes au format PDF \(61 KB\)](#)