

Minutes of the Scientific Steering Committee Meeting of 11-12 January 2001

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

The chairman welcomed the participants of the Scientific Steering Committee. He apologised Prof. Knudsen. Prof. Leneindre represented the Scientific Committee for Animal Health and Animal Welfare (SC-AHAW). Prof. Le Neindre was however not entitled to participate in the possible adoption of opinions, as SC-AHAW had not yet been formally newly installed and therefore had not yet elected its chairperson and vice-persons.

Declarations of interest:

No member declared an interest in any of the items on the agenda of this specific meeting.

2. Approval of the agenda

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

3. Approval of the minutes of the meeting of 7-8 December 2001.

The minutes of the meeting of 7-8 December 2000 were adopted without changes.

4. Multidisciplinary matters:

a. Co-ordination: Reports of the Chairmen of the 8 Scientific Committees

As agreed at its meeting of 7-8 December, when it discussed its working procedures, the SSC started the main part of its meeting with a tour de table of the chairpersons of the 8 sectorial committees each providing a "Reports of the Chairperson".

The multidisciplinary matters requiring co-ordination or having the potential of becoming a scientific matter of increasing concern were discussed in more detail. At the end of this discussion, the following actions were agreed upon:

- Toxicity of minerals such as Cu and Zn in animal feed: regarding the possible environmental aspects of these minerals, the SC-Animal Nutrition (SCAN) will request inputs from the Scientific Committee for Toxicity, Ecotoxicity and the Environment (SC-TEE).
- Novel feeds: the scientific aspects will be addressed in the Working Group "Biotechnology", which comprises representatives from the Scientific Committee for Plants (SC-P), the Scientific Committee on Food (SC-F) and the SCAN).
- Hygienic measures to avoid pathogens to pass production lines and to enter in food and the environment. This is being addressed by Scientific Committee on Veterinary Measures relating to Public Health (SC-VMPH). Inputs are being provided and will further be needed from all scientific Committees.
- Maximum Residue Levels in veterinary medicinal products. Setting these levels falls under the competence of the EMEA. The Scientific Committee for Medicinal Products and Medical Devices (SC-MPMD) intend to start a review of the scientific procedure for setting these limits. It will need the inputs from several other committees.

More detailed information on the activities of the various Scientific Committees is attached as Annex 3.

b. Harmonisation of risk assessment methods: (draft) mandate for a task force.

At its meeting of 26-27 October 2000 the SSC adopted a final opinion and report on *Harmonisation of risk assessment methods*.

Following this, the SSC at its meeting of 7-8 December 2000 underlined the need to establish as soon as possible an Inter-Committee Task Force. As agreed at that meeting, the draft of a detailed remit for the Inter-Committee Task Force was presented by Prof. Bridges. The SSC discussed the draft in detail and proposed several amendments. The draft will be updated and further discussed at the meeting of 8-9 February 2001. Meanwhile, the membership of the task force will be composed on the basis of proposals to be made by the members of the SSC and including at least one representative from each sectorial Scientific Committee.

c. Safety of cotton

The SSC was asked to advise the Commission on how best to address a new interdisciplinary question regarding the safety of cotton products such as feminine hygiene products (e.g. tampons, sanitary pads etc), baby or adult incontinence products (e.g. nappies, etc), "medical cotton" product (cotton balls, make-up pads, gauze, etc) and cotton fabrics and garments.

The rapporteur, Prof. Hardy, briefly presented a first version of the draft report. It was now being circulated for comments and possible contributions from competent members of the SC-P, SC-MPMD and SC-CNFP. Final discussion and possible adoption of an opinion would be done by the SSC, possibly at its next meeting of 8-9 February 2001.

d. Emerging scientific issues (progress reports from task forces, working groups and scientific committees)

The state of affairs of the work on the following issues, taken from the SSC opinion adopted on 26-27 October 2000 on "*Strategies for dealing with emerging and re-emerging scientific issues that have the potential to impact human health, directly or mediated through the environment*" was presented:

