

Minutes of the Scientific Steering Committee Meeting of 13-14 April 2000

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

Prof.Dr.Pascal welcomed the participants. He apologised, for the afternoon of 14 April, Profs.W.Bridges and M.Gibney. He also welcomed Dr E. Vanopdenbosch who would, on 13 April 2000, report on several of the draft opinions prepared by the TSE/BSE *ad hoc* Group. The list of participants is attached as annex 1.

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. It is attached as annex 2.

3. Approval of the minutes of the meeting of 2-3 March 2000

The minutes of the meeting of 2-3 March were adopted with changes. It was clarified that each country for which the geographical BSE risk had been assessed would only receive its own individual draft report.

4. Multidisciplinary matters:

a. Emerging health issues

Prof.Bridges prepared a first draft report on the basis of contributions from Profs. Pascal, Klein, James, Hardy and Knudsen and on the basis of the provisory list of emerging issues established at previous SSC meetings. The document was discussed and the draft list of possible emerging issues was amended. It is attached as annex 3. The SSC confirmed again that this annex should still be considered to be the result of a brainstorming. It is not ranked in terms of priority or in any other way. The SSC stressed that it is in no way to be considered as list of priority public health concerns. Many other, and in many cases more important, public health and consumer protection issues do not figure on the list, for example because they are being addressed already, because they are not a "possibly emerging risk", because they are not within the mandate of the SSC, etc. The principle of re-organising the list into real possible emerging hazards and possible re-emerging hazards was accepted. There was also a consensus that a number of items would eventually have to be deleted from the list.

A work distribution and work-plan were agreed upon and it was decided that an updated document would be further discussed and possibly adopted at the meeting of 25-26 May 2000.

b. Emerging health issues: pilot exercise applied to GMOs

No further progress was made on this issue. It will be further discussed at the next meeting.

c. Harmonisation of risk assessment procedures (progress report and discussion)

The Working Party on "Harmonisation of Risk Assessment procedures" hold its third meeting on April 3, 2000 and discussed the following issues:

- *Priorities and timetable.* Priority should be given to addressing issues which relate directly to the improvement of risk assessment across the nine DG Sanco Scientific Committees and/or improve their ability to carry out their mandates.

The intention is to produce a report for the SSC by mid September 2000 at the latest.

- *Form of the final report.* It was agreed that the report would consist of a main report with a number of appendices. These would include the reports of the sub-groups and of individual expert advisers.

- *Definitions.* A set of working definitions has been agreed. Members were further asked to identify sub-definitions which are necessary to further explain a particular use of terms in a risk factor specific context.

- *Quantitative Risk Assessment.* The work continues to be focused on developing a strategy for introducing quantitative risk assessment across the various Scientific Committees. Based on a report produced by an individual expert adviser, guidelines would be developed on when and how should quantitative risk assessment be applied for non-threshold and threshold chemicals. It was also agreed to establish two working sub-groups to cover the issue of quantitative risk assessment for microbiological hazards. One would tackle with microbiological contamination of food and other products, the other with infection spread (with particular reference to imported animals).

- *Committee guidelines.* The work is progressing in three directions:

i) development of general guidelines for hazard identification and hazard characterisation,

ii) establishment of a working sub-group to develop general guidelines on exposure assessment,

iii) harmonisation of presentation of scientific opinions.

- *Interface between risk assessors and risk managers.* The working party examined a draft proposal for guidelines on the procedures to ensure effective and efficient dialogue between risk assessors and risk managers. It was agreed to develop the proposal, while giving attention to the involvement of public interest groups in phrasing questions to the scientific committees, and to gaining back information from risk managers on the usefulness of the scientific opinions provided by the different scientific committees.

