

**SPONGIFORM ENCEPHALOPATHY ADVISORY COMMITTEE**

**Draft Minutes of the 74th meeting held on 13th June 2002 at DEFRA,  
Conference Room A&B, Whitehall Place West, London**

- Members:**
- Professor P Smith (Chairman)**
  - Professor J Ironside (Deputy Chairman)**
  - Professor R Anderson**
  - Professor C Bostock**
  - Mr R Bradley**
  - Professor R Carrell**
  - Dr D Cunningham**
  - Professor H Kimbell**
  - Mr P Jinman**
  - Professor C Masters**
  - Professor I McConnell**
  - Dr J Safar**
- Technical Advisors:**
- Mr P Soul (DEFRA)**
  - Dr H Gates (DEFRA)**
  - Dr J Stephenson (DH)**
  - Ms A Conroy (FSA)**
- Observers:**
- Mrs Meg Wilson (BBSRC)**
  - Dr Mark Pitman (MRC)**
  - Dr Jim Nielson (HSE)**
  - Dr Peter Crook (EA)**
  - Dr Mike Simmons (NAW)**
  - Dr Martin Donaghy (SEHD)**
  - Professor John Wilesmith (VLA)**
  - Miss Karen Dell (FSA)**
  - Mrs Mary Holt (DH)**
- Secretaries:**
- Dr M Bailey (DEFRA)**
  - Dr R Jecock (DH)**
  - Mr D Carruthers (FSA)**
- Secretariat:**
- Dr L Harbron (DEFRA)**
  - Mr D Wood (DEFRA)**
  - Dr A Leigh (DH)**
  - Mr M Hall (DH)**
  - Mr Martin Pemberton (FSA)**
- Also in attendance:**
- Professor Paul Brown (NIH, Bethesda, USA) - item 4**
  - Dr Noel Gill (Chair, Epidemiology sub-group) - item 5**
  - Mr Philip Comer (DNV) - item 4**

**Dr Mark Purcell (DNV) - item 4**  
**Dr Peter Bennett (DH) - item 4**  
**Dr Philippa Edwards (DH) - item 4**  
**Dr Lincoln Tsang (MCA) - item 4**  
**Mrs Mary Holt (DH)**  
**Miss Karen Dell (FSA) - item 7 only**  
**Mr Lucian Hudson (DEFRA) - item 9 only**  
**Mr Tony McDougal (DEFRA) - item 9 only**  
**Mr Oliver Cattermole (DEFRA) - item 9 only**

## **Item 1- Chairman's introduction**

1.1 The Chairman noted that this would be the last closed meeting of the Committee. From September, meetings will be held in public.

1.2 Apologies for absence were received from John Collinge, Adriano Aguzzi and Grahame Bulfield.

1.3 The Chairman informed Members that, since the last meeting, Grahame Bulfield had been appointed Dean to the new College of Science and Engineering at the University of Edinburgh and that Robin Carrell had been elected to the Royal Society. Additionally, the Chief Medical Officer had appointed James Ironside as Deputy Chairman to the Committee.

1.4 The Chairman thanked two outgoing members, John Collinge and Ray Bradley, for their outstanding contributions to the Committee. Both had been longstanding members of the Committee and had extended their membership by six months beyond the permitted maximum while efforts were being made to replace them. The Chairman recorded his and the Committee's thanks, for the invaluable contribution both had made to the work of the Committee over many years. Adverts to replace these members would be issued shortly.

1.5 The Chairman introduced Martin Pemberton, who would shortly be taking over responsibility within FSA for SEAC secretariat work. He also announced that this would be Lucy Harbron's last meeting as she was moving to another position in DEFRA. The Chairman praised the key role she had played in the Secretariat, which had been invaluable, and which he had appreciated particularly during his time as acting Chairman as well as Chairman.

1.6 The Chairman updated the Committee on recent developments in the organisation and staffing of the Secretariat. He explained that following discussions with senior officials from the three departments and the Office of Science and Technology (OST), it had been decided to have a unified SEAC Secretariat rather than basing it in three departments as at present.

1.7 A new SEAC Secretary was in the process of being appointed and, together with the Secretariat staff, would be based in a single location (yet to be determined) and consist of staff seconded from the three sponsor departments. Although the Secretariat will no longer have a physical presence in each of the three departments, liaison with the departments will still have to be very close.

1.8 The details of the new arrangements were still being developed but they should be in place in time for the Open Meeting in September. Also by this time, the new SEAC website should be up and running.

