

# **Minutes of the Scientific Steering Committee Meeting of 18-19 March 1999**

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

Prof.Dr.Pascal welcomed the participants. Apologies were received from Prof.Dr.A.Osterhaus (for 19.03.99), Prof.Dr.M.Gibney (for 18.03.99), Prof.Dr.W.Bridges (for 19.03.99), Prof.Dr.A.Garrido (replaced by Prof.Dr.P.Le Neindre), Prof.Dr.R.Hardy (replaced by Prof.Dr.M.Maroni) and Prof.Dr.K.Jones. The list of participants is attached as annex 1.

No member declared an interest in any of the point of the agenda which could conflict with his independence.

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

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

## **3. Approval of the minutes of the meeting of 18-19 February 1999**

The draft minutes of the meeting of 18-19 February 1999 were approved without changes.

## **4. Progress on multidisciplinary matters:**

### **4.1. *"Considerations for the evolution of scientific advice to address emerging health issues"*.**

The Working Group did not meet since last SCC meeting and no progress was to report on. However, the WG Members were sending their individual contributions to the chairman. Progress will be reported on at the May meeting of the SSC.

### **4.2. *Harmonisation of risk assessment procedures***

Prof.Dr.W.Bridges, chairman of the Working Group, reported on the progress made. The various Scientific Committees had provided their contributions and a summary overview of their respective approaches towards risk assessment was discussed during the WG meeting of 17 March 1999. At that meeting, a work programme was established as well as a list of priority issues to be addressed. Amongst these priorities are the elaboration of a glossary of commonly accepted definitions and the preparation of an harmonised lay-out (procedural approach) for the risk assessment accompanying most scientific opinions (including also the use of safety factors/margins and the logical base for their use). Other items that will be addressed are the taking into account of ethical aspects in risk assessment, how to address accumulated effects and the relation between risk assessment, risk management and risk communication.

Prof.Bridges invited the SSC members to provide him, via the SSC secretariat, with comments on the issue and copies of any publication or document (including "grey" literature) which may be relevant in this field.

The next WG meeting are scheduled for 21 April, 26 May and 23 June 1999.

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

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

Prof.Dr.A.Osterhaus, replacing the chairman of the TSE/BSE ad-hoc group, provided a summary report on the recent activities of the ad-hoc group. Details are given under the subsequent points of the minutes.

## 5.2. Upcoming questions related to TSE

Prof. Osterhaus reported that 4 new working groups have been set-up at the last meeting of the ad-hoc group. One group will establish criteria for an efficient TSE surveillance. A second group will address the issue of the critical human exposure to the BSE-agent. A third looks into the possible risks related to breeding and introducing scrapie resistant sheep. The fourth will assess if the development of the UK-BSE-epidemic is in line with scientific expectations (see previous minutes).

For each of these working groups draft mandates were proposed by the TSE/BSE ad hoc group. They were discussed, amended and eventually adopted by the SSC (see annex 3).

The reports and draft opinions will be discussed at the May and June meetings of the SSC.

In the context of the discussions on the "Fallen stock" opinion (see further), the SSC asked the TSE/BSE ad hoc Group to address also the issues of the safety and the processing of mammalian blood meal.

### *Production systems and Products*

## 5.3. "Fallen stock": The risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials.

Prof.Dr.M.Vanbelle, rapporteur, presented the report of the Working Group and introduced the draft opinion prepared by the TSE/BSE *ad hoc* Group. The draft was discussed in detail and several sections were amended.

The opinion was adopted as a "preliminary opinion", to be made available to the public for comments *via* internet. Comment on the Working Group report would also be welcomed. The deadline for sending in comments was fixed at 12 April 1999. They will be discussed at the TSE/BSE *ad hoc* Group meeting of 15 April, and may possibly result in an amended/modified draft opinion. Further discussions and the possible adoption of the final opinion is scheduled for the SSC meeting of 22-23 April 1999.

The preliminary opinion is attached as Annexe 4. The Working Group report, which is also open for comments until 12 April, is attached as annex 5.

## 5.4. Intra-species recycling of animals waste.

Contrary to the expectations, no progress was made since last SSC meeting. This because of the heavy workload of the rapporteur, who is also involved in various other activities of the TSE/BSE *ad hoc* Group. It is now expected that a draft will be available for discussion by the SSC at its meeting of 19-20 May 1999.