- ***Emerging viruses.*** Commission Services will prepare a draft mandate for next meeting, when the membership will also be discussed
- ***Anti-microbial resistance.*** The composition of the Working Group will be discussed at the meeting of 8-9 February 2001.
- c) ***High-frequency electro-magnetic fields.*** The Scientific Committee for Toxicity and Ecotoxicity of the Environment has started the verification whether since the adoption in June 1999 of the SSC opinion on Electro-magnetic waves, any new scientific evidence became available. Prof.. Klein and Prof.Silano have joined the SC-TEE's working group.
- d) ***Xeno-transplants.*** This issue is already being addressed by the SC-Medicinal Products and Medical Devices, however no Working Group meeting has been held since last SSC meeting. Prof. Löwer will further regularly report to the SSC.
- e) ***Endocrine disrupters.*** At its last meeting, the SSC agreed that members of the SCF, the SCVPH and, possibly, the SCAN would join the existing Working Group of the Scientific Committee Toxicity and Ecotoxicity of the Environment (SC-TEE). No further progress was made since last meeting.

e. New questions

The secretariat informed the SSC of the new questions submitted to the SSC:

On anti-microbial resistance: verify whether in the dossiers recently submitted by the industry to the Services of the Commission, there is any evidence that would justify a revision of the SSC opinion on Antimicrobial Resistance.

On BSE/TSE issues, new questions were submitted on:

- Medical instruments;
- Treatment and disposal of animal waste by alkaline hydrolysis at elevated temperature;
- Safety of a soil conditioner;
- Alternative ways of disposal;
- Safety of collagen;

5. Multidisciplinary matters relating to TSE/BSE

5.1. Report by the chairman of the TSE/BSE *ad-hoc* group meeting of 4 January 2001

Prof. Silano reported briefly on the meeting of the TSE/BSE *ad hoc* Group of 4 January 2001. All items addressed by the *ad hoc* group are further dealt with in detail under point 5.2 of these minutes.

5.2. Reports on specific issues:

- a. The answer to 5 of the questions resulting from the Council of Ministers meeting of 4 December 2000**, was grouped into one opinion, covering items 5.a through 5.e of the original agenda on the safety of bovine vertebral column and T-bone-steaks, the safety of bovine thymus and spleen, the safety of bovine rendered fats, the safety of hydrolysed proteins (all sources) and the safety of ruminant-derived mechanically recovered meat (MRM).

Following in-depth discussions, the SSC adopted the *Opinion on the questions submitted by EC services following a request of 4 December 2000 by the EU Council of Agricultural Ministers regarding the safety with regard to BSE of certain bovine tissues and certain animal-derived products*. It is attached as Annex 4.

- b. BSE epidemiology (survey methods).**

Together with the 5 above questions, Commission Services had submitted a question on BSE epidemiology. (See the minutes for the meeting of 7-8 December 2000 for the exact formulation of the question.)

As the SSC and the TSE/BSE *ad hoc* Group had been requested to give priority to the 5 above questions, no progress had been made. The question will be further addressed at the TSE/BSE *ad hoc* Group meeting of 1 February 2001.

- c. Geographical BSE-risk: update and possible adoption of an opinion on the GBR of Uruguay.**

The secretariat gave a short update on the GBR-assessment exercise and informed the SSC on the ongoing assessment of 27 Third Countries: It is currently foreseen that the SSC adopts a first set of country reports on the GBR-assessment at its meeting of February 2001. The remaining reports would then be discussed and adopted at the March and/or May 2001 meetings. The need was stressed to verify the GBR of level I

and II countries already assessed in July 2000 in the light of recent results concerning the appearance of BSE cases in countries such as Germany, Italy and Spain.

The SSC also expressed its concern about the possible existence of not recorded exports of ruminant meat-and-bone meal from the UK to other countries.

The SSC further discussed and amended a report and draft opinion prepared by the Working Group on Geographical BSE Risk Assessment (GBR) on the BSE risk in Uruguay. It adopted the opinion that is attached as Annex 5.

d. Pre-emptive opinion on risk scenarios, should BSE in sheep be found under natural conditions. Monitoring of research results on experimental BSE in small ruminants.