## **Item 2 - Approval of minutes from 10 April 2002 meeting (SEAC 74/1)**

2.1 Members considered the minutes from the previous meeting in April. These had been published in draft form following the last press briefing, subject to final agreement by Members.

2.2 Apart from the inclusion of minor amendments, Members agreed the minutes. A final version would replace the draft version on the SEAC web page.

**Action: Secretariat**

## **Item 3 - Review of DEFRA science-based Executive Agencies (SEAC 74/10)**

3.1 A Review of the Department for Environment, Food & Rural Affairs (DEFRA) science-based Executive Agencies was announced in March this year and report back in October 2002. A departmental Review Team was consulting a wide range of science stakeholders, including SEAC.

3.2 The Chairman explained that this had been a late inclusion on to the agenda and as such there would be insufficient time at the meeting to address the issues in the questionnaire sent to him by the Review Team. He also pointed out the overlap of this item with 74(7) on DEFRA's TSE Research.

3.3 Members were referred to the letter from the Head of the Review Team setting out the areas on which comments were sought. As far as SEAC was concerned this related mainly to the VLA as that was where the focus of the TSE related research and surveillance activity was undertaken. In particular the Committee's views were sought on:

- The role fulfilled by those DEFRA science-based executive agencies whose work impinges on SEAC - what they do and how well they do it.
- How the government should obtain scientific services (R&D, surveillance and advice) in future.
- The likely future trends in the work currently covered by DEFRA's science-based executive agencies.

3.4 The Committee enquired as to how much was spent on TSE research at the VLA. Officials advised that the figure was in the region of £8m per annum, with an additional £5m per annum being spent at the agency on surveillance for clinical cases of BSE. Nearly £13m will be spent at VLA on active surveillance this financial year. It was also pointed out that DEFRA had invested over £50m of capital expenditure at the VLA to provide facilities to undertake TSE research.

3.5 The Chairman suggested that that if any Member had any substantive comments they should send them to the Secretariat within the next two weeks, so that a SEAC response could be drafted.

#### **Item 4. Risk assessment of exposure to vCJD infectivity in blood and blood products**

4.1 The Committee was asked to consider a draft risk assessment prepared by Det Norske Veritas (DNV) on the potential risk of exposure to vCJD which may be associated with medical treatment with blood components or plasma derivatives.

4.2 The risk assessment would be used by the CJD Incidents Panel to assess the potential risk to individual recipients of blood/components or plasma derivatives where these were subsequently found to have contained a donation from someone who had gone on to develop vCJD.

4.3 The Committee's views were sought on whether the key assumptions used in the risk assessment were reasonable.

4.4 The Committee emphasised that the data available to support some of the assumptions underlying the risk assessment were extremely limited. A number of research projects were currently in progress and the results of these studies might necessitate revision of the assessment later. The Committee was informed that the views of the Committee on the Microbiological Safety of Blood and Tissue for Transplantation and the Committee on the Safety of Medicines would also be sought on the risk assessment. Members provided DNV with comments which would be taken into account, together with comments from the other committees, in the revision of the report for the CJD Incidents Panel.

#### **Item 5: Report from the CMO/SEAC Epidemiology Sub-Group meeting (29 April 2002) SEAC 74/3**

5.1 The Committee was informed that the Food Standards Agency has commissioned a survey of butchery practices and historic uses of mechanically recovered meat. It was intended to give an assurance of anonymity to survey participants.

5.2 The Committee was informed that the National CJD Surveillance Unit case-control study has been approved for a further 3 years funding. This study, commissioned in 1990, was set up to investigate risk factors for CJD and, after 1996, vCJD. Relatives of patients with suspect CJD and controls have been interviewed using a standard questionnaire, which includes a wide range of questions relating to putative risk factors, including residential, occupational, dietary and medical histories.

5.3 The Committee noted the progress made to date with geographically associated cases. Investigations are conducted jointly by the National CJD Surveillance Unit, the Communicable Disease Surveillance Centre/Public Health Laboratory Service, the London School of Hygiene and Tropical Medicine and the Department of Health. In contrast to the Leicestershire cluster, no unusual butchery practices had been identified which could be linked with other geographically associated cases.

5.4 The Committee was informed of the SEAC Epidemiology Sub-Group discussions on the pair of vCJD cases who shared the same batch of diphtheria/tetanus vaccine. Calculations presented to the Sub-Group indicated that the likelihood was high that two individuals aged 14-15 in 1995 would both be vaccinated with the same batch of this vaccine by chance, given the large vaccine batch size (about 377,000 doses).