## 5.5. The possible vertical transmission of Bovine Spongiform Encephalopathy.

The report of the Working Group was presented. Prof.Dr.P.P.Pastoret, rapporteur of the Working Group, submitted the report of the Working Group and introduced the draft opinion prepared by the TSE/BSE *ad hoc* Group. Following detailed discussion of these documents, the WG was congratulated for the high quality of its report and the draft opinion was amended and adopted.

The opinion and the report are attached as Annexes 6 and 7.

The opinion states, amongst others, that the results of all epidemiological studies undertaken to date have been consistent with a rate of maternal risk enhancement of approximately 10% in the offspring of dams within 12 months of the onset of clinical signs of BSE, that there are no scientific data to support the hypothesis that infected calves are

unduly sensitive to infection on a genetic basis, that it is unlikely that semen constitutes a risk-factor for BSE and that transmission of BSE by *via* embryos is unlikely provided International Embryo Transfer Society (IETS) protocols are used.

It also states that it is uncertain, whether infectivity is transferred directly before birth or after birth by a variety of mechanisms.

The SSC recommends that research is carried out into the identification of these various possible mechanisms (including on possible calf infection by contaminated material or in a contaminating environment of feces, blood, feed, contact with the dam, etc).

#### **5.6. Safety of tallow derived from bones as a by-product in the gelatine production.**

No draft opinion was yet available for discussion. This because it appeared, in the course of the discussions of the Working Group, that additional information was to be obtained from the industry producing tallow from bones. This information has now been requested by the SSC secretariat. As a result, the submission of a draft opinion to the SSC is not likely before the May 1999 meeting.

*Human exposure risk.*

#### **5.7. Progress report**

The WG did not meet since the last SSC-meeting but continued its work on a report. The next meeting is scheduled for 24/3/99 and a draft report is expected for discussion at the next SSC-meeting.

*Geographical risk.*

#### **5.8. Assessment of the geographical BSE risk (report on the risk evaluation exercise held from 1 - 5 March 1999)**

In the period 1-5 March 99 the geographical BSE-risk of 12 Member States was assessed by 20 independent external experts. Most of these countries sent country experts who were very helpful in clarifying aspects not sufficiently covered by the dossiers prepared by the MS. Others provided on-line connections that also proved to be very useful.

In general the assessment went very smoothly but certain clarifications on the method have been brought forward by the assessors. Draft reports for all assessed countries were distributed to the SSC.

The SSC appreciated the good co-operation of the Member States and their representatives.

The proposed amendments of the method were in principle accepted by the SSC but it was agreed that the members would provide the secretariat with comments on an outline of these modifications before 25/3/99. On the basis of this outline the secretariat should prepare a new version of the manual, with a view of adopting it at the next SSC-meeting. The new version should be available for the next risk assessment exercise.

The latter is scheduled for 3-8 May and will concern the MS still lacking (NL, PT and GR) and third countries who did provide dossiers.

After intensive discussion on the follow-up of the risk assessment exercise, it was agreed to provide each MS with a copy of its "report on the geographical BSE-risk assessment", but without indicating the proposed risk level and with clear indications that the report is still a draft under revision. Member States should be invited to comment on the draft reports, in particular with a view to clarify misunderstandings, wrong interpretations and errors. In the light of the comments received the SSC will decide at its next meeting if a re-assessment is required or not. The necessary re-assessments will be carried out on 10, 11 and 12 May. An outline of a letter / cover note to the Member States was agreed.

The SSC will try to establish a preliminary opinion on the geographical BSE-risk of the Member States at its meeting in May (27/28 May).

The SSC underlined once more that the BSE-risk is one essential element on which the BSE-Status of a country is to be based, but not the only one. The TSE/BSE ad-hoc group was asked to continue the work on the BSE-Status in order to underpin the discussion of the SSC.

### **5.9. Initial TSE infection (progress report).**

At its previous meeting the SSC discussed the definition of "initial BSE-infection". A working group on this subject has still to be installed by the TSE/BSE *ad hoc* Group, which has to formulate a detailed mandate.

### **5.10. BSE-status categories (progress report, discussion)**

The TSE/BSE ad-hoc group has continued its discussion but was not yet able to provide a discussion document. The SSC asked the ad-hoc group to continue its work with a view to allow adopting a preliminary opinion on a methodology for defining the BSE-Status on the basis of the geographical BSE-risk and other parameter in May.

## **6. Organisational matters.**

No organisational matters were discussed.