The next Working Group meetings have been scheduled for 22 May and 5 July.

d. White paper on Food Safety

Prof.Kroes presented the draft document he prepared on the basis of the SSC's first in-depth discussion on the *White Paper on Food Safety* held on 2-3 March 2000. The paper was very positively welcomed. Following discussion, further amendments were introduced. The scientists agreed with the Commission's approach to set up an independent body, but strongly advocate to extend its mandate beyond food safety alone to all public health issues, including the safety of non-food products and environmental issues. Amongst other recommendations (see Annex N°4), they also recommended that sufficient human resources should be allocated to the scientific secretariats of the Food Safety Authority in order to guarantee their optimal functioning.

David Byrne, Commissioner for Health and Consumer Protection, attended part of the discussions and made a presentation with as principal theme the future Food Safety Authority. The Committee presented the broad lines of its document and exchanged of views with David Byrne, especially about the plans for a Food Safety Authority as developed in the Commission's White paper on Food Safety.

A final statement explaining the SSC views on the matter was adopted after Commissioner Byrne had left. It is attached as Annex N° 4.

e. Statement on the functioning of the EC's Scientific Committees

No progress was made in this field. Prof.Wierup will prepare an updated draft statement, to be discussed at the next meeting.

5. Multidisciplinary matters relating to TSE/BSE

5.1. Report by the chairman of the TSE/BSE ad-hoc group

Prof.V.Silano reported briefly on the meeting of the TSE/BSE ad hoc Group of 30 March 2000. All items addressed by the group are further dealt with in detail under point 5.2 of these minutes.

5.2. Reports on specific issues

: In the course of its discussions on the various SRM-related opinions hereafter, the SSC considered that the opinion of December 1997 on Specified Risk Materials (SRM), should be updated in the light of its SRM-related opinions adopted since then.

a. Safety of ruminant blood

The report of the Working Group and the draft opinion prepared by the TSE/BSE *ad hoc* Group at its meeting of 30 March 2000, were discussed in detail and amended. The opinion *The Safety of ruminant blood with respect to TSE risks* was adopted . It is attached as Annex 5.

b. Handling and storage of possibly BSE contaminated MBM

Prof.W.Bridges presented briefly the first draft *is on the safe handling, transport and storage of MBM and other bovine derived materials which may be contaminated with BSE or other pathogens*, he prepared as agreed upon at the last SSC meeting. The report will now further be finalised by a working group and the TSE/BSE *ad hoc* Group. It is expected to be submitted for adoption by the SSC at either the May or the July 2000 meeting.

c. The safety of UK bone-in beef

The report of the Working Group and the draft opinion prepared by the TSE/BSE *ad hoc* Group at its meeting of 30 March 2000, were discussed in detail and amended. The *Opinion on the UK decision to lift the ban on the consumption of meat on the bone* was adopted. It is attached as Annex 6.

d. Safety of bones: re-assessment of the safety with respect to TSEs, of certain types of specified risk materials in small ruminants.

The report of the Working Group and the draft opinion prepared by the TSE/BSE *ad hoc* Group at its meeting of 30 March 2000, were discussed in detail and amended. The *Opinion Specified Risk Materials of Small Ruminants. (Follow-up to the SSC opinion of 24-25 September 1998 on the Risk of Infection of Sheep and Goats with BSE Agent)* was adopted. It is attached as Annex 7.

e. The safety of ruminant vertebral column for the production of gelatine and tallow

The report of the Working Group and the draft opinion prepared by the TSE/BSE *ad hoc* Group at its meeting of 30 March 2000, were discussed in detail and amended. The opinion *Quantitative Risk Assessment on the Use of the Vertebral Column for the production of Gelatine and Tallow* was adopted. It is attached as Annex 8.

Regarding the report of the Working Group it was decided to make it available as a pre-report on Internet, for public comments until 10 June. Further discussion and possible adoption by the SSC is then expected for 6-7 July 2000, following possible further discussion by the TSE/BSE *ad hoc* Group at its meeting of 22 June 2000. The Pre-report is attached as annex 9.

f. Human Exposure Limit Line

The Scientific Steering Committee (SSC) adopted at its meeting of 2-3 March 2000 a Preliminary Opinion on *Oral*

exposure of humans to the BSE agent: infective dose and species barrier. The document was put on Internet on 6 March 2000 and the international scientific community was invited comment on its contents. Only two comments have been received by the secretariat of the SSC:

These comments were discussed by the SSC and amendments in the pre-opinions were introduced, as shown in the final opinion and report in Annex 10.