5.5 Dr Noel Gill, the chairman of the SEAC Epidemiology Sub-Group, suggested that further epidemiological data on vaccines, nationally and internationally, particularly data from non-BSE and non-vCJD countries, could be important for future investigations. SEAC agreed. The National CJD Surveillance Unit was charged with determining the information they might need for such investigations in conjunction with the SEAC Epidemiology Sub-Group.

5.6 In November 2001 SEAC had requested further information on various vaccine reviews on potential TSE risks conducted by the Medicines Control Agency. At the June 2002 meeting, the Medicines Control Agency provided SEAC with a confidential, pre publication summary of the CSM consolidated review of TSE Agents and the Safety of UK authorised Human Vaccines. In addition, the MCA provided documents from the reviews by the European Agency for the Evaluation of Medicinal Products (28 Feb 2001) “Public Statement on the Evaluation of Bovine Spongiform Encephalopathies (BSE) – risk via the use of materials of bovine origin in or during the manufacture of vaccines”, the US Food and Drug Administration CBER “Bovine Spongiform Encephalopathy (BSE)”, the US Food and Drug Administration CBER “Joint Meeting of the Transmissible Spongiform Encephalopathies Advisory Committee and Vaccines and Related Biological Products Advisory Committee” – Preliminary Summary (27 July 2000) and “Australia’s Response to Bovine Spongiform Encephalopathy (BSE) in animals, *commonly known as “Mad Cow Disease”* and its links to Variant Creutzfeldt – Jakob Disease (vCJD)” (1 November 2000).

5.7 SEAC was informed that on the evidence before them, the CSM, taking into consideration the advice from the TSE Expert Working Party and its Sub-Committee on Biologicals, came to the following conclusions:

- There were no demonstrable TSE related safety issues arising from the use of relevant animal derived materials, including UK bovine (from cattle) materials, in the manufacture of vaccines currently available on the UK market.
- With regard to the hypothesis that BSE might have emerged as early as the 1970s, the CSM re-affirmed their conclusions in relation to vaccine safety.

5.8 Overall, the CSM considered that

- vaccination provides a demonstrably large contribution to public health protection in reducing the spread of serious infectious diseases; and
- this benefit far exceeds any theoretical risk of the transmission of TSE through vaccination with vaccine products that have been marketed, or are marketed, in the UK.

5.9 The United States Food and Drug Administration and its Center for Biologics Evaluation and Research, the Committee for Proprietary Medicinal Products at the European Medicines Evaluation Agency and the Australian Therapeutic Goods Administration have independently arrived at similar conclusions.

5.10 SEAC members were asked to provide any observations to the Secretariat within a month. These would then be put to the CSM. The CSM report was expected to be published in the near future.

## Item 6- vCJD update

6.1 The Committee conducted its regular review of epidemiological information on vCJD. The Committee was informed that the total number of definite or probable vCJD cases in the UK, as at 5<sup>th</sup> June 2002, stood at 122 (89 confirmed cases, 20 probable cases where there is no neuropathological confirmation, 4 awaiting neuropathological confirmation and 9 still alive). There were 6 cases in France, 1 in the Republic of Ireland and 1 in Italy (Sicily) and 1 in the USA. The last case had been resident in the UK but was regarded as a US case as cases are generally assigned to the country of residence at the time of onset of symptoms.

6.2 The Committee noted that there were 66 male and 56 female cases in the UK. The mean age at death for both genders was 29 years (range 14-74) and at onset was 28 years (range 12 –74), the median duration of illness was 13 months (range 6 – 39 months). It remained the position that all of the cases tested for their prion protein (PrP) genotype, 102 in total, were Methionine/Methionine at codon 129 of the PrP gene (37 per cent of the UK population being Methionine/Methionine).

6.3 The Committee noted an analysis from the Public Health Laboratory Service (January 1994 – March 2002), which showed that the trend in the number of vCJD cases since 1995 continued to be significant, at an increasing rate of 18 % per year for onsets and 22 % per year for deaths. These estimates were, however, lower than those obtained a year ago when the estimated trends were 26 % per year for onsets and 33% per year for deaths. This analysis was available on the National CJD Surveillance Unit website: [www.cjd.ed.ac.uk](http://www.cjd.ed.ac.uk). The Committee emphasised that it was too early to forecast longer-term trends of the disease with any certainty.

6.4 Information supplied to the National CJD Surveillance Unit suggested that the likelihood of a post mortem being performed decreased with a patient's age, that post mortems were less likely to be performed where dementia was on the death certificate and that the primary purpose of the Coroner's post mortem was to determine whether death was natural or unnatural, and not necessarily to establish the underlying cause of death. Therefore deaths might be attributed to pneumonia, or to disorders of the circulatory system, even when due to an underlying neurological disease.