## **7. Co-ordination:**

### **7.1. 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 (21-22 January 1999). A summary of their reports is given in annex 6.

The Scientific Committee on Animal Health and Animal Welfare had adopted its opinion covering the animal welfare aspects of the use of BST. The Scientific Committee on Veterinary Measures Relating to Public Health adopted its opinion on the safety of recombinant Bovine Somatotropine (rBST), covering the public health aspects. The respective chairmen of these Committees presented the opinions in detail. The SSC congratulated the two Committees on the high standard of their opinions. It had an exchange of views on the opinions and formulated some comments. It concluded that the two opinions were comprehensive and fully complementary and that therefore there was no need to of adopting a SSC statement providing an overall view.

### **7.2. Exploitation of opinions.**

In view to demonstrate the exploitation of the 22 opinions adopted by the SSC since November 1997, the committee received a list of the legislation proposals made by the Commission and subsequently submitted to the appropriate structure or institution (e.g. Standing Veterinary Committee, Council, and/or Parliament), that referred to these opinions.

### **7.3. Information from DG XII on a possible procedure for providing the SSC with regular updates on Research & Development projects in the field of TSEs.**

Mr. Hansen, the co-ordinating director of the Life Sciences Programme of the Fifth Framework Programme presented the structure and content of that programme. He focussed on those elements that are of particular interest to the SSC and also explained the new operational aspects. He invited the SSC to communicate knowledge gaps to him as input in orienting the programme.

The SSC thanked him for this information and appreciated to be kept informed of the development.

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

Postponed to the next meeting..

## **9. Any other business**

- Internal SSC seminar on molecular biology, neuropathology and testing for prion-related diseases.

Due to a lack of time, the TSE/BSE *ad hoc* Group did not discuss this item at its meeting of 11 March 1999. The discussion on this topic was therefore postponed until the next meeting.

- Research & Development priorities (TSEs, antimicrobials, GMOs, ...): exchange of views and discussion.

No discussion held on this issue.

- *Composition of Working Groups.*

The SSC agreed that as a question of principle Working Groups should not become closed circles of a limited number of scientists, but that the list of experts from which WG members are selected should be systematically updated and enlarged. This would guarantee that the WGs are always confronted with new ideas and possibly conflicting opinions and would contribute to the establishment of sound and balanced opinions. Prof.Dr.Osterhaus stated that the TSE/BSE *ad hoc* Group shares this view and that, in the composition of the recently created working groups, several specialists who so far had not been involved in WGs of the *ad hoc* Group, had been included in the list of potential members, to be invited by the secretariat.

The Commission invited the SSC members to provide co-ordinates of outstanding scientists for inclusion in the expert data base of the SSC secretariat.

- *Publication on internet of (pre-)opinions and scientific reports.*

The SSC agreed that the pre-opinion and report on "Fallen stock" and the opinion and report on "Vertical transmission of BSE" would be made available *via* internet as separate entities.

It further agreed that an in-depth discussion would be held at a later stage on the best approach to follow when making opinions available to the public *via* internet.

As a final point, it was stated that the WG reports should largely deal with scientific aspects alone. Final draft conclusions should be presented in the draft opinion (to be prepared, for TSE/BSE matters, by the TSE/BSE *ad hoc* Group).

The meeting ended on Friday 19 March 1999, at 17h30.

The next meeting will be held in Brussels, on 22-23 April 1999.

### **Annex 1: List of participants of the Scientific Steering Committee meeting of 18-19 March 1999**

*List of presence*

#### ***Members of the SSC:***

Prof. Georges Bories, Prof. James W. Bridges (not present on 19 March 1999), Prof. Fulgencio Garrido Abellán (not present on 18 March 1999) \*, Prof. Michael J. Gibney (not present on 18 March 1999), Prof. Anthony R. Hardy (not present) \*\*, Prof. Philip T. James, Prof. Keith H.Jones (not present), Prof. Fritz H.Kemper, Prof. Werner Klein, Prof. Ib

Knudsen, Prof. Robert Kroes, Prof. Albert Osterhaus (not present on 19 March 1999), Prof. Gérard Pascal, Prof. Vittorio Silano, Prof. Marcel Vanbelle, Prof. Martin Wierup, Prof. Paul-Pierre Pastoret (present on 19 March 1999 morning)

\*Dr. Pierre Le Neindre replaced Prof.F. Garrido Abellán on 18 March 1999, \*\* Prof. Marco Maroni replaced Prof. A.R. Hardy on 18 March 1999