The SSC briefly discussed a first draft report by a special working group and a summary prepared by the TSE/BSE *ad hoc* Group. It considered that the issue required further discussion by the Working Group.

6. Organisational matters.

No other organisational matters were discussed.

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

This point was not addressed.

8. Any other business.

No other business was discussed.

The meeting ended on Friday 12 January 2001, at 17h30

Annex 1: List of participants in the Scientific Steering Committee meeting on 11-12 January 2001.

List of presence

Members of the SSC:

- Ing. Georges Bories
- Prof. James W. Bridges
- Prof. Johanna Fink-Gremmels
- Prof. Anthony R. Hardy
- Dr Keith Jones
- Prof. Werner Klein
- Dr Ada Knaap (present on 11 January 2001 only)
- Dr Ib Knudsen (*excused*)
- *Dr Pierre Le Neindre*
- Prof. Johannes Löwer
- Prof. Albert Osterhaus
- Prof. Gérard Pascal
- Prof. Pere Puigdomenech
- Prof. Vittorio Silano
- Prof. Staffan Skerfving
- Dr Ian White

Participants from the Commission:

DG SANCO: C. Berlingieri, P. Vossen, J.Kreysa, J.L. Jouve, S. Abildgaard, I. Rollier, G. Morrison, V. Van Haeperen, M. Walsh, G. Costa David, J. Ferrière A. Somogyi, A. Fokkema, A. Wilhelm, I. Demade.

DG AGRI : J-M Bertrand.

DG RTD: A. Di Giulio, I. Minguez.

Annex 2:

Draft agenda of the Scientific Steering Committee Meeting of 11-12 January 2001

[items marked with an asterix (*) are priority]

1. Welcome, apologies, introductory remarks, declaration of interest.
2. Approval of the agenda + review of planning of SSC meetings.
3. Approval of the minutes of the meeting of 7-8 December 2000
4. Multidisciplinary matters:
 - a. Co-ordination: Reports of the Chairmen of the 8 Scientific Committees
 - b. Harmonisation of risk assessment methods: (draft) mandate for a task force.
 - c. Safety of cotton (progress report)
 - d. Emerging scientific issues (progress reports from task forces, working groups and scientific committees)
 - *e. New questions
5. Multidisciplinary matters relating to TSE/BSE
 - 5.1. * Report by the chairman of the TSE/BSE *ad-hoc* group meeting of 4 January 2001
 - 5.2. Reports on specific issues:

Questions resulting from the Council of Ministers meeting of 4 December 2000:

 - *a. Safety of bovine vertebral column and T-bone-steaks.
 - *b. Safety of bovine thymus and spleen.
 - *c. Safety of bovine rendered fats.
 - *d. Safety of hydrolysed proteins (all sources).
 - e. Safety of ruminant-derived mechanically recovered meat (MRM).
 - f. BSE epidemiology (survey methods).

Geographical BSE-risk (GBR).

 - g. Update and possible adoption of an opinion on the GBR of Uruguay.

Other issues:

 - *h. Pre-emptive opinion on risk scenarios, should BSE in sheep be found under natural conditions. Monitoring of research results on experimental BSE in small ruminants.
6. Info on the follow-up given to the opinions adopted at the previous SSC meeting.
7. Information by the Commission services on matters related to consumer health.
8. Any other business.

Annex 3: Reports from the chairpersons of Scientific Committees on the major activities and milestones since the SSC meeting of 7-8 December 2000.

(COMPLETE INFORMATION AT THE WEBPAGES OF THE SCIENTIFIC COMMITTEES AT THE ADDRESS [HTTP://EUROPA.EU.INT/COMM/FOOD/FS/SC/SCF/INDEX_EN.HTML.](http://europa.eu.int/comm/food/fs/sc/scf/index_en.html))

Scientific Committee on Food (SCF)

The following lists display the requests for opinions that are currently under consideration by or are being submitted to the SCF.