The SSC noted that, in its comments, the Meat and Livestock Commission (MLC) refers to cattle to cattle transmission studies on brain material obtained from affected cattle which have now been completed in the UK. The results will be published later this year. These studies seem to show that actual titres in cattle are significantly lower than those calculated by the Committee and it is therefore suggested that more reliance should be placed on these actual titres and less on the calculation of the titre in the Opinion.

The SSC invites the MLC and the research institute(s) involved in this research to communicate these results to the Committee. It will then, if appropriate, amend the attached opinion.

g. Geographical risk: position paper and reports on the risk assessments of Member States and Third Countries.

The SSC secretariat reported on the state of affairs. The reports on the geographical risk assessments of Member States and Third Countries had been finalised. Each of the Member States (except Greece that did not submit a dossier) had received its individual country report. The reports on the third countries were in the process of being mailed. Comments and possible additional information were expected to reach the secretariat before 28 April (Member States) or 8 May 2000 (Third Countries).

On behalf of Prof. Silano, the secretariat also presented the update of the overall opinion ("Avis chapeau") on geographical BSE risk. Adoption of the overall opinion is expected either as a separate document at the SSC meeting of 25-26 May 2000 or together with the individual country reports.

An updated planning was proposed and agreed upon.

h. TSE and culling.

No progress on this issue was made since the last SSC meeting, as priority was given to the Geographical BSE Risk Assessment exercise and to the preparation of the opinions related to the safety of ruminant materials.

i. Origin of BSE.

No progress on this issue was made since the last SSC meeting.

j. Criteria for diagnosis of clinical and pre-clinical TSE disease in sheep and for differential biochemical diagnosis of TSE agent strains (for opinion)

The report of the Working Group and the draft opinion prepared by the TSE/BSE *ad hoc* Group at its meeting of 30 March 2000, were discussed in detail and amended. The Opinion on *The criteria for diagnosis of clinical and pre-clinical TSE disease in sheep and for differential biochemical diagnosis of TSE agent strains*, was adopted. It is attached as Annex 11.

k. GME protocol on TSE inactivation

This item was not discussed, due to a lack of time.

6. Organisational matters

No organisational matters were discussed

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

The chairmen of all Scientific Committees provided written reports on the activities of their committees since the last SSC meeting (2-3 March 2000; see annex 12)

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

Mr. Eric Poudellet, DG SANCO E.3., reported on the Commission proposals on (1) the application of rapid BSE diagnosis tests in support of present BSE surveillance systems and (2) the regulation of the use of material presenting risks as regards transmissible spongiform encephalopathies.

9. Any other business

No other businesses were discussed.

The meeting ended on Friday 14 April 2000, at 17h00.

The next meeting will be held in Brussels, on 25-26 May 2000, starting at 10h00.

Annex 1: List of participants of the Scientific Steering Committee meeting of 13-14 April 2000

List of presence

Members of the SSC :

Prof. Georges Bories, Prof. James W. Bridges (not present on 14 April 2000 afternoon), Prof. Fulgencio Garrido Abellán (not present on 14 April 2000 afternoon), Prof. Michael Gibney, Prof. Anthony R. Hardy, Prof. Philip T. James, Prof. Keith H. Jones, Prof. Fritz H. Kemper, Prof. Werner Klein, Prof. Ib Knudsen, Prof. Robert Kroes, Prof. Albert Osterhaus, Prof. Gérard Pascal, Prof. Vittorio Silano, Prof. Marcel Vanbelle, Prof. Martin Wierup, Dr Emmanuel Vanopdenbosch (Present on 13 April 2000)

