

The BSE Inquiry / Statement No 11B
Dr David Tyrrell
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STATEMENT OF
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ENCEPHALOPATHY ADVISORY COMMITTEE
Chairman May 1990 to November 1995

1. This Statement to the Inquiry is made to establish certain matters of fact which may not be sufficiently established by evidence at present published by the Inquiry and to supplement the information set out in **Witness Statement No: 014** issued by the Inquiry on 20 March 1998.
2. I was Chairman of the Spongiform Encephalopathy Advisory Committee from its inception in May 1990 until November 1995.

A. AMBIT OF SEAC's WORK

3. SEAC was, and is, an advisory committee and its terms of reference were:

"To advise the Ministry of Agriculture, Fisheries and Food and the Department of Health on all matters relating to spongiform encephalopathies".
4. The members of SEAC believed that they were chosen for their expertise on SE and the Secretariat members from the sponsoring department and ministry provided administrative back-up and an interface with those sponsors. The membership changed from time to time. Furthermore, on occasion, SEAC supplemented the knowledge and expertise of its members by consulting other scientists or other specialists. Although SEAC's terms of reference are unchanged it now includes a lay member.
5. The terms of reference were wide. The members were not told that they were joining a scientific advisory committee. By way of example, the letters inviting the members to join SEAC asked the new member to advise on "all" matters relating to spongiform encephalopathies. It did not refer to a Scientific Advisory Committee.
6. All of the members of SEAC held other positions; some of them were employed full time by Universities or Research Institutes or working as independent consultants. Their employers allowed them to spend some time on the work of SEAC in the public interest. Details of the appointments held by the members of SEAC at the time that they were members are set out in

Appendix 1 (**SEAC DCA, Appendix 1**). The time commitment of SEAC membership was initially expected to be small.

7. The terms of reference were not read by the members of SEAC as requiring policy advice, as opposed to advice on scientific and other matters which might affect policy, or advice going beyond the expertise of its members. Members did not see any formal restriction on the advice they could offer, but, on occasion, information or assurances were sought from others before giving their opinion.
8. The terms of reference enabled the members of SEAC to consider and advise on scientific questions concerning spongiform encephalopathies. The members of SEAC recognised that the underlying science of spongiform encephalopathies is complicated. Partly because of this, the practical and policy implications are difficult to separate from scientific matters when giving advice. It was often necessary to explain the practical implications of the science in more detail than was common with the more usual types of infection.
9. The role of the Committee was to provide collectively advice on matters relating to SE of animals and man. Between 1990 and March 1996, the period with which the Inquiry is concerned, SEAC was particularly interested in BSE.
10. The members of SEAC felt that it would be irresponsible of them to avoid offering advice when this was sought, as collectively, they did represent a body of expertise on the transmissible spongiform encephalopathies. On occasions they deferred giving advice, as is plain from the minutes of their meetings, until they had more information.
11. From time to time, advice was sought from the members of SEAC most urgently. The members had not foreseen that they would be asked to give urgent advice in the way that they were; the first request for urgent advice coming within weeks of the first meeting of SEAC.
12. Sometimes, the consideration by SEAC members of the science raised a range of possible measures through which their advice could be implemented. They thought it within their terms of reference, which are set out above, to give recommendations based on their view of the relative usefulness of practical measures.
13. It was immediately obvious and inevitable that such advice might influence or even determine policy. SEAC did not have the power of decision. Those with the power, notably Government Ministers, could make a policy decision to accept the advice of SEAC as determining policy for them, as the recipients of SEAC's advice.
14. The terms of reference of SEAC were considered and minuted at the first meeting on 1st May 1990 (**YB 90/05.01/2.1-2.4**). The then members adopted as SEAC 3/1 (**SEAC 3 Tab 1**) a note on methods of offering advice which

was approved at the meeting on 13th June 1990 (**YB 90/06.13/1.1-1.5**). SEAC meetings were attended by secretariat and observers from DH and MAFF. The role of SEAC was again questioned at the meeting on 23rd and 24th March 1996 (**YB 96/03.23/1.1-1.7**) and, on that occasion, members present were told by the Secretariat that SEAC was being asked by Ministers to give advice on the topics which they were then considering. SEAC was never advised that it had exceeded its proper role.

15. The members of SEAC became conscious that their advice was passed, through others, onto the general public. They recognised the difficulty of expressing a straight forward consensus view based on analogy, general scientific principles and, more often than not, a limited amount of BSE data. Sometimes they gave their advice in the form of a written statement, when asked to do so. If the statement made by them was further simplified for the general public that was the responsibility of others.

B. RANGE OF SCIENTIFIC EXPERTISE WITHIN SEAC

16. The membership of SEAC at the time of SEAC's establishment was not my responsibility. It appears that the initial membership of SEAC was determined at an inter-departmental meeting of Permanent Secretaries on 3rd November 1989 (**YB 89/11.03/4.1-4.3**) attended by representatives from DOH and MAFF.
17. The departments agreed that the members of the Research Committee which had produced the Interim Report in June 1989 **IBD 4 (IBD Vol 1 Tab 4)**, that is, myself as Chairman, Dr Kimberlin, Dr Will and Dr Watson should be appointed to SEAC. Professor Bourne was not invited to sit on the new Committee but, instead, a virologist, Professor Fred Brown was invited to become a member and he accepted.

Human Epidemiology Expertise

Veterinary Epidemiology Expertise

21. The Committee had ready access to Mr John Wilesmith, an expert veterinary epidemiologist. He worked in CVL. His work gave everyone their first understanding of the incidence and spread of BSE in cattle and identified the major risk factors. He continued his surveillance work. He regularly assisted SEAC, for example, by providing updates on the state of the epidemic in cattle.
22. Professor Barlow was well known for contributions to veterinary science and was an expert pathologist. He had performed the first experiments to show that BSE could be transmitted orally to mice and he was invited to join SEAC, which he did on 19th September 1990 (YB 90/09.19/2.1-2.5).
23. Dr Watson, the recently retired Director of the Central Veterinary Laboratory, had been involved with the initial research programme on BSE. He had a background of experience in veterinary diagnosis and animal disease control and was already a member of SEAC.
24. Dr D B Pepper was a veterinarian working in the field. He provided a link with the field through long experience in farm animal clinical practice and with clinical BSE. He was invited to join SEAC, which he did on 19th September 1990 (YB 90/09.19/2.1-2.5).
25. Although he was not a member of SEAC Mr R Bradley, a veterinary pathologist with previous experience in general veterinary practice, was an observer who attended all meetings and provided information to the members. In addition to taking part in discussions Mr Bradley presented summaries of current research, including joint CVL/NPU projects to the meetings of SEAC. He was the BSE Research Co-ordinator at CVL employed by MAFF from 1987 until 1995.

Additional Value in Veterinary Epidemiology

26. To gain additional value in veterinary epidemiology, a person in the top class was needed and there was no one else available at the outset. When Dr Hueston became available he was invited to become a member.

Public Health Expertise

27. At the outset the most urgent issues were seen to be primarily related to animal health although a potential risk to humans was also recognised. The risk to humans was addressed by the members who had been appointed to SEAC who looked at issues from individual and community perspectives. Thus, at the outset and for some years, public health was not seen as an issue needing the particular attention of someone from that discipline as a member. Indeed, Dr Painter, when he joined on 1st January 1996, was impressed with the quality of thinking about public health issues that SEAC members demonstrated.