***Participants from the Commission:***

**DG III:** O. Rohte, **DG V** H. Martin, **DG VI** T. Chalus, J. Pérez-Lanzac, I. Peutz, **DG XII** A. Fabre, B. Hansen, M. Vidal, **DG XXIV:** B. Carsin, C.Diez, J.Kreysa, M. Lauridsen, G.Morrison, J. Moynagh, D. Pettauer, W. Schuller, A. Somogyi, A. Van Elst, J. Vergnettes, P.Vossen, P. Wagstaffe

Stagiaires: Blanca Alonso, Morgan Avetta, Amélie Raphaël, Sandrine Stefanidis

***Annex 2:***

***Agenda of the Scientific Steering Committee Meeting of 18-19 March 1999***

1. Welcome, apologies, introductory remarks, declarations of interest
2. Approval of the agenda
3. Approval of the minutes of the meeting of 18-19 February 1999.
4. Work plan for the SSC
  - 4.1. Progress on multidisciplinary matters:
    - a. "Considerations for the evolution of scientific advice to address emerging health issues" (progress report)
    - b. Harmonisation of risk assessment procedures (progress report)
  - 4.2. Multidisciplinary matters relating to TSE/BSE
    - a. Report by the chairman of the TSE/BSE ad-hoc group.
    - b. Reports on specific issues:

***Production systems and products.***

- b.1. "Fallen stock" (for opinion).
- b.2. Intra-species recycling of animal waste (progress report).
- b.3. The possible vertical transmission of Bovine Spongiform Encephalopathy (for opinion)
- b.4. Safety of tallow derived from bones as a by-product in the gelatine production (for opinion).
- b.5. Closed herds (report and opinion)

***Human exposure risk.***

- b.6. Discussion of the draft report and opinion.

***Geographical risk.***

b.7. Assessment of the geographical BSE risk (report on the risk evaluation exercise held from 1 - 5 March 1999)

b.8. Initial TSE infection (progress report).

b.9 BSE-status categories (progress report, discussion)

5. Organisational matters.

6. Co-ordination:

a. reports of the Chairmen of the 8 Scientific Committees.

b. Exploitation of opinions.

c. information from DG XII on a possible procedure for providing the SSC with regular updates on Research & Development projects in the field of TSEs.

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

8. Any other business.

- internal SSC seminar on molecular biology, neuropathology and testing for prion-related diseases.

- Research & Development priorities (TSEs, antimicrobials, GMOs, ...): exchange of views and discussion.

### **Annex 3: Mandate of 4 new Working Groups created by the TSE/BSE *ad hoc* Group**

#### **Mandate for the Working-Group "Decline of the UK epidemic" (WG-DUKE)**

**Established by the TSE/BSE ad-hoc group at its meeting of 1999-03-10**

***Members of the WG-DUKE (subject to confirmation):***

**Chairman:** Dr.P.Willeberg (or E.Vanopdenbosch), Member of the ad-hoc group

**Rapporteur:** Prof. Dr.Le Fevre (to be confirmed)

**Members:** Dr.J. Valleron, Dr.M. De Jong, Prof.Dr.H.Dietz, Dr.R.Bradley, Prof.Dr.P.Willeberg, Dr.E.Vanopdenbosch

#### ***General Mandate***

Under the impression that the decline of the epidemic in the UK is not as fast as expected, the Commission (DG XXIV) asked the SSC the following questions:

- *How does the SSC assess the current and expected (1999-2004) evolution of the number of BSE cases (epidemic) in the UK, in the light of the OTMS ("Over thirty Months Scheme") and of the selective culling programme. Are the current numbers of cases in line with the scientific expectations?*

- *In the light of the confirmed 1998 incidence, is it necessary to continue the OTMS for animals falling under the Date Based Export Scheme, i.e. animals born after the 1 August 1996?*

At its meeting of 18/19 February 1999 the SSC accepted the questions and asked the TSE/BSE ad-hoc group to prepare draft opinion for discussion by the SSC with the shortest possible delay.

#### ***Mandate of the Working Group - "DUKE"***

The working group is requested to provide the TSE/BSE ad-hoc group with a report responding to the questions given below and a draft opinion for adoption by the SSC responding to the questions posed to the SSC, given above:

1. What is the scientifically sound estimate of the future decline of the UK-BSE-epidemic assuming a fully operational OTMS and selective culling programme with a compliance of 100% (90%) ?
2. What is the evidence derived from the confirmed 1998 incidence that animals falling under the OTMS and being older than 30 months could carry BSE and, if there is evidence, how big is that risk?