Food Additives: 31 dossiers presently under consideration

Food Contact Materials: 50 – 70 individual substances per year, separate request on Food Consumption Factors

Novel Foods and Novel Processes: meetings will be held jointly with the SCP WG on GMOs and experts from SCAN. Ongoing work includes dossiers on GM and non-GM food products, update of the SCF Guidelines for Irradiation, and SCF Guidelines on Novel Foods.

Nutrition: Upcoming requests relate to update of guidelines on Population Reference Intake, update of SCF specifications for infant formulae, and guidelines for and evaluation of vitamins and minerals for use in dietetic foods.

Upper Levels for vitamins and Minerals: Approximately 20 individual substances are under evaluation.

Food Contaminants: Individual Fusarium toxins are under finalisation, a group evaluation will be considered. An urgent request has been received for updating the evaluation of 3-MCPD. Upcoming requests include the re-evaluation of some heavy metals, polyaromatic hydrocarbons and organotin compounds.

Food Microbiology and Hygiene: The development of a risk profile on microbial contamination of fruits and vegetables eaten raw is under finalisation. Upcoming requests will be considered in close co-operation with the SCVPH.

Flavourings: The evaluation of “active principles” in flavourings is ongoing as a priority. The evaluation of the substances included in the Community Register on Flavouring Substances (200 substances per year foreseen by legislation) has just started and is done in co-operation with SCOOP. In this context, appropriate methods for exposure assessment of flavours will be considered.

Dioxins: The SCF has just finalised its risk assessment of dioxins and dioxin-like PCBs in food.

Scientific Committee for Plants

Evaluation of GM plants in the context of Directive 90/220/EEC: the meeting of the SCP *ad hoc* working group on GMOs will be held jointly with the SCF working group on novel food and novel food ingredients. Additional experts from the SCAN will be invited to participate to this joint working group. The first joint meeting is planned to take place on 1 February 2001.

Contamination of conventional seeds by GM seeds: for the first time, a question relating to the prevention of the contamination of conventional seeds by GM seeds was referred to the SCP. A specialised *ad hoc* working group, involving in experts in seed production, gene flow, biotechnologists, will meet on 16 and 17 January.

The next plenary meeting of the SCP will take place on 26 January.

Scientific Committee on Animal Nutrition (SCAN)

The 7th SCAN met for the last time of its mandate (1997-2000) on 20 October 2000. This extraordinary plenary was dedicated to the discussion on the draft opinion on dioxins in feed. The Committee discussed the draft opinion in detail and agreed to adopt it using the Written Procedure, after inclusions of the modifications requested by Committee members. The final opinion was adopted on 06 November.

The SCAN was renewed by the Commission at the end of November, met on 06 December, elected during this meeting its chairpersons: Prof. Bories (Chairman), Prof. Chesson (First Vice-Chairman) and Prof. Wester (Second Vice-Chairman), adopted its rules of procedures and agreed on the plenary meetings' dates for the year 2001. The Working Groups continue their work. New questions to the Committee are expected for early 2001. Since the last SSC meeting (7-8 December 2000), nothing new has therefore to be reported on.

Scientific Committee Veterinary Measures relating to Public Health

Since the last SSC plenary meeting, no meetings of the Scientific Committee on Veterinary Measures relating to Public Health have taken place.

In January, a meeting is planned on 25th WG on Vibrios. The next plenary is organised for 14th –15th February, the discussion will be focused on:

- (i) some reports to be finalised and adopted;
- (ii) some draft opinions will be presented for initial discussion;
- (iii) new possible mandates (e.g. Norwalk Viruses (NLVs), Salmonella methods).

Scientific Committee on Animal Health and Animal Welfare

The Scientific Committee on Animal Health and Animal Welfare had no plenary session since the last SSC meeting.