External Experts

28. Although the membership was small in number it had regular access to external experts. This was noted in the minutes of the meeting on 1st May 1990 (**YB 90/05.01/2.1-2.4**).
29. The issue was considered again at the eighth meeting of SEAC on 10 May 1991 (**YB 91/05.10/2.1-2.8**) when paragraph 11 of the minutes records a discussion about observers and members. The minute reads “The Committee would be happy to invite observers from the Research Councils to participate in relevant discussions, as indeed had been intended from the start. They did not however want to see the permanent membership of the Committee expanded.”
30. If Professor Smith, who had particular expertise in human epidemiology, had joined earlier I foresaw that he would have had relatively little to contribute to the matters discussed at the meetings of SEAC. With time and more information statistical analysis was possible and useful. However, external discussions were encouraged. For example, there was an epidemiology meeting on 7 February 1991 (**YB 91/02.07/2.1-2.10**).
31. For item 3 of the agenda of the seventeenth meeting on 30th August 1994 (**YB 94/08.30/2.1-2.15**). Dr Cuzick was in attendance. The minute says:

“Dr Tyrrell welcomed Dr Cuzick, a Medical Epidemiologist from the Imperial Cancer Research Fund who had been co-opted on to the Committee for this item, and Dr Cousens of the London School of Hygiene and Tropical Medicine who had provided the analyses in the report”.
32. It was open to either of the sponsoring departments, DH and MAFF, to suggest additional members. Indeed, Sir Donald Acheson suggested new members in a letter dated 30 May 1990 (**YB 90/05.30/7.1**).
33. I recognise that Sir John Pattison, my successor as Chairman, had different views about who could usefully be a member of SEAC. However, it is worth noting that the range of problems had changed and the amount of information had increased by that time.
34. I had in mind the advantages of a small group. Those advantages were:
 - (i) access to external experts where appropriate;
 - (ii) better discussion amongst the group;
 - (iii) greater ease of fixing meetings; and
 - (iv) the ability to gain access to experts when they want it without asking those experts to commit themselves to meetings where most of the time would be spent on issues to which they would not be able to make any useful contribution.

C. REVIEW AND ANALYSIS OF CURRENT KNOWLEDGE CONCERNING TSEs

35. SEAC was an Advisory Committee and I first saw its role formalised in the form of duties in the course of this Inquiry. I did not regard SEAC as having duties but did see it as part of their role to (a) keep abreast of current knowledge and developments in research relating to spongiform encephalopathies, domestically and overseas; and (b) maintain an overview of research which they were made aware of in this country, so that they could then give advice.
36. SEAC members recognised that they needed to be well informed. Individual members' interests and expertise were such that they were aware of most, if not all, of the relevant literature between them. It was not necessary and would not have been practicable for the members to have read, individually, all of the literature.
37. Their knowledge was supplemented by review seminars and attendance at major meetings on SE, epidemiological, and genetic work.
38. The minutes of SEAC meetings do not record the details of many of the discussions. The members of SEAC regularly and freely discussed the topic of SE and shared their knowledge.
39. SEAC arranged to be informed about published literature from the first meeting on 1st May 1990 (YB 90/05.01/2.1-2.4). They set up a system whereby all members were kept informed (see paragraphs 50 to 58 below).

Development of 1992 and 1994 SEAC reports

40. At the eighth meeting of SEAC on 10th May 1991 (YB 91/05.10/2.1-2.8) the minutes include a section, labelled C, on research co-ordination. paragraph 9 of the minutes of that meeting record:

“It was agreed that the Chairman and Secretariat would try and work up a description of, and commentary on, the current research programme which could be considered at the next meeting and then circulated widely in draft to interested parties, with a view perhaps to the preparation ultimately of a further “interim” report which took account of the feedback received.”
41. The minute records SEAC's consideration of SEAC 8/3 (SEAC 8 Tab 3) which was the regular review of the progress of research initially recommended by the Tyrrell Consultative Committee and being undertaken in the United Kingdom and, in some cases, elsewhere.
42. At the ninth meeting of SEAC on 28th June 1991 (YB 91/06.28/2.1-2.7) paragraph 7 includes the following: “...the Committee was developing its role of reviewing research..”

43. At the tenth meeting of SEAC on 6th September 1991 (**YB 91/09.06/3.1-3.7**), the minutes include the section on “the second interim report” (**YB 91/09.06/3.4**). The first interim report was the interim report of the Tyrrell Consultative Committee. This was to be the first report of SEAC **IBD 4 (IBD Vol 1 Tab 4)**.
44. The first report produced by SEAC became the 1992 report **IBD 13 (IBD Vol 2 Tab 2)**. The second became the 1994 report **IBD 21 (IBD Vol 2 Tab 9)**.
45. At the twelfth meeting of SEAC on 28 April 1992 (**YB 92/04.28/2.1-2.8**) item F is headed “Further report on research” and the minute reads:
- “The Committee considered what further work to do so as to fulfil their remit to maintain an overview of research. It was clear that adequate machinery existed to evaluate the quality of individual research programmes and that the committee did not have a role in this process. The committee did however need to keep abreast of developments in research across the whole field of SE’s, in the UK and overseas – on the basis of published reports and of information from workers – and to consider whether it would be helpful to draw attention to the wider implications and conclusions as they emerged. There need be no commitment at this stage to produce a further report. The Secretariat would consider with the Chairman how this process should be carried forward”.
46. Following that meeting I wrote to the Minister enclosing the 1992 report (**YB 92/05.01/5.1**).
47. At the fifteenth meeting of SEAC on 7 October 1993 (**YB 93/10.07/2.1-2.5**) a topic was “Third interim report” which was, in fact, the 1994 report **IBD 21 (IBD Vol 2 Tab 9)**. The minute reads:
- “General comments on this were produced by the Committee. It was agreed that the Report should aim to reach as wide an audience as possible. To do this, some of the difficult concepts e.g. on PrP – the gene, gene product, modified PrP and role of it, need to be introduced after a general introduction so that information built up as it was read. A “further reading” section after each chapter was suggested...”
48. The report was further considered at the sixteenth meeting of SEAC on 26 January 1994 (**YB 94/01.26/2.1-2.5**). The minute reads:
- “H Draft Report
- The committee made detailed comments on the report on a page-by-page basis. Dr Tyrrell stressed the importance of getting the report right. It was agreed that the top priority in producing the report should be quality rather than speed...”

49. Time was needed to unite the drafts, consult on them and have them considered in the programme of SEAC meetings. The minute of the meeting on 26 January 1994 (**YB 94/01.26/2.1-2.5**) explains that the view of SEAC was that accuracy rather than speed was the priority.

D. SEAC's RECEIPT OF ONGOING RESEARCH ON TSEs

50. The minutes of SEAC meetings show that SEAC put in place machinery to ensure that it received systematic information on the progress and current status of research into TSE's world wide. SEAC believed it was appropriate machinery.

51. The first meeting of SEAC was on 1st May 1990 (**YB 90/05.01/2.1-2.4**). Item 2.2 of the minutes records:

“The main difficulty for the Committee was thought to be how to keep abreast of developments in research, both domestically and overseas. A list of groups known to be interested in spongiform encephalopathies was drawn up”.

52. Item 2.3 of the minutes said (**YB 90/05.01/2.2**):

“Particularly for members without ready access to large libraries, it was difficult to keep up with the literature. Mr Bradley and Dr Pickles agreed to make arrangements for appropriate listings and papers to be circulated. Mr Lawson would pursue the collation of relevant extracts from the non-specialist press”.

53. SEAC would receive comprehensive listings of titles and often abstracts of relevant publications worldwide. In the case of especially important publications, photocopies were produced to the members of SEAC. Initially, Mr Lawson also obtained newspaper and trade journal cuttings.

Item 3.1 of the minutes of the first SEAC meeting on 1st May 1990 said,

“The Group should aim to keep itself informed about all relevant research – on a confidential basis when necessary.” (**YB 90/05.01/2.2**).

54. At the fourth meeting of SEAC on 2nd July 1990 (**YB 90/07.02/3.1-3.4**) the minutes show:

“C-Literature Searches:

The Committee considered how these should be conducted by DOH and CVL Libraries in view of the enormous amount of material to which initial searches had given rise, even after the elimination of “false drops”. With some amendments, a list of key words was adopted...”.