For addressing the first task, the WG should invite Prof.Roy Anderson, University of Oxford, and Mr.John Wilesmith, CVL, to present their respective predictions in order to establish an opinion as to their validity. It is not requested from the WG to prepare its own prediction but if the WG feels this to be necessary and possible, it might do so.

### ***Schedule***

- The WG should be established as soon as possible and produce a first progress report for the meeting of the TSE/BSE ad-hoc group on 20/5/99.
- Taking account of the input from the TSE/BSE ad-hoc group a final report and a draft opinion should be provided to the ad-hoc group for discussion at its meeting of 17/6/99.

### **Mandate for the Working Group "Human Exposure Limit Line"**

**Established by the TSE/BSE ad-hoc group at its meeting of 1999-03-10.**

#### ***Members of the WG-HELL (subject to confirmation):***

Chairman : Prof. Dr.D.Dormont, Member of the TSE/BSE ad-hoc group

Rapporteur: to be determined

Members: Dr.M.Pocchiari (LD50), Dr.Somerville (LD50), Dr.R.Bradley (LD50), Prof.Dr.H.Diringer (LD50), Dr.H.Budka ad-hoc, Dr.Kretschmar ad-hoc

#### ***General Mandate:***

Because the BSE agent infective dose for cattle and sheep is low (less or equal 1g of homogenised infected brain tissue), concern has been raised for the limits of the human exposure dose that could theoretically establish a persistent infection.

The working group should

1. Produce a document, summarising the state of the art in relevant scientific disciplines.
2. Produce an estimation of the order of magnitude of the human infective dose, based on the most accurate scientific data available.

#### ***Time Frame:***

- The WG-EL should be established as soon as possible and provide a first interim report to the TSE/BSE ad-hoc group on 20.5.99.
- A draft final report should be made available to the TSE/BSE ad-hoc group for discussion at its meeting on 15/7/99.
- A final report should be ready for adoption by the ad-hoc group on 9/9/99.

### **Mandate for the Working-Group "Scrapie Resistant Sheep" (WG-SRS)**

**Established by the TSE/BSE ad-hoc group at its meeting of 1999-03-10**

***Members of the WG-TSES (subject to confirmation):***

**Chairman:** Dr.E.Vanopdenbosch, Member of the ad-hoc group

**Rapporteur:** Dr.N.Hunter

**Members:** Dr. J.L.Laplanche., Dr.B.Schreuder, Dr.L.Detwiler, Dr.M.Ulvund, Prof.Dr.M.Groschup

### ***General Mandate***

The SCHAAW raised the attention of the Commission to the potential of TSE-resistant sheep races to hide, and not to eradicate, the disease.

The Commission therefore will ask the SSC to provide its scientific opinion on this issue.

The exact wording of the question is not yet available but it will be based on the statement of the SCAHAW:

"The Committee noted that there was a need for advice on the policy of breeding and genotyping of sheep, i.e. whether sheep should be bred to be resistant to scrapie with the risk of producing more silent cases of the disease or whether they should be bred to be susceptible, which would make the disease more evident."

Assuming that the SSC accepts the question at its next meeting, the TSE/BSE ad-hoc group established a WG-"SRS" with the following specific mandate.

### ***Mandate of the Working Group - "SRS"***

The WG is requested to provide the TSE/BSE ad-hoc group with a report responding to the questions given below and a draft opinion for adoption by the SSC.

1. What is the risk that herds of scrapie resistant sheep would carry the scrapie agent without showing clinical signs but at the same time being able to transmit the agent horizontally, vertically or via rendering?
2. Would this risk be reduced, and to which degree, if scrapie sensitive sheep would be included into resistant herds as indicator animals? How many indicator animals would be needed?
3. Would the risk of undiscovered scrapie be further reduced by flocks only composed of sentinel susceptible sheep?

In addressing these questions the WG should also discuss the theoretical possibility of BSE occurring in sheep. Would the risk be similar?

### ***Schedule***

- The WG should be established as soon as possible.
- Dr. Hunter should be asked to produce a discussion document for a first meeting before 11/5/99 in order to allow the TSE/BSE ad-hoc group receiving an oral progress report from Prof. Vanopdenbosch on 20/5/99.
- Taking account of the input from the TSE/BSE ad-hoc group a final report and a draft opinion should be provided to the ad-hoc group for discussion at its meeting of 17/6/99.