6.5 The Department of Health informed the Committee of a Home Office Review of the Coroner System and of a planned public consultation on the removal, retention and use of human organs and tissue - the Law in England and Wales undertaken by the Department of Health and the Welsh Assembly Government. Members requested that SEAC's concerns about the decline in autopsies should be conveyed to those carrying out the Home Office review and that they be provided with further information on these reviews at their next meeting.

## Item 7 – Intra-species recycling (SEAC 74/5)

7.1 At its meeting in June 2001, the Committee identified a number of permitted practices that would potentially allow intra-species recycling within the livestock industry. The Committee had agreed that they would consider tallow, gelatin, hydrolysed proteins, and fishmeal, eggs and egg proteins and milk and milk products at a future meeting.

7.2 The Committee were asked to consider whether the risks posed by any of these products were sufficient to warrant controls over and above those currently applying to their use. They also considered whether the risks posed by any of the products were sufficient to warrant a complete ban on their use.

### ***Tallow***

7.3 The Committee were informed that tallow had been commonly used to produce calf-milk substitutes. It had been suggested that this practice may have been responsible for the recent spread of BSE in some European countries; in particular for the appearance of BSE in young animals in Germany and Denmark. From a domestic point of view, only tallow from animals under 30-months of age which are fit for human consumption, could be used for animal feed. Information from renderers and feed manufacturers indicated that tallow was no longer used in calf-milk substitutes in the UK – evidence given to the BSE Inquiry indicated that the practice was voluntarily discontinued in 1986. It is understood that most UK tallow is used for soap manufacture. Industry sources suggest that annually an estimated 2,000 tonnes of mammalian tallow is used in feed – almost exclusively in the poultry industry.

7.4 Although Members acknowledged that tallow is not, in practice, recycled to animals in the UK, they expressed concern that there was a potential legal loophole where tallow from cattle could be fed back to other cattle in certain limited circumstances, e.g. although tallow in calf milk replacements is not used in the UK it could find its way into milk replacements manufactured in Europe. The problem lay not in tallow itself but in the possible contamination with protein that may occur in production.

7.5 Members considered that although UK feed manufacturers did not voluntarily use tallow in milk replacements, the non-use of tallow should have the force of legislation rather than leaving it as a voluntary measure. Members considered that despite strict precautions such as the 30-month rule there was the legal possibility that tallow from animals over 30 months of age manufactured from Europe or elsewhere, could be used in milk replacements in the UK.

7.6 The Committee considered that the risk from tallow was likely to be low. Even though the Committee were informed that tallow is not used in the UK in calf milk substitutes, they concluded that intra-species recycling should be avoided wherever possible. Feeding tallow to animals, other than intra species, would not be of concern but officials pointed out that although this would be acceptable from a scientific point of view, the industry would find it unachievable. To ban intra species recycling would effectively be banning the use of tallow in animal feed.

7.7 It was pointed out to the Committee that tallow would be included in the large quantities of by-products in human food manufacturing which is fed back to animals, such as bread waste. This waste would have pig tallow in it. Banning this practice may have enormous implications, including environmental implications, depending on how this was structured into potential legislation.

7.8 The Chairman recognised the constraints that may arise with the Committee's advice, but it was for Ministers to decide on what would be proportionate action against the likely small risks involved.

### ***Gelatin***

7.9 The Committee was informed that non-ruminant gelatin continues to be permitted for use in coating feed additives and remains an essential part of the binding agent for mineral blocks. As no alternative realistic means have yet been identified to aid the delivery of additives, an immediate ban would create serious welfare problems for the livestock industry.

7.10 The Committee also had before it, the EU's Scientific Steering Committee (SSC) paper updating its opinion on the safety, with regard to TSE risks, of gelatin derived from ruminant bones or hides from cattle sheep and goats. The SSC had agreed that the careful sourcing of raw materials in combination with appropriate processing would result in safe gelatin.

7.11 The Committee noted that although the risk was very small, the increasing incidence of BSE in bovines in other countries and the impossibility of confirming that bones from animals were under 30 months of age, increased the risks of re-importing BSE through bovine derived gelatine. The Committee concurred that safe sourcing was critical and saw no reason to change its earlier view on gelatin provided the SSC's recommendations were followed.

### ***Fishmeal***

7.12 The Committee were informed that fishmeal could be fed to all farmed livestock, including fish, apart from ruminants. Virtually all the fishmeal used in the UK is sourced from South America (two species) and Europe (seven). None of these are species that are specifically farmed to manufacture fishmeal.