55. At the sixth meeting of SEAC on 1st November 1990 (YB 90/11.01/7.1-7.9) item H records:

“There was general agreement that the provision of abstracts was very valuable and should be continued (although it would be helpful if clearly irrelevant material were weeded out and if some items could be deleted – notably references to cited literature and search categories). Requests for copies of articles should be channelled through the Secretariat”.

56. The minutes of the SEAC meeting on 28th April 1992 (YB 92/04.28/2.1-2.8), item F, reads:

“F. Further report on research
The Committee considered what further work to do so as to fulfil their remit to maintain an overview of research. It was clear that adequate machinery existed to evaluate the quality of individual research programmes and that the Committee did not have a role in this process. The Committee did however need to keep abreast of developments in research across the whole field of SE’s, in the UK and overseas – on the basis of published reports and of information from workers – and to consider whether it would be helpful to draw attention to the wider implications and conclusions as they emerged. There need be no commitment at this stage to produce a further report...”

57. It is worth noting the basis (published reports and information from workers) on which the Committee anticipated keeping abreast of such research. It properly recognises the limitations on knowledge.
58. It is not always possible to formalise, or make public, the mechanism by which an advisory committee, like SEAC, acquires its information about the results of current research. SEAC tried hard to maintain the confidentiality of information it received before publication of the research because, if it had not done so, it would not have received information about that work before publication.

E. SOUTHWOOD REPORT

59. The members of SEAC were constantly engaged in reviewing the research and knowledge on SE and consequently forming their own view on the issues. They gave advice in the light of their knowledge, which was not limited to the contents of the Southwood Report **IBD 2 (IBD Vol 1 Tab 2)**. Each group which had looked at matters in the past, including Southwood and the Consultative Committee, had a particular remit which they had addressed and, having fulfilled it, had been disbanded. The members of SEAC looked at the original sources of material which had led previous groups to reach their conclusions and at events and research results that had since become available. They noted the conclusions of earlier groups but formed their own views.

60. The SEAC members did not regard it as part of their role to revisit and formally comment on the Southwood Report **IBD 2 (IBD Vol 1 Tab 2)**. They took that report as setting out the knowledge and opinions of the members of the Southwood Working Party as at February 1989.
61. A study of the minutes of SEAC meetings shows that they recognised that further research work was essential. They considered the results of that work when it was available to them and in the light of increased knowledge gave advice from time to time.

F. SEAC REPORT, APRIL 1992 – CONSIDERATION GIVEN TO VARIOUS ISSUES

Consideration of criteria governing priorities recommended by Tyrrell Committee

62. SEAC saw no necessity to consider or explain the criteria of the Consultative Committee. For their part, they had no uniform or shortlist of items that could be called criteria. They considered a variety of factors, which had varying degrees of importance depending on the research project being considered. There was no checklist. It would not have been a justifiable use of their time to write out such a list. Instead, the Committee's members considered projects and ideas at their various meetings, as can be seen from a study of the minutes.
63. SEAC started to consider the priorities allocated to projects by the Tyrrell Committee from the first meeting of SEAC on 1st May 1990 (**YB 90/05.01/2.1-2.4**).
64. The minutes of the first meeting show that the members of SEAC considered a table setting out details of all of the research work, cross-referenced to the Tyrrell Committee's interim report **IBD 4 (IBD Vol 1 Tab 4)**. Item 3.3 of the minutes of the meeting on 1st May 1990 (**YB 90/05.01/2.2**) record:

“The table summarising research work being undertaken in relation to the Tyrrell recommendation was thought very helpful...Mr Bradley amplified the current position for each item. The Group wanted (the) table to be kept updated, with an indication of results/progress when possible”.

At the time Mr Bradley was attending as an observer and not a member of SEAC.

On 1st November 1990 SEAC met for the sixth time. Item C of the minutes of that meeting read:

“C RESEARCH UPDATE

9(ii) the proposed attempt to extract a large quantity of abnormal PrP from infected cattle brains was welcomed, but the Committee emphasised the

crucial importance of quality control in view of the minute differences between normal and abnormal material.”

and

“(iii) on transmission studies, there were no new developments to report. Mr Bradley tabled paper RB264 updating information on studies in progress.”

65. On 28th June 1991 (**YB 91/06.28/2.1-2.7**) SEAC met again and the minutes record, again, that the members received details of research.
66. SEAC was, in practice, considering the various research projects recommended by the Tyrrell Committee from the outset.
67. The purpose of the 1992 report **IBD 13 (IBD Vol 2 Tab 2)** was, as explained in the report itself, to document SEAC’s review of the research work then underway. The 1992 report was only a review of work underway; see paragraph 2 of the summary of the 1992 report.

Reconsideration of priorities for research in light of current scientific developments

68. The 1992 report **IBD 13 (IBD Vol 2 Tab 2)** did not document its consideration of priorities. In order to produce the report SEAC did, in fact, review research and, as a necessary step, the scientific developments which had occurred between 1989 and April 1992. In the introduction to the 1992 report paragraph 1.4 states:

“In producing this report we have reviewed current UK-sponsored research and referred to important initiatives taking place internationally.”

69. As the minutes show, SEAC conducted an exercise whereby the progress of research was assessed, further information collated and considered and priorities reviewed.
70. The recipients of the report, principally the Department of Health and the Ministry of Agriculture, Fisheries and Food, were aware from the 1992 report itself what had been done.

Consideration of highest priority research in Tyrrell Report

71. Paragraph A1 of the Tyrrell interim report **IBD 4 (IBD Vol 1 Tab 4)** reads:

“A.1...

(d) More detailed investigation into the fate of bovine (and ovine) tissues and products that could lead to infection being spread by as-yet-unrecognised routes. Some uncertainty remains as to whether all the possible routes of transmission from bovine (and ovine) tissues to other

species have been considered and appropriate action taken. Small scale users of bovine products, such as the cosmetic industry, may not be covered by the present regulations and guidelines. There are no formal proposals for work of this sort and consideration should be given as to whether such a study should be commissioned. ***”.

The research envisaged was no longer a high priority. It had been re-graded as low priority on 1st May 1990. The relevant minute of the minute of the first meeting of SEAC on 1st May 1990 (**YB 90/05.01/2.3**) reads:

“24. Now low priority, as the trade had adjusted of its own accord”.

It was realised that a high grading had been given to this work which was really an information gathering exercise, which was no longer needed.

72. As to titration experiments which were mentioned in the Tyrrell Committee’s interim report, the recommendation of the Tyrrell Committee was to enable material to be made available to pharmaceutical companies if they needed it for research which might be needed.
73. The pharmaceutical work diminished in importance for SEAC because the industry itself developed an explicit policy of sourcing from BSE free animals in BSE free herds in BSE free countries.
74. It is worth noting that the point is made on the Schedule prepared by Mr Bradley (**YB 90/05.00/14.1**) for the first meeting of SEAC on 1st May 1990 (**YB 90/05.01/2.1-2.4**). It records:

“Trade restrictions and industry sourcing form outside UK has lowered the priority on this”.

75. However, the 1992 report **IBD 13 (IBD Vol 2, Tab 2)** did deal with pharmaceuticals in paragraph 4.15. It said:

“At the time the first Interim Report was written it was assumed that additional work would be needed to reassure the licensing authorities of the safety of human pharmaceuticals manufactured from all of these tissues from British cattle. Now that BSE has been reported outside the British Isles the same issues could arise by biological pharmaceuticals sourced in other countries. However, the pharmaceutical industry, acting in part on advice of the Committee on the Safety of Medicines (CSM) and the Veterinary Products Committee (VPC) has produced guidelines for the medicine products industry and sought information from them via questionnaire on products using animal matter (including bovine materials)...the relevance of studies on the safety of pharmaceuticals manufactured from tissues from British cattle is now questionable.”