Participants from the Commission:

DG ENV: B. Jensen

DG SANCO: B. Carsin, C. Berlingieri, G. Costa-David, J. Crespo Arce, W. de Klerck, M. de Solà, C. Diez, A. Fokkema, G. Fracchia, J.L. Jouve, J. Kreysa, G. Morrison, E. Poudellet, J. Savio, A. Somogyi, A. Van Elst, J. Vergnettes, P. Vossen, P. Wagstaffe, A. Wilhelm

Stagiaires: J. Côté, S. Gamsjäger, A. Szklanna

Annex 2: Agenda of the Scientific Steering Committee Meeting of 13-14 April 2000

1. Welcome, apologies, introductory remarks, declaration of interest
2. Approval of the agenda
3. Approval of the minutes of the meeting of 2-3 March 2000
4. Multidisciplinary matters:
 - a. "Considerations for the evolution of scientific advice to address emerging health issues" (progress report and discussion)
 - b. Possibly emerging fields of concern with respect to health and consumer protection (further discussion and

amendments)

- c. Harmonisation of risk assessment procedures (progress report and discussion)
- d. White paper on Food Safety (discussion).
- e. Statement on the functioning of the EC's Scientific Committees (discussion and possible adoption)

5. Multidisciplinary matters relating to TSE/BSE

5.1. Report by the chairman of the TSE/BSE ad-hoc group, including also the proposed planning for:

5.2. Reports on specific issues:

Production systems and products.

- a. Safety of ruminant blood (discussion and possible adoption of an opinion)
- b. Handling and storage of possibly BSE contaminated MBM (discussion and possible adoption of an opinion)
- c. The safety of UK bone-in beef (discussion and possible adoption of an opinion)
- d. The safety of ruminant vertebral column for the production of gelatine and tallow (discussion and possible adoption of an opinion).
- e. Safety of bones: re-assessment of the safety with respect to TSEs, of certain types of specified risk materials in small ruminants. (discussion and possible adoption of an opinion)

Human exposure risk

- f. "Human Exposure Limit Line" (discussion of the comments received on the preliminary opinion and possible adoption of a final opinion).

Geographical risk.

- g. Geographical risk: position paper and reports on the risk assessments of Member States and Third Countries (further discussion).
- h. TSE and culling (discussion).
- i. Origin of BSE (progress report).

Other TSE/BSE related issues:

- j. criteria for diagnosis of clinical and pre-clinical TSE disease in sheep and for differential biochemical diagnosis of TSE agent strains (for opinion)
- k. GME protocol on TSE inactivation

6. Organisational matters.

- Transparency regarding the membership of working groups; guidelines.

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.

Commissioner Byrne will attend the meeting on Friday 14 April 2000, 12h30. The principal theme of his presentation and of the discussion will be on the future Food Safety Authority.

Annex 3: Draft initial* list of possible fields for concern in the medium-term future

(Updated listing as on 14.04.00)

Item
1. Agents and media
a. Viruses (including genetically modified viruses), prions .
b. Antibiotic resistant micro-organisms (including new infections because of antimicrobial resistance and/or because of increased virulence of agents).
c. Natural toxins (including "natural" medications), including, amongst others, mycotoxins and toxins in algae ;
d. Non-ionizing radiation (including new claims on supposed diseases (re cancer) due to cellular phones.
e. Climate change , (including extreme weather events and results of increased temperatures)
f. Macronutrient imbalance and its direct and indirect consequences for disease;
g. Industrial chemicals in the environment (including non communicable chronic diseases, causes and prevention: role of industrial chemical and chemical pollutants from food and environment).
h. Physical and psychological stress
i. Addictive substances
j. Urban terrorism using chemical or biological agents
k. Gene therapy ; safety of vectors used in gene therapies;
2. Media for transmission
a. Drinking water (including ground water) , (including Unexpected microbial diseases linked with (drinking) water);
b. Blood transfusions (including upcoming diseases due to blood transfusion).
c. Xeno transplants
d. New processes of waste treatment , eg: recycling (including health hazards due to the recycling of toxic substances for example when recycling animal waste);
e. Indoor air J .
3. Particular effects of concern
a. Endocrine disruption (human and environmental) (including environmental pollutants and endocrine disrupters and their interference with the immunosystem).
b. Allergenicit y,
c. Behavioural changes
d. Special and protected environments
e. Musculo-skeletal damage ,
f. Synergy between chemicals/chemicals and micro-organisms , (with increased life expectancy as an exacerbating factor).
4. Methodology
a. Identification of susceptible individuals / groups ,