Scientific Committee for Toxicity, Ecotoxicity and the Environment

A. Opinions were adopted on the following:

1. *“Terrestrial environment - Available scientific approaches to assess the potential effects and risks of chemicals on terrestrial ecosystems”.*

2. Risk assessment reports of:

a) Acetonitrile; b) 1,4-Dichlorobenzene; c) 1,4-Dioxane; d) Methacrylic acid; e) 4-Chloro-2-methylphenol [all these produced under the so-called Existing substances Regulation (793/93)].

B. The CSTEE is also pursuing its activities on the following opinion requests:

i) *The use of exposure data in risk assessments (multidisciplinary)*

ii) *Proposed EU Water Framework Directive – Development of a specification for the intercalibration of biological monitoring methods – Final Draft (European Commission Directorate General XI), Report No: CO 4751/1 – October 1999 (WG meeting scheduled for 22 January 2001).*

iii) *Margins of safety (multidisciplinary - WG meeting took place on 9 January 2001).*

iv) *Evaluation of sludge treatments for pathogen reduction (WG meeting scheduled for 29 January 2001).*

v) *Carcinogenic and non-carcinogenic effects of Cadmium, Nickel and Arsenic in ambient air, and*

vi) *Derivation of limit values for PAH in ambient air*

vii) *Health effects of Radio Frequency and Electromagnetic fields (emerging issue?).*

viii) *Assessment of the risks to human health posed by azo colorants in toys, writing inks and paper products, and analysis of the advantages and drawbacks of restrictions on their marketing and use – LGC report ETD/99/502495*

ix) *The availability of substitutes for soft PVC containing phthalates in certain toys and childcare articles – RPA final report ETD/99/502498*

x) Evaluation of the following Regulation 793/93 Risk Assessment Reports:

On Risk assessment reports on Human health & Environmental effects:

a) *Acrylonitrile; b) Anisidine; c) Acrylamide; d) Methyl methacrylate.*

On Risk assessment reports on Human health effects:

a) *Nonylphenol and nonylphenol (branched).*

D. The next (21st) CSTEE plenary meeting is due to take place on 30 January 2001.

Scientific Committee for Cosmetics and Non-Food Products

Since the last SSC plenary meeting, no meetings of the Scientific Committee on Cosmetic Products and Non-Food Products have taken place.

In January, however, meetings are planned on 16th (WP 'Hair Dyes') and on 17th January (WP 'Preservatives') during which :

- (i) the new members will be briefed on the respective pending issues;
- (ii) some draft opinions will be presented for initial discussion.

Of particular interest are the ongoing evaluations of the safety of certain fragrance substances. It is considered that for some substances there should be a mechanism to assess consumer exposure from all sources to provide an overall risk assessment.

Scientific Committee for Medicinal Products and Medical Devices

At their Plenary Meeting on 4th. December 2000 the following item were adopted:

- a) Creation of a Working Group on "Veterinary medicines".
- b) The Working Group on "Xenotransplantation", created during the last mandate, will continue its work in order to prepare a state of the art report.
- c) Another Working Group on "Tissue Engineering", covering cell therapies, embryonic stem cells and the related matters, was created in order to prepare a state of the art report.
- d) The group on "Blood" must continue its work in order to review the previous opinions in the light of new scientific evidence as and when necessary.

Annex 4



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C1 - Follow-up and dissemination of scientific opinions

SCIENTIFIC STEERING COMMITTEE

**OPINION ON THE QUESTIONS SUBMITTED BY EC SERVICES
FOLLOWING A REQUEST OF 4 DECEMBER 2000 BY THE EU COUNCIL
OF AGRICULTURAL MINISTERS REGARDING THE SAFETY WITH
REGARD TO BSE OF CERTAIN BOVINE TISSUES AND CERTAIN ANIMAL-
DERIVED PRODUCTS**

ADOPTED ON 12 JANUARY 2001

(Distributed separately)

Opinion of the
Scientific Steering Committee
on the
GEOGRAPHICAL RISK OF
BOVINE SPONGIFORM
ENCEPHALOPATHY (GBR) in
URUGUAY

Adopted on 12/01/2001

(Distributed separately)