Consideration of the relative susceptibility of calves to BSE

76. Paragraph A1(g) of the interim report of the Tyrrell Committee **IBD 4 (IBD Vol 1 Tab 4)** referred to the further examination of the relative susceptibility of calves and gave that work one star, indicating that it was of low priority. By 1st May 1990 that work was not being undertaken although it was noted that, if it was to be carried out, it would be funded by MAFF.
77. The relative susceptibility of calves is encompassed in Paragraph 4.11 of the 1992 SEAC report **IBD 13 (IBD Vol 2 Tab 2)**. Although the relative susceptibility of calves was not the subject of a dedicated research project that does not invalidate the general conclusion in the 1992 report (**ibid**). It was a general conclusion and this work had been given a single star in the report of the Tyrrell Consultative Committee. I believe the general conclusion in the report that we were content with the progress in implementing the recommendations overall was sound.

Consideration of Transmission of BSE to mink

78. This work was not allocated any priority in Paragraph C1 of the interim report of the Tyrrell Committee **IBD 4 (IBD Vol 1 Tab 4)**. However, mention was made of this issue in the 1992 Report. Paragraph 4.12 of the SEAC 1992 report **IBD 13 (IBD Vol 2 Tab 2)** says:

“Further experiments are in progress with marmosets, chickens in the UK and mink in the USA.”

Paragraph A3.8 of Appendix III to the 1992 report **IBD 13 (IBD Vol 2 Tab 2)** says:

“Transmissibility studies – to determine the transmissibility of BSE to mink by intra-cerebral and by oral exposure to brain homogenate from BSE affected cattle.”

The work was said to have started in 1991, partly funded by MAFF because the BSE infected material had to be collected in the United Kingdom.

Consideration of transmission of BSE to horses and rabbits

79. Neither of those projects were given any priority by the Tyrrell Committee, indicating that they were not thought necessary. The 1992 Report **IBD 13 (IBD Vol 2 Tab 2)** therefore did not mention this work.
80. Work in relation to rabbits was the subject of an outline proposal mainly because previous attempts to transmit SE to rabbits had failed and it would be of scientific interest if BSE was an exception. That work was not considered to be of any other significance. It was not thought essential for the understanding of pathology or to counter human or animal disease.

Consideration of pharmacological manipulation of infectivity

81. This work was given one star by the Tyrrell Committee, indicating that it was of low priority, to be the subject of an outline proposal from the Neuropathogenesis Unit. However, other proposals were considered to be of greater importance. It was not possible to carry out all of the studies that were proposed.

Consideration of effect of bovine PrP on neuronal function and gene regulation

82. This work was said by the Tyrrell Committee's report to be of medium priority, the subject of an outline proposal or suggestion for work at the Neuropathogenesis Unit. Paragraph 4.16 of the 1992 report **IBD 13 (IBD Vol 2 Tab 2)** records:

“There is much useful work in progress on the morphology, distribution, properties and genetics of PrP both using animal and human material. It is too early to review this work. The implications of the many fundamental studies in this area will be considered in more detail by our Committee at a later date”.

83. Paragraph 4.17 said:

“General studies on the genetics of BSE infection and on bovine PrP gene are in progress. The well established studies in scrapie are continuing...The suggestion in the Interim Report that the effects of PrP on neuronal function might be studied, for example, as a way of elucidating what may be behind the functional abnormalities in spongiform encephalopathies, has not yet been taken up but other studies are underway and are of relevance of molecular mechanisms of pathogenicity”.

General Comments

84. In each of the paragraphs referred to in paragraphs 76 to 83 above, there was cross-referencing to the particular studies.
85. The fact that a project has been mentioned in the 1992 report means that it was considered. The converse is not true. The fact that a matter has not been specifically mentioned in the 1992 report does not mean that it was not considered by SEAC, simply that it was not thought worth a specific mention in that report.

Consideration of experiments

(a) Embryo Transfer Experiment

91. Paragraph 4.11 of the 1992 report **IBD 13 (IBD Vol 2 Tab 2)** said, amongst other things, as follows:

“Embryo transfer using embryos derived from BSE positive cows mated by artificial insemination to BSE positive or BSE negative bulls has commenced (A3.1)”.

92. Ignoring the money cost, SEAC recognised an inevitable tension between different views on how best to use the limited resources for experimental infection of cattle. At the time of writing the 1992 report they did not see it as necessary to comment on the expense of a particular experiment which they knew was underway.

(b) Attack Rate Experiment

93. The 1992 report commented on the first transmissibility study in cattle, the pathogenesis experiment and the attack rate experiment. However, reference must also be made to Appendix III which mentions, explicitly, the attack rate experiment in sections A3.4, A4.1 and A4.2.

94. Appendix III, A3.4, describes the first transmissibility study which had been started in 1988 and funded by MAFF. Appendix III, A4.1, deals with the pathogenesis experiment in BSE in cattle to study the distribution of infectivity and pathogenesis in cattle challenged orally with homogenised brain from field cases. That project was started in about June 1991 funded by MAFF. Appendix III, A4.2, was a study of the effects of oral inoculum dose on attack rate of BSE in cattle. The objective was said to be to determine the attack rate and incubation period of BSE in cattle exposed orally to four different dose levels of brain homogenate from affected cattle, to determine if there was a dose response on the incubation period, and to establish the effect of multiple exposures compared to a single exposure on attack rate and incubation period. The project was started, when the first cattle were inoculated, in about December 1991 or January 1992 and funded by MAFF.

95. SEAC meetings were attended by two Joint Secretaries, one from MAFF and the other from the DH, and observers from the DH and MAFF. They were therefore aware of the studies being proposed to SEAC and prepared papers on behalf of MAFF and/or DoH for consideration by SEAC members. The members were conscious that the joint secretaries and observers could report back to their ministry/department, as they did.

96. In the event, SEAC members thought the design of the attack rate experiment justifiable given the decision to proceed with the pathogenesis experiment as soon as possible. The attack rate experiment started in January 1992 (**YB 92/01.15/1.1-1.2**) and the pathogenesis experiment had started in July 1991.

Ideally, in order to obtain realistic answers to questions of pathogenesis which includes the spread of infection through the body, it was desirable that the study used doses approximating to those probably occurring in the field. However, this would have been unpractical because, in contrast to field exposure to BSE, the design of the pathogenesis experiment required the use of an oral dose of infectivity that could be guaranteed to give a 100% rate of infection. Yet neither SEAC nor the experimenters could know what this dose of infectivity was for some years. If they used too small a dose then no infections at all might occur or only a few animals would be infected. Discussions involving SEAC continued until proposals were found acceptable and the pathogenesis study started using doses that were likely to be comparable to field exposure. That was a compromise which they thought was necessary even though it might bias the results. Therefore, one objective of the attack rate study was to investigate the infection rate with lower doses than was used for the pathogenesis study. The results could contribute to the interpretation of the pathogenesis experiment and to an understanding of the BSE epidemic.

(c) Maternal Transmission Experiment

97. The maternal transmission experiment was commented on in the 1992 report, Paragraph 4.3 which was cross referred to Appendix A1.6 **IBD 13 (IBD Vol 2 Tab 2)**.
98. I am aware that the members of SEAC saw the explanation given by the Consultative Committee of the maternal transmission experiment.
99. I drew everyone's attention to the limitations, not weaknesses, of the experiment in a letter dated 21st March 1989 (**YB 89/03.21/2.1-2.1**).