b. Harmonisation of risk assessment ,
c. Quantitative risk assessment (including Increase precision to deliver quantitative estimates of risks involved with (unexpected) exposures to agents (chemical, biological and physical);
d. Sustainability (Including: implementing the sustainability principle across the various scientific committees; its implications for risk assessment and scientific advice).
e. Risk communication , (Including scientific illiteracy as a possible (emerging) (individual and public) health hazard; including aspects such as risk perception and risk communication).
f. improved testing methods (human and environmental),
g. Use of human volunteers (including: the need for a world-wide acknowledgement and agreement on the use of human (volunteers) in biological experiments: > amendments to the "Declaration of Helsinki" (World Association of medical Doctors) > rules for participation of humans in potential harmful trials (e.g., aiming the immune system; intentional sensitisation; corrosivity on the skin or mucous membranes;)
h. Better international collaboration (including: mutual recognition of results in the same [above] fields of science and regulatory/administrative acknowledgement (e.g., EC, EU, Council of Europe, OECD, ...).
i. Improved monitoring and surveillance systems for early detection of adverse effects (including?:better prediction of harmful effects of chemicals and other products on humans and the environment (e.g., carcinogenic effects): > support of appropriate methodologies (R&D).

* : This list should still be considered to be the result of a brainstorming. It is not ranked in terms of priority or in any other way. The SSC stresses that it is in no way to be considered as list of priority public health concerns. Many other, and in many cases more important, public health and consumer protection issues do not figure on the list, for example because they are being addressed already, because they are not a "possibly emerging risk", because they are not within the mandate of the SSC, etc.

Annex 4: Integrated comments and remarks of the Scientific Steering Committee (SSC) on the White Paper for Food Safety adopted by the SSC at its meeting of 13-14 April 2000 (Distributed separately)

Annex 5: Opinion on The Safety of ruminant blood with respect to TSE risks adopted by the Scientific Steering Committee at its meeting of 13-14 April 2000 (Distributed separately)

Annex 6: Opinion on the UK decision to lift the ban on the consumption of meat on the bone adopted by the Scientific Steering Committee at its meeting of 13-14 April 2000 (Distributed separately)

Annex 7: Opinion of the Scientific Steering Committee on specified risk materials of small ruminants. (Follow-up to the SSC opinion of 24-25 September 1998 on *the Risk of Infection of Sheep and Goats with BSE Agent*) adopted at its meeting of 13-14 April 2000 (Distributed separately)

Annex 8: Opinion on Quantitative Risk Assessment on the Use of the Vertebral Column for the production of Gelatine and Tallow. Adopted by the Scientific Steering Committee at its meeting of 13-14 April 2000 (Distributed separately)

Annex 9: Preliminary Report on Quantitative Risk Assessment on the Use of the Vertebral Column for the production of Gelatine and Tallow. Submitted to the Scientific Steering Committee at its meeting of 13-14 April 2000

THIS REPORT IS OPEN FOR PUBLIC COMMENTS UNTIL

10 JUNE 2000

Comments can be sent to:

Paul.vossen@ec.europa.eu

or:

joachim.kreysa@ec.europa.eu

Please pay special attention to the assumptions made and to the proposed probability distributions (including their key-values).