### **Mandate for the Working-Group "TSE-Surveillance" (WG-TSES)**

**Established by the TSE/BSE ad-hoc group at its meeting of 1999-03-10**

***Members of the WG-TSES (subject to confirmation):***

**Chairman:** Dr.E.Vanopdenbosch, Member of the ad-hoc group

*Rapporteur:* Dr.E.Vanopdenbosch

*Members:* Prof.Dr.P.Willeberg (Member of TSE/BSE ad-hoc group), Dr.Van der Velde (CH) or somebody else from his group, Dr.H.Schlüter, Dr.Kramer or Dr.Mönig from DE, Dr.M.Savey, Dr.J.Wilesmith

### ***General Mandate***

During the Geographic risk assessment exercise the importance of the quality of a surveillance system for the risk management became evident. Given the fact that the current manual for the assessment does not contain specific criteria on surveillance, the wish was expressed to establish the conditions for an "ideal" TSE-surveillance system.

This wish was discussed by the TSE/BSE ad-hoc group and a working group was established with the following specific mandate.

### ***Mandate of the Working Group - "SRS"***

The WG is requested to establish simple criteria that can be used to assess the capacity of a surveillance system to detect BSE at very low levels of incidence (less than 1case/million adult cattle).

### ***Schedule***

- The WG should be established as soon as possible.
- Prof. Vanopdenbosch in co-operation with Prof. Willeberg will prepare a draft working document.
- A meeting of the WG is scheduled for the 6 or 7 April.
- The final report of the WG should be delivered to the TSE/BSE ad-hoc group for its meeting on 15/4/99. If appropriate it will be annexed to the revised version of the manual for the next round of assessment.

### ***Annex 4:***

#### **Preliminary Scientific Opinion on**

**The risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials.**

**The present preliminary opinion results from the SSC meeting of 18-19 March 1999.**

**For the final opinion to be based on an as wide scientific consultation as possible, the SSC decided to invite Scientists, research laboratories and interested parties to communicate their comments, further contributions, possible additional evidence/material, etc. to the SSC secretariat *before 12 APRIL 1999***

**A final opinion should then be adopted at the SSC meeting of 22-23 April 1999**

**Comments should be sent to: [paul.vossen@ec.europa.eu](mailto:paul.vossen@ec.europa.eu) (fax +32 2 295 95 79)**

(This annex was distributed separately)

### ***Annex 5:***

#### **Preliminary Scientific Report on**

**The risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals**

(including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials.

The present preliminary report prepared by a SSC Working Group was submitted to the SSC at its meeting of 18-19 March 1999. The preliminary opinion resulting from these discussions is available on internet as a separate document

For both the final report and the opinion to be based on an as wide scientific consultation as possible, the SSC decided to invite

Scientists, research laboratories and interested parties to communicate their comments, further contributions, possible additional evidence/material, etc. to the preliminary opinion and the attached report to the SSC secretariat, *before 12 APRIL 1999*

Comments should be sent to: [paul.vossen@ec.europa.eu](mailto:paul.vossen@ec.europa.eu) (fax +32 2 295 95 79)

(This annex was distributed separately)

#### **Annex 6:**

**OPINION ON THE POSSIBLE VERTICAL TRANSMISSION OF BOVINE SPONGIFORM ENCEPHALOPATHY (BSE).** Adopted by the Scientific Steering Committee at its meeting of 18-19 March 1999

(This annex was distributed separately)

#### **Annex 7 :**

**THE POSSIBLE VERTICAL TRANSMISSION OF BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)**

#### **Report of the Working Group**

Submitted to the Scientific Steering Committee at its meeting of 18-19 March 1999

(This annex was distributed separately)

**Annex 8: Reports from the secretariats of Scientific Committees on the major activities and milestones since the SSC meeting of 18-19 February 1999.**

#### ***Scientific Committee for Food***

This Committee had no plenary session since the last SSC meeting.

#### ***Scientific Committee on Plants***

At its Plenary Meeting on 4 March, the Committee adopted an opinion on the draft protocol for the monitoring of resistance to Bt which is available as SCP/GMO/094-Final. The opinion was expressed in response to a Commission request for an evaluation of a draft protocol for the monitoring of corn borer resistance to Bt-maize. The Committee made a number of recommendation which should be taken into account when finalising the protocol and made recommendations for additional scientific research. It also drew attention to the important relationship between the implementation of effective resistance management plans to delay the appearance of resistance to Bt in the target pests and any monitoring plan.