G. SEAC ADVICE ON SLAUGHTERHOUSE PRACTICES.

100. Mr Pepper joined SEAC in September 1990 and was a practising field veterinary surgeon who had experience of slaughterhouse practices.
101. The other members had no relevant professional experience that would have enabled them to feel comfortable giving advice without making a visit. Not all the members of an advisory committee could have relevant experience for all issues; to do so would defeat the purpose of a committee.
102. There was discussion about slaughterhouse practices at the SEAC meeting on 17 May 1990 (**YB 90/05.17/1.1-1.4**). The minutes of that meeting include, at Item 3, the following:

“The Committee recommended additional attention should be directed at abattoir methods in order to minimise cross (sic) contamination of meat with banned offal”.

The request for advice was made by MAFF. The request was announced by the Minister of Agriculture in a House of Commons debate on 21st May 1990 (**M7 Tab 9**).

103. On 23rd May 1990 Mr Robert Lawson, a MAFF employee acting as Joint Secretary to SEAC, wrote to me (**YB 90/05.24/26.1-26.2**) saying:

“...this Ministry [meaning MAFF] has already obtained advice on the methods that should be used for removing brains and has prepared advice for enforcement authorities”.

He went on to say:

“The Minister made it clear in the House of Commons on Monday evening that he wanted the Committee to consider this advice on the removal of brains and any other aspects of slaughterhouse practice relevant to the BSE problem”.

Later in the letter it was said:

“Obviously, were you to clear these guidelines we would like to get them out quickly and we hope therefore that you can deal with them separately from the question of other slaughterhouse practices. Perhaps we could discuss whether there is any further work which needs to be initiated in relation to these other practices. Meanwhile, as I indicate above, I hope that we can resolve the brain removal issue quickly”.

Attached to the letter was draft guidance prepared by MAFF officials.

104. The matter was considered by SEAC at its third meeting on 13th June 1990. (**YB 90/06.13/1.1-1.5**) The minute reads:

“G Slaughterhouse Practices

12. Paper SEAC 3/5 (**SEAC 3 Tab 5**) was discussed. The Committee felt that precautions about the removal of the brain from bovine skulls were a common sense measure. It was not consistent with this policy to permit the removal of the brain before head meat was harvested.

13. Similar issues arose with spinal cord; If it made sense to avoid contamination by brain tissue of meat for human consumption it appeared on the face of it to make equal sense to avoid the contamination of such meat with spinal cord, which was just as likely to carry infection. Further information was needed on this”.

105. The agenda for the fourth meeting on 2nd July 1990 (**YB 90/07.02/3.1-3.4**) included, as an item:

“6 Slaughterhouse Practices

- (a) to finalise advice on bovine head splitting
- (b) to consider possible further work”.

106. In the minutes of the meeting on 2nd July 1990 (**YB 90/07.02/3.4**) it is said in relation to slaughterhouse practices:

“H. Slaughterhouse Practices.

12. Mr Lowson reported that MAFF were working on a paper on slaughterhouse practices relevant to BSE for consideration at a future meeting. The Committee agreed that after receiving this it would probably be necessary to see the slaughtering process at first hand before offering further advice”.

107. At the fifth meeting SEAC on 15th [19th] September 1990 (**YB 90/09.19/2.1-2.5**) the minutes say:

“H. Slaughterhouse Practices.

20. If the Committee was to reach worthwhile views about the implications of those slaughterhouse practices which it had not examined, it would need both to see the papers on the topic that had been promised by the Secretariat, and to see at first hand how the practices under review worked. The Secretariat will pursue this”.

108. Members of SEAC visited an abattoir [not all the same abattoir] to see whether it was feasible to remove the SBOs and were shown that it was feasible.

109. At the meeting on 1st November 1990 (**YB 90/11.01/7.1-7.9**) a paper prepared by MAFF and labelled “SEAC 6/1” (**SEAC 6 Tab 1**) was provided to SEAC. In the introduction to the paper, paragraph A.1, it said:

“This note considers those aspects of the conventional slaughtering process which could in theory lead to the contamination of material for human consumption with potentially infectious material”.

110. Paragraph 8 of the paper set out possible research and paragraph F set out the conclusion which read (**SEAC 6 Tab 1**)

“The Committee is invited to consider on the basis of the available evidence whether any action or guidance is required in relation to slaughterhouse practices, and whether any new R&D is needed, and if so with what priority”.

The paper described carcass splitting and mechanically recovered meat.

111. Item E16 of the minutes of the meeting on 1st November 1990 (**YB 90/11.01/7.1-7.9**) record the conclusion of the Committee:

“Those members who had been involved in the slaughterhouse visit had noted that, if proper procedures were followed, specified offals could be satisfactorily removed at the slaughterhouse, and in particular that the spinal cord could be extracted from the carcass without difficulty. The Committee therefore concluded that, provided all the rules were properly followed and supervised, there was no need to recommend further measures on the grounds of consumer protection (operator safety was a matter for HSE)”.

112. The conclusion of SEAC, at the meeting, did not cover research and development or its priority. It gave advice, from the perspective of its expertise, which was properly qualified.
113. The Minister had told the House of Commons that he would seek the advice of SEAC and in these circumstances it is unreasonable to expect SEAC to have declined to give the Minister the advice which he sought.
114. The advice given by SEAC was expressed to be subject to a proviso or condition. That condition or proviso is set out above and is in the use of the words “if” and “provided”. It is necessary to read the conclusion in full to understand it. It was for Ministers and their officials to consider SEAC’s advice and decide if the provisos or conditions explicitly mentioned could be met. Sir Derek Andrews said, in **Witness Statement No 281 (At paragraph 132)**, that SEAC’s conclusion was that:

“So long as the rules were properly observed and proper supervision was maintained, there was no need to recommend further control measures on grounds of food safety”.

It is clear that he understood, at the time, the conditions or provisos attached to the advice.

115. SEAC members regarded giving advice, in the qualified terms in which it was expressed, to be within their role and expertise. The conclusion was, essentially, negative.
116. The advice given by SEAC left it open to those considering the advice, who knew the composition and expertise of the Committee, to seek other advice.
117. Within MAFF there was a specialist meat hygiene section responsible for the oversight of slaughterhouse standards. MAFF appointed practising veterinarians as OVS who were, or should have been, regularly visiting slaughterhouses and had the opportunity to view abattoir practices in the course of their ordinary work at first-hand. The opportunity to acquire information at first-hand available to MAFF employees was known to members of SEAC, particularly Dr Watson, who had been a MAFF employee and Mr Pepper, who was a practising field veterinarian.
118. The Committee learned at the meeting on 21st June 1995 (**YB 95/06.21/2.1-2.9**) that their previous understanding about the enforcement of the SBO ban

was mistaken. The issue arose when the use of gelatin and blood products in ruminant feeding stuff was on the agenda for the meeting. There then ensued a discussion about the wider implications and Dr Matthews, a MAFF member of staff who was in attendance at the meeting, explained MAFF's then understanding. The minute reads (**YB 95/06.21/2.3**):

“11. Dr Matthews said that in looking at the procedures in abattoirs for the review of the SBO order, MAFF had become uneasy about what it had found. There were problems with the quantities of SBO arriving with the renderers not being commensurate with the throughput of the abattoirs and the use of the patent blue stain, orders for which were negligible. In head boning plants which split skulls and removed brains as SBO, it appears that some brain tissue was being left behind though there did not appear to be any problems with the removal of spinal cord. As a result of these findings MAFF was carrying out an Audit of Practice. Over a period of 2 months, unannounced visits were being made and any deficiencies noted and put in writing to the OVS and the MHS, with a further visit after 2 weeks. If deficiencies were still found, prosecutions would be recommended. So far, on the basis of a very small sample, it appeared that there were some problems with the separation of SBOs and that less than 50% were complying with staining requirements”.

119. The matter was considered by the members of the Committee and the minutes go on to say:

“12. The Committee was very concerned with these reports given the previous understanding that the position had been satisfactory. It was now recognised that previous reports based on pre-arranged visits to premises had given a falsely reassuring picture. The Committee felt that, if there was evidence that something was going wrong, action should be taken as a matter of the highest priority”.