7.13 The Committee were content with the current controls, although they repeated an earlier recommendation that farmed fish should not be allowed to be fed back to farmed fish.

### ***Hydrolysed Proteins***

7.14 The Committee were advised that Hydrolysed Proteins are obtained from two sources; skins and hides and fish and feathers. These could only be used in animal feed for non-ruminant animals. The Committee noted that there are specific conditions for the production of these proteins, namely that they have to achieve a molecular weight of below 10,000 Daltons. This is not practically achievable and as such the production of these proteins does not actually happen in the UK.

### ***Milk and Milk Products***

7.15 The Committee were informed that there were presently no restrictions on milk and milk products as they are excluded from the controls and regulations. It is acceptable to use them in animal feed, other than milk derived from clinical cases of BSE.

7.16 The Chairman commented that if BSE infectivity should ever be found in milk the Committee would need to re-assess the situation.

7.17 It was also observed that the covering sheet for this paper referred to a further study which looked for Prion Protein and Infectivity in Milk. The Chairman requested that details of this study should be sent to Members.

**Action: Secretariat**

### ***Eggs And Egg Protein***

7.18 The Committee were advised that there were no restrictions concerning egg and egg protein and the Committee recommended no changes.

### ***Blood***

7.19 The Committee were informed that the inclusion of blood and blood products is banned from animal feed. Under current Animal By-Products Regulations it can be spread on land or incorporated into fertilisers as well as being used in veterinary products. Thus, there was scope for intra-species recycling through these routes.

7.20 The Committee were informed that the new EU Animal By-Products Regulations, which are expected to come into force in early 2003, would place many additional restrictions on the manner in which blood can be disposed. For example, for inclusion in fertilisers, mammalian blood would first have to pass an anti-mortem inspection, then rendered to a pressure cooking standard. Similarly mammalian blood which had passed both ante and post mortem inspections before rendering (although not to pressure cooking standards), could also be used in pet food. However fertilisers containing blood or blood products would not be allowed to be applied on pastureland on which animals graze. Furthermore the mammalian blood would be from animals that were going into the human food chain and as such would be classified as low risk.

7.21 The Committee were content with the position although some concern was expressed over the potential recycling link of sheep blood, which could be distributed on fields containing sugar beet where sheep may graze.

## **Item 8 – Review of DEFRA funded TSE research and surveillance (SEAC 74/7)**

8.1 The Chairman explained that this paper, which had been written by a Review Team Chaired by Professor McConnell, had been presented to Members for information only. Professor Howard Dalton, DEFRA's new Chief Scientist, will be attending the September SEAC meeting, where he will talk in detail about the way forward for science in DEFRA generally and for TSE research in particular. His presentation would also include a discussion on how the recommendations in the Report either have, or will be, taken forward.

8.2 Until such time as the report is released the content should remain confidential. The release report will be put on the DEFRA website once it has been approved by Ministers. [This [report](#) is now available.]

## **Item 9 - Committee Business**

### ***SEAC Communications issues (SEAC 74/9)***

9.1 The Chairman explained that last month he and officials from the Secretariat had met with the Press Offices from DEFRA, DH and the FSA to discuss communication issues relating to the move from closed to open meetings. They had subsequently been invited to prepare a strategy document for consideration.

9.2 It was agreed that departmental Press Offices would work with the Committee to enable it to continue to be open and transparent. The Committee accepted offers of help with respect to the appointment of a SEAC press officer and media training. This would help the Committee to continue to be able to work in a professional and business-like manner once open meetings begin in September.

9.3 Discussions between the Committee and Press Offices on other issues will continue in the run up to the open meeting.

***FSA review of their scientific advisory committees and OST Code of Practice for Scientific Advisory Committee (SEAC 74/6)***

9.4 The Committee had been asked to consider two recent reports from the Food Standards Agency and the Office of Science and Technology on scientific advisory committees.

9.5 Members agreed to defer this item to the next SEAC meeting as it was considered that it would be an appropriate topic to discuss at an open meeting, especially as it highlights issues which concern the Committee with its move into public meetings.

9.6 Members also agreed to consider at the September meeting, the FSA's core stakeholder BSE and TSE sheep report, which was being considered by the FSA Board on June 13<sup>th</sup>.

**Item 10 – Approval of Minutes from previous meetings (SEAC 74/8)**

10.1 Members gave their agreement to the revised minutes from meetings 64 to 70 as being the official record of these meetings.