The Committee also examined a number of existing and new dossiers relating to plant protection product active substances and draft assessment guidance documents. The Committee also noted progress on a number of GM plant questions dealing with notifications and safeguard applications pursuant to Directive 90/220/EEC.

#### ***Scientific Committee on Animal Nutrition (SCAN)***

The work is continuing within the several working groups of SCAN. Draft opinions should be discussed in the next plenary for possible adoption.

### ***Scientific Committee Veterinary Measures relating to Public Health***

The plenary of the SCVPH on 15-16 March mainly concentrated on

#### **1. Cooling of carcasses during transport**

The Committee had a final exchange of views on the revised draft report, which had been discussed in previous plenary sessions. The report, as amended during the discussion, was adopted unanimously. The report indicates that cooling during transport will introduce an additional risk for consumer health and lists a series of recommendations which have to be taken into account should it be considered to authorise this procedure.

#### **2. Public Health Aspects of the use of Bovine Somatotrophin**

The Committee was provided with copy of the report on "Animal Welfare Aspects of the Use of Bovine Somatotrophin" which had been adopted by the Scientific Committee on Animal Health and Animal Welfare on 10 March.

The scientific reasoning as well as the summary and conclusions of the draft report on the public health aspects of the use of rBST were discussed in detail. The report, as amended during the meeting, was adopted unanimously and was made available to the SSC.

### ***Scientific Committee on Animal Health And Animal Welfare***

The scientific Committee on Animal Health and Animal Welfare met on 10 March and adopted two reports, Animal Welfare Aspects of the use of Bovine Somatotrophin in Dairy Cows and Criteria for the use of Emergency Vaccination against Foot and Mouth Disease.

The following working group meetings took place in the period;

#### ***1. Eradication of Bacterial Kidney Disease***

This group met for the first time on 22 January and have begun the preparation of a working document. A second meeting of the group took place on 16 March. Progress has been good and a report may be ready for the next meeting of the health subcommittee.

#### ***2. Brucella melitensis***

A first meeting of this group took place on 10 March. Tasks have been allocated among the members and a working document will be prepared. This question will take several meetings.

#### ***3. Working group on the welfare of broilers***

This group met on 2 March. Much of the data collection is now complete and an initial working document is prepared. However, this is a substantial question which will involve several meetings.

#### ***4. Working group on the effect of BST treatment on the welfare of the dairy cows***

State of Progress: In the period in question the question was discussed at meetings of the Animal Welfare subcommittee on 16 February and 1 March. The sub committee approved the report on 1 March.

#### ***5. Ventilation standards for animal transport vehicles***

This question has been discussed in the sub committee. DGVI have indicated that they will be expanding this question to cover also the ventilation standards necessary if the animals are being rested on board the lorry.

Some additions will now be made to the draft report and a meeting of a small drafting group is scheduled for early April.

### ***Scientific Committee for Medicinal Products and Medical devices***

This Committee had no plenary session since the last SSC meeting.

### ***Scientific Committee Cosmetic and non-Food Products***

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

A series of Working Parties took place, during which the following items were discussed :

*1. Alternatives to animal testing* : possible strategies for using in vitro validated methods to assess eye irritation for selected classes of cosmetic ingredients as well as the minimal criteria of the in vitro test protocols for assessing percutaneous absorption of cosmetic ingredients were discussed with COLIPA.

In view of a possible prohibition of animal testing for the safety evaluation of cosmetic ingredients in the European Union, the SCCNFP is very much concerned by the use of human volunteers. The Committee presently discusses (i) the minimal criteria of the protocols for the testing of potentially cutaneous irritant cosmetic ingredients or mixtures of ingredients on human volunteers and (ii) guidelines on the use of human volunteers in the safety testing of finished cosmetic products.

*2. Hair Dyes* : the Working Party evaluated a first series of 5 hair dyes and approved draft opinions on them since the special Task Force finalised its status report on all pending files.

Three further meetings are already fixed to continue with this task before the next plenary meeting in order to present a reasonable number of draft opinions to this meeting.

*3. Preservatives, Colorants & Fragrances* : in the framework of the committee's work on the safety evaluation of fragrance ingredients, Dr. Ladd W. Smith, president of RIFM - Research Institute for Fragrance Materials - was invited to present and to discuss the document 'Criteria for Development of a Database for Safety Evaluation of Fragrance Ingredients'.