120. Although it is speculative, I believe that if SEAC members had been told earlier than June 1995 what they were told at the meeting on 21st June 1995 (**YB 95/06.21/2.1-2.9**) they would have had the same misgivings and expressed the same view that they did in 1995 on that earlier occasion. However, that involves the use of hindsight and, of course, there would not necessarily have been all the information at an earlier date which was available in 1995 when the information about the SBO ban's enforcement was considered in the context of “born after the ban” cases.
121. The issue was considered again at the next SEAC meeting on 8th September 1995 (**YB 95/09.08/2.1-2.7**) and again at the meeting on 23rd November 1995. (**YB 95/11.23/1.1-1.13**) At the meeting on 23rd November 1995 (**YB 95/11.23/1.1-1.13**) Mr Eddy, a member of the Secretariat, reported to SEAC on the outcome of visits to slaughterhouses to check on the level of compliance with regulations for the removal and disposal of SBO. Amongst the information which he gave to SEAC was that spinal cord had been found

both in stamped carcasses and in carcasses awaiting deferred inspection. The minutes then read (YB 95/11.25/1.3):

“Dr Will stated that he was appalled by this information: SEAC had previously been reassured that there was little chance of spinal cord remaining in situ and they must infer that this had been happening throughout the last 5 years. The use to which vertebral columns were put must now be seriously considered.

10. Dr Kimberlin agreed with Dr Will. He felt that 0.4% incomplete removal of spinal cord was unacceptable under the circumstances. Comparative titration suggests that the whole epidemic has probably been driven by re-cycling of CNS tissues rather than other SBOs...the Chairman stated that SEAC must be reassured that policing is in place, and that the outcome of investigative visits are recorded accurately in relation to the sequence of events”.

122. Having learned the true position in mid to late 1995, when SEAC subsequently gave advice, notably on 20th March 1996, it did so in imperative terms (YB 96/03.20/45.1-45.2).

H. SEAC ADVICE ON SAFETY OF BEEF 1990 - 1996

1990

Events leading to letter of 24 July 1990

123. An emergency meeting of SEAC took place on 17th May 1990 (YB 90/05.17/1.1-1.4). At the start of the meeting, I, as Chairman, explained that I wanted to deal first with those items on which immediate advice was sought. This was in part to amplify the advice given previously on the safety of beef. At that meeting the members had before them the draft of a letter addressed to the Chief Medical Officer. Paragraph 3 of the minutes of the meeting sets out some of the points which were expressly considered by the members of SEAC in relation to the letter. It then contains a paragraph which says:

“In describing the risk as no greater than those of everyday life, this was not to imply that they were in any way comparable, say to smoking. BSE was of a much lower order of magnitude. But in the present state of knowledge, it would not be justified to state categorically that there was no risk to humans and it was not appropriate to insist on a zero risk”.

It is worth noting that SEAC specifically exclude the possibility of excluding all risk.

124. The draft was not agreed at that meeting. The members wished to give a detailed and deliberate response and had some concern that they had been asked to give advice at short notice and outside the ambit of their role. However, they concluded that it was within their role.

125. The issue was considered again at the third meeting of SEAC on 13th June 1990 (YB 90/06.13/1.1-1.5). The minutes contain the note:
- “C. Draft letter to the CMO
3. ...In discussion of the general principles underlying the Committee’s advice, it was recognised that its job was to assess scientific data and opinions as objectively as possible, then to set down judgements on these in writing. It was important to communicate the message that science was not absolute and it was for policy-makers to decide what measures to adopt; what action might be appropriate depended not just on what the science indicated but on what the policy objective was.
4. It was agreed that it would be necessary to resume discussion on presentation of the arguments on the safety of beef at a later date”.
126. At the same meeting the members of SEAC approved paper SEAC 3/1 (SEAC 3 Tab 1) which included the following:
- “2. All the advice which it [SEAC] produces will, therefore, go to both Departments in the first instance... The assumption must be that all of it will be made publicly available in one way or another...
3. The minutes of meetings are not intended as part of the Committee’s advice to the Departments, although the Departments see them and may want to take account of views reflected in them”.
127. It is clear that the SEAC members appreciated that it was not only their advice which went to the DH and MAFF but the minutes of their meetings which set out their reasoning in more detail in many cases.
128. The matter was considered again at the fourth meeting of SEAC on 2nd July 1990 (YB 90/07.02/3.1-3.4). The minute records:
- “E. Safety of beef
- The Committee considered SEAC 4/2. Subject to some amendments, the draft letter to the CMO was agreed”.
129. The terms of reference of SEAC were wide enough to permit SEAC members to give advice on this issue which was a matter relating to spongiform encephalopathies. SEAC was a body with extensive knowledge of spongiform encephalopathies and it would have been irresponsible of them to have declined to give advice to the Chief Medical Officer when specifically asked to do so.
130. SEAC gave its definitive advice on 24th July 1990 (YB 90/07.24/3.1-3.12). It had, by then, had more than one month in which to reflect on the advice

sought and earlier given. It had collectively discussed the matter on 3 occasions.

131. The advice given orally was not the subject of reflection and collective discussion. Insofar as oral advice was given prior to or on 16th May 1990, the advice was correct at the time and the seeker knew that the individuals had not had an opportunity to reflect or discuss the matter collectively.
132. The members of SEAC knew there was a risk. However, at the time they did not think that “safe” meant “no risk”.
133. SEAC is in the same position as Sir Donald Acheson who told the Inquiry, in Paragraph 2 of **Witness Statement Number 251**:

“It was several years after the event that I became aware that for some people the word “safe” without qualification means “zero risk”.

134. The recipients of the advice in MAFF and DH would have learned at the SEAC meeting on 17th May 1990 (**YB 90/05.17/1.1-1.4**) that SEAC thought it was important to communicate the message that science was not absolute.
135. The position of SEAC was explained by me to the House of Commons Agriculture Select Committee in June 1990 **IBD 7 (IBD Vol 1 Tab 7 at page 85, para 313)** when I said:

“So one can say to people, “We think it is perfectly safe to eat beef and have steak on Sunday, that is fine but if you want to be absolutely sure that you never taken anything into your body, even traces which Richard’s [Kimberlin] mouse inoculations cannot detect, then you should not eat beef and you should not eat products which contain beef protein””.

The advice of 24 July 1990

136. It is important to examine the words used in the letter dated 24th July 1990. (**YB 90/07.24/3.1-3.12**) First, the opening paragraph deals with the position at 24th July 1990 and looking forward. It said:

“The Spongiform Encephalopathy Advisory Committee, having reviewed the evidence available, have concluded that British beef can be eaten safely. The rationale for this view is as follows”.

“Having reviewed the evidence available SEAC have concluded that British beef can be eaten safely”.

Then, in paragraph 7 (**YB 90/07.24/3.2**) we said:

“In our judgement any risk as a result of eating beef or beef products is minute. Thus we believe there is no scientific justification for not eating British beef and that it can be eaten by everyone.”

In paragraph 8 (**YB 90/07.24/3.2**) we said:

“We propose to keep the matter under review as additional evidence becomes available.”

It is plain from an ordinary reading of that letter that we were not saying that there was no risk.

137. It is also plain from an ordinary reading of the text that the advice was given on the evidence available. The recipients at MAFF and DH knew that there was a large amount of evidence about TSEs in other species and there was a limited amount of BSE evidence. It is also plain that we were limiting our advice to a scientific justification. In consequence, our advice was based largely on analogy and general scientific principles. Finally, it was plain that we were going to keep the matter under review and that, in itself, was an indicator that our advice was not final. Whatever else may be said about the letter and its annex, it is plain that it mentions hazards and risks and the only understanding of the letter is that there is some risk, although it is described with varying terms. For example, Paragraph 1.2 of the Annex to the letter of 24 July 1990 (**YB 90/07.24/3.3**) says:

“The strong probability is that BSE, like scrapie, is no hazard for humans in any event, although the possibility of a modification to the agent cannot be excluded”.