(Distributed separately)

Annex 10: Opinion Oral Exposure of Humans to the BSE Agent : Infective dose and species barrier adopted by the Scientific Steering Committee at its meeting of 13-14 April 2000 following a public consultation via Internet between 6 and 27 March 2000 (Distributed separately)

Annex 11: Report and Opinion on The criteria for diagnosis of clinical and pre-clinical TSE disease in sheep and for differential biochemical diagnosis of TSE agent strains adopted by the Scientific Steering Committee at its meeting of 13-14 April 2000 (Distributed separately)

Annex 12: Reports from the secretariats of Scientific Committees on the major activities and milestones since the SSC meeting of 2-3 March 2000.

Scientific Committee for Plants

Scientific Committee on Animal Nutrition (SCAN)

Several groups met between 01 March and 15 April in order to prepare the plenary meeting of 27-28 April 2000.

Scientific Committee Veterinary Measures relating to Public Health

Working groups continue their work. Two of them finalised a draft report which was discussed for adoption at the plenary meeting.

A report on food-borne zoonoses was adopted on 12 April 2000. The Committee accepted the review of its opinion on growth promoting hormones of 30 April 1999, subject to confirmation that the working group supported the Rapporteur's amendments that took account of the very recently received report from JECFA (Toxicological evaluation of certain veterinary drug residues in food, WHO Food additives Series 43, prepared by the 52nd meeting of JECFA).

The Committee agreed to adopt the opinion by a written procedure provided that no major problems were raised by the working group.

Scientific Committee on Animal Health and Animal Welfare

1. Meeting of the Committee 21 March 2000. At its meeting on 21 March, the Committee adopted two major reports:

- a.** Report on Possible Links between Paratuberculosis in Animals and Crohn's Disease in man
- b.** Report on The Welfare of Chickens kept for Meat Production.

Both reports were adopted unanimously by the committee.

2. Working Group meetings

a The use of vaccination against avian influenza

This newly established WG had its first meeting on 23 March. This item is urgent and of significance because of the current outbreak of the disease in Italy.

b The use of vaccination against bluetongue in the current european context

This newly established WG had its first meeting on 11 April. This item is urgent and of significance because this vector borne disease was reported in Greece and Bulgaria in 1999 and may, depending on climatic conditions, reappear this year.

c The Welfare of Animals kept for fur production.

This working group met on 23 March. This will be a major report and several meetings of the group are liable to be necessary before the report is completed.

d Report on Brucella melitensis in sheep

This working group met on 12 April 2000 to continue its work. This disease is of concern because of both animal and public health aspects.

Scientific Committee for Toxicity, Ecotoxicity and the Environment

Scientific Committee for Cosmetics and Non-Food Products

Two Working Party meetings took place, during which the following items were discussed :

1. Preservatives, Colorants & Fragrances :

The Committee initiated the 2nd phase of their mandate on the review on the safety of perfumery materials, namely to respond to the question if they could agree that all materials that IFRA (International Fragrance Association) recommend should not be used as fragrance compounds are included in Annex II - List of substances which must not form part of the composition of cosmetic products - to Directive 76/768/EEC on cosmetic products.

In the absence of specific regulations for fragrances, IFRA introduced self-regulatory disciplines for the industry, such as the IFRA list of prohibited fragrance ingredients. This list, which is based primarily on cutaneous safety concerns, was used as the basis for a discussion.

Draft opinion on Lithium and Calcium hydroxide : the WP approved this draft and addressed it to the plenary for formal adoption. The draft opinion specifies the 'other uses' of these substances in cosmetic formulations (entries 15b and 15c of Annex III to the cosmetics directive).

2. Inventory :

During the meeting it was possible to reach a final agreement on the modifications concerning issues such as the chemical identity of problematic ingredients, functions, the improvement of the identification of botanical ingredients, which should be integrated in the first Update of the Inventory of cosmetic ingredients. It is planned to adopt the revised document in June 2000.

Scientific Committee for Medicinal Products and Medical Devices