*Nitro Musks* : the preliminary conclusions concerning the toxicological data on Musk Ketone and Musk Xylene were presented. As the final version of the 'human milk study' has now been submitted, the rapporteurs are in a position to conclude their work.

*Polycyclic Musks* : the evaluation will take much more time as the data provided are very detailed and comprehensive. As a preliminary conclusion, it was stated that further photo-tox and photo-mutagen/genotox studies might be required.

### ***Scientific Committee for Toxicity, Ecotoxicity and the Environment***

Since the last meeting, a plenary meeting of the CSTEE took place (4<sup>th</sup> of March 1999).

1 The CSTEE adopted its opinion on ***Human and Wildlife Health Effects of Endocrine Disrupting Chemicals, with Emphasis on Wildlife and on Ecotoxicology Test Methods***. Given the need for a final editorial revision and finalisation of the list of references copies of the opinion are not yet available at the time of writing this note.

The scope of the opinion is reflected in its conclusions and recommendations which can be summarised as follows:

#### ***Human health effects:***

- A causative role of the EDCs in diseases and abnormalities possibly related to endocrine disruption has not been verified scientifically. The following usually purported health effects *need further evaluation* before one can identify chemicals of being a cause/contributor to:

1. Decline in sperm count
2. Increased prevalence of cryptorchidism
3. Increased incidence of testicular cancer
4. Increased incidence of prostate cancer
5. Increased incidence of breast cancer
6. Increased incidence of thyroid cancer
7. Change in sex ratio with declining proportion of male new-borns

### ***Effects on wildlife***

- There is strong evidence obtained from semi-field and laboratory studies that show that several chemicals cause endocrine disruption in wildlife at environmental prevalent exposure levels.
  - The affected species are very varied and include mammals, reptiles, fish, birds and molluscs.
  - The observed abnormalities include, among others:
1. Disturbed sex differentiation with malformed sex organs
  2. Changed sexual behaviour
  3. Altered immune function
  4. Egg shell thinning (in birds)

Therefore the CSTEE recommends:

1. Assessment of full environmental significance of endocrine disruption.
2. That more field and semi-field studies be carried out to better establish causality links.
3. Establishment of long term consequences of EDC effects on wildlife populations.

### ***Ecological risk assessment***

- Given the lack of evidence on ecological end-points which could help the scientific community establish clear cause and effect relationships, the CSTEE recommends that research be carried out in order to:
1. Establish links between long term tests and ecologically EDCs' relevant effects
  2. Establish margins of safety and uncertainty factors with a view to extrapolating ecotoxicological thresholds from laboratory relevant end-points
  3. Consider need for species-focused assessments particularly for protecting endangered ones.

### ***Toxicological test guidelines and testing strategies***

The CSTEE recommends:

- The development/enhancement of test guidelines with a major emphasis on in vivo assays. In order to achieve this, international co-operation (EU, OECD, other) should be fostered. This should also avoid duplication of effort.
- The EU legislative framework should be changed to include additional toxicity testing of chemicals (including tests for reproductive toxicity and fertility) produced in quantities of less than 100 tons per year.
- The so-called Technical Guidance Document in support of Regulation 793/93 (Existing substances) should be developed to include hazard identification and a testing strategy focussing on endocrine effects.

2 During the plenary meeting a first discussion took place on the subject '***Ground level ozone***'. Given, however, the relative scarcity of contributions and their late availability (some arrived just one day before the meeting) it was not possible for the *rapporteur* to prepare a draft for discussion; hence only an oral debate could take place. The CSTEE

secretariat is now aiming to organise the first working group meeting on the 16.04.99.

**3** further work has been carried out on the subject '*Substitutes of phthalates in teething rings and other child care articles intended to be put in the mouth*' since the previous meeting. Another, presumably important, document has in the meantime been made available to the CSTEE secretariat by the citrates industry. The CSTEE secretariat is still waiting for data that, as agreed, should be made available by Industry and M. States to DG III who then would ensure redistribution.

**4** The SCTEE has two ongoing areas where it is proactive :

- risk assessment strategies for the terrestrial environment
- strategies for assessing human exposure to chemicals which are widely distributed in the environment.

**5** The **next CSTEE plenary** is confirmed for the 6<sup>th</sup>/7<sup>th</sup> of May 1999.