The examination of the Annex to the letter supports that. In paragraph 7.3 (**YB 90/07.24/3.9**) for example:

“There are some individuals who wish to have a guarantee of complete safety. For people who remain worried about the level of risk present in beef from the British Isles, foreign beef also may not be acceptable”.

That is far from saying that there is no risk.

138. SEAC did not quantify the risk in numbers because we could not do so with a useful degree of precision. SEAC recognised that there was a risk although that risk was described with different words on different occasions.
139. SEAC rested its advice on the SBO ban. SEAC believed what we were told about the SBO ban and we were told that it had been implemented. In the letter dated 24th July 1990 paragraph 6 (**YB 90/07.24/3.2**) sets out the cumulative effect of a number of factors. Factor (iv) was:

“those offals likely to contain the highest amounts of infective agent in any sub-clinical cases are removed from human consumption. This is now required by law”.

140. In the Annex, at Paragraph 4.2 (**YB 90/07.24/3.6**):

“Since 13th November 1999 in England and Wales... various bovine offals have been prohibited for human consumption...”.

141. In doing that, SEAC were drawing attention to the SBO ban.
142. SEAC gave advice, in 1990, on the basis of the information known then. If the members of SEAC had waited until wholly reliable data was available it would have been too late. SEAC thought it was appropriate and responsible to draw on the scrapie data, make assumptions where appropriate, draw inferences where appropriate and give advice. I believe each member personally thought that it was safe to eat beef at that time. Further, that SEAC took the view then, and now, that it would have been irresponsible to have declined to give advice.
143. If SEAC had waited until wholly reliable data were available that would have meant declining to give advice altogether. Advice had been sought on a matter within SEAC’S role and it was proper to give advice. The advice was thought out advice, albeit with the limitations known or expressed.

The uncertainties regarding pathogenicity to man once the scrapie agent had crossed the species barrier into cattle

144. In the letter dated 24th July 1990 SEAC members said, in Paragraph 2(iii) (YB 90/07.24/3.1):

“The origin appears to be scrapie-infected feedstuffs”.

SEAC was aware of the uncertainty about pathogenicity. In Paragraph 4 of the letter dated 24th July 1990 (YB 90/07.24/3.1) it said:

“...if BSE is exactly like scrapie, oral transmission (and any form of natural exposure) should not represent a hazard to man. Because the possibility that the agent might have changed cannot be dismissed, we agree that the measures that have already been taken in response to BSE in cattle are appropriate...”

145. Later, in the Annex, Paragraph 6 (YB 90/07.24/3.7) deals with the species barrier. In Paragraph 6.5 :

“The epidemiology strongly suggests that it was not a change in the pathogenicity of the scrapie agent that led to infection in cattle. However, changes, sometimes permanent, can occur as a result of passage through a different species and the agent to which humans are now exposed may behave differently from scrapie”.

146. It was this uncertainty which led SEAC to believe that BSE might have a different pathogenicity to scrapie for man. It could have been higher or lower. It was not known in 1990 that BSE differed from all known forms of scrapie. Although it was possible, it was not known that BSE would have a different pathogenicity to scrapie in man. In consequence, SEAC thought that the

legislative steps, which would protect public health, directly or indirectly, were important. The principal measures were the slaughter and compensation scheme, which was directed to removing sick animals from the food chain, and the SBO ban.

147. Now, in 1999, it is my understanding that the BSE strain in cattle is not biologically indistinguishable from nv CJD by current testing methods. The best hypothesis, in 1999, is that nv CJD is the same as BSE or closely related to it; that knowledge did not exist in 1990.
148. The discussions and decisions of SEAC in 1990 about the advice which they were asked to give took place with a limited amount of information about BSE. SEAC based its advice on the best available evidence. If we had advised the slaughter of all cattle in the United Kingdom or declined to say beef was safe to eat, SEAC members anticipated that we would have been asked to justify that advice by reference to the science. We did not believe we could.

The possibility that BSE might be derived from a mutant strain of scrapie with a different host range from strains of scrapie that had previously been discovered, studied and used in scientific experiments

149. The members of SEAC considered BSE to be a transmissible spongiform encephalopathy. The Annex to the letter addressed the issues, considered the evidence, including the possibility that the agent in cattle might be different from scrapie or had been mutated. Paragraph 2.2 of the annex said (YB 90/07.24/ 3.3):

“Having entered a new host, however, it is possible that certain strains have been preferentially selected”.

At that time, 1990, SEAC were conscious of the need to monitor the strains of scrapie and make comparisons with BSE to see if there was selection or mutation.

The possibility that BSE might be a previously unrecorded disease of cattle with its own peculiar properties distinct from scrapie, particularly as regards pathogenicity to man

150. The members of SEAC considered that if BSE was different to scrapie in any way it might have properties which were more hazardous to man and therefore some public health measures were appropriate. We knew that public health measures had been taken.

The experimental evidence indicating various differences had been identified between scrapie and BSE

151. The first experiment which positively identified the strain properties of the agent in infectious brain material from several field cases of BSE were not completed until 1992. The experiment which confirmed oral transmission of

BSE to sheep was only completed in November 1993. It was not knowledge which existed in 1990. The earlier experiment only gave pathological confirmation of the transmission of a TSE to sheep and did not prove that BSE had been transmitted.

152. The Annex sets out, at Paragraph 5.2 (**YB 90/07.24/3.7**), details of experimental studies with BSE. It said:

“In the transmission work with BSE, the incubation period in mice was longer after large oral doses of BSE-infected cattle brain than after much smaller parental injections.”

153. The literature references for those propositions were a paper by Fraser et al on The Transmission of Bovine Spongiform Encephalopathy to Mice published in the Veterinary Record in 1988 (**J/VR/123/472**) and a paper by Barlow et al on Dietary Transmission of Bovine Spongiform Encephalopathy to mice in the Veterinary Record of 1990 (**J/VR/126/111**).

Little was known in 1990 about BSE

154. The members of SEAC recognised that although relatively little was known about BSE there was a sufficient understanding of the related TSEs to allow SEAC to give advice. Not to have done so until sufficient knowledge specifically on BSE was available would, have been inappropriate. Section 7 of the annex to the letter dated 24th July 1990 (**YB 90/07.24/3.9**) addressed the risk assessment. The section concluded (paragraph 7.4) by saying:

“Our own judgement based on our assessment of the available scientific evidence is that the BSE risk, if there is one, is so slight that it can be ignored. We hope our scientific opinion will help others to make their own decisions, whether personal or national. This will depend on their viewpoint, the weight they give to our opinion and the view they take of what risks they are prepared to accept and what they are prepared to pay for. For our own part, and as we discussed with the Chief Medical Officer before he made his statement on the 16th May 1990, “there is no scientific justification for not eating British beef”...we have no hesitation in saying that beef can be eaten safely by everyone, both adults and children” (**YB 90/05.16/1.1**).

The members of SEAC knew that there were limitations to the knowledge about BSE. We do not believe that it would have been reasonable for us to have advised in 1990 that beef posed such a risk that, after the introduction of the SBO ban, the further measures being suggested by some, principally the slaughter of all cattle in the United Kingdom, were necessary measures to protect public health.

155. The measures that had been introduced, up to 1990, were taken on the assumption that the BSE agent might pose a greater risk to humans than scrapie. Those measures would have been effective regardless of the nature of infectious agent. Even if BSE was due to an agent in cattle different to scrapie

the measures would have been beneficial. Indeed, the measures taken would have been very effective in reducing the risk to the human population particularly if they had been fully implemented.

The efficiency of BSE transmissibility via the oral route

156. The transmission of Kuru does not mean that the oral route is efficient. It is likely that transmission occurred because of exposure to high titre tissue, that is brain tissue and no species barrier being present. The epidemiological character of Kuru, which affected predominantly women and children who ate a greater proportion of CNS tissues than men, suggests that exposure to high titre tissue is necessary for transmission. Efficiency is a relative term. The TME data simply shows that oral transmission can occur if mink are exposed to high infectivity tissue, like unprocessed brain, which is believed to have been the cause of rare outbreaks of TME.
157. Paragraph 5.1 of the Annex says (**YB 90/07.24/3.6**):

“The oral route is clearly capable of transmitting spongiform encephalopathies in the diseases of BSE and transmissible mink encephalopathy (TME) and it is assumed to be an important natural route of transmission in scrapie and kuru”.
158. Paragraph 5.2 (**YB 90/07.24/3.7**) goes on to say:

“Experimental studies, however, show ingestion to be very inefficient...”.
159. The oral transmission of BSE to mice showed that large doses of inoculum were sufficient. The inoculum was high titre brain tissue. As lower doses were not tested, the experiment could not show what dose was necessary to transmit infection. The experiment does not show that oral infection is as efficient as intra-cerebral infection.
160. Throughout the BSE epidemic, cases occurred in a pattern which suggested that the contamination of feed was uneven, in the form of infected “packets”. Therefore, many batches of cattle feed contained little or no infectivity and some batches contained packets of infectivity sufficient to cause oral transmission. However, the number of infected packets was low so that the consumption of a large amount of feed was necessary for there to be a significant risk that an individual animal would be infected. Even then, SEAC thought that most cattle fed concentrated rations before the introduction of the feed ban did not become infected. Furthermore, different tissues were thought likely to have differing levels of infectivity. Brain tissue was regarded as likely to have a high titre of infectivity and muscle tissue no infectivity. The members of SEAC thought that the likelihood was that BSE occurred because cattle feed was unevenly contaminated with high titre tissue like brain tissue. This was the hypothesis that best explained the epidemiological pattern of BSE cases. The members of SEAC believed that very large amounts (or doses) of feed were necessary for oral transmission to occur as often as it did.

161. 0.5 gm of brain tissue contained sufficient infectivity to cause oral transmission to some sheep. This finding is not inconsistent with the fact that one gram of brain tissue was sufficient to cause infection orally of some cattle. Neither finding contradicted the relative inefficiency of the oral route compared to intra cranial inoculation. Nor are there any contradictions between these findings and the observations of the BSE epidemic because cattle feeds did not consist solely of unprocessed brain from confirmed clinical cases. It should be noted that the attack rate study was not started until January 1992 (**YB 92/01.15/1.1-1.2**) and it was not known that oral transmission of BSE to sheep had been caused until November 1993.

Feline SE

162. The minute of the meeting on 13th June 1990 reads (**YB 90/06.13/1.1-1.5 at 1.2**):

“(a) Cats

7. the Committee considered the question of possible human health implications in the recent discovery of a spongiform encephalopathy in three cats, noting that specialists at Bristol believed this to be a new condition rather than one that had hitherto not been recognised... The Committee was in no position to offer advice on the implications for human health until more was known about the condition”.

163. The occurrence of FSE did not (necessarily) imply anything regarding the risks to humans. The minute is intended to reflect the concerns of SEAC members about:

- (i) the origin of FSE;
- (ii) possible numbers of future cases; and
- (iii) by what routes infection might be transmitted from cats to humans.

Of course, FSE had implications in relation to the general uncertainty about risks from BSE for humans. That was reflected in the Annex to the letter dated 24th July 1990 (**YB 90/07.24/3.1-3.12**).

The SBO ban

164. The value of the SBO ban was recognised both in the letter dated 24th July 1990 and in the Annex (**YB 90/07.24/3.1-3.12**).
165. It is accurate to say that the danger from sub-clinical animals is less than from clinically affected animals. That is a scientifically justifiable statement made by scientists in a scientific statement for the benefit principally for scientifically qualified recipients, namely the advisors on the staff of MAFF and DH. The increased risk as an animal nears the point where it is clinically affected with a TSE arises particularly from the infectivity in the central nervous system which increases progressively with time after infection and, ultimately, is higher there than anywhere else in the body.

166. The importance of the SBO ban was emphasised to the recipients at MAFF and DH, e.g Paragraph 6(iv) of the letter dated 24th July 1990 (YB 90/07.24/3.2).
167. In 1990 SEAC believed that the SBO ban was in place and was being enforced. I know of no evidence in 1990 that the SBO ban was not being enforced.
168. In any event, the first part of (iv) says:

“those offals likely to contain the highest amounts of infected agent”.

That is not an expression of factual certainty; within its own terms it is an expression of likelihood. The provision then goes on to say that removal of offals is required by law. As a factual statement, that was correct. The SBO ban did have that effect. It was not SEAC’s role at the time to ask the question – Is the law being enforced? We took it that the law was being enforced. We were not there to police the regulations.

169. SEAC believed that there was a risk and we did attempt to communicate the message that science was not absolute. It should be borne in mind that the principal recipients of the advice were an informed audience.

1991

Article appearing in Food Microbiology, Lacey & Dealer, 30.8.90 (J/FM/7/253)

170. At its seventh meeting on 7th March 1991 (YB 91/03.07/2.1-2.9) SEAC considered this article. This article did not provide the members of SEAC with new information nor raise any issues of which we were unaware and, consequently, there was no reason for SEAC to reconsider matters. The minute reads:

“The Committee did not want to be involved in a response”.
(Paragraph 21 of the minutes (YB 91/03.07/2.8))

1992/1993

The occurrence of CJD in a farmer

171. The occurrence of CJD in a dairy farmer was first mentioned at a SEAC meeting on 15th October 1992 (YB 92/10.15/2.1-2.8 at 2.4). The minute reads:

“F. Cattle farmer with CJD

8. Dr Will reported that a cattle farmer, one of whose animals had been a confirmed BSE case in 1989, had developed CJD two years later and had died 3 months’ after that. It was intended to publish a report of the study, which would probably draw the conclusion that there was no evidence that this was not a chance occurrence of normal disease. He

went on to report that an analysis of the occupational backgrounds of CJD cases in his study revealed no trend”.

172. SEAC considered the occurrence of CJD in a farmer again at its meeting on 22nd April 1993 (YB 93/04.22/2.1-2.8 at 2.2). The minute of that meeting records:

“Creutzfeldt-Jakob disease

5. Dr Will expressed disappointment over the breach of patient confidentiality in media coverage of the case of CJD in a cattle farmer. There were no other confirmed CJD cases related to farmers but one farmer’s wife was alive with suspect CJD. There had been no cases of BSE on the farm and the wife had not handled the animals. Dr Will was also aware of a case of CJD in a Belgian farmer but Belgium had of course no confirmed cases of BSE. He went on to report that the CJD study continued to show no link with occupation or diet. Although 1992 had seen the highest number of CJD cases, the increase was not significant and probably just reflected increased ascertainment”

I. ADVICE ON INFECTIVITY IN DISTAL ILEUM OF CALVES

173. SEAC members were asked to attend an emergency meeting of SEAC on 25th June 1994 (YB 94/06.25/4.1-4.5) to discuss the discovery of infectivity in the lower small intestine (distal ileum) including the lymphoid tissue of a 10 month old calf which was part of the pathogenesis experiment.

174. The meeting of SEAC members on 25th June 1994 led to a note which stated (paragraph 14(a)) (YB 94/06.25/4.4) stated.

“The Committee considered that the theoretical risk of infection of man via food derived from infected calves is minuscule if it occurs at all but information on calves is still very limited and as the experiment is still in progress and further information is expected, it will be necessary to monitor the results carefully to see if this basic conclusion is correct and to see whether further action is needed.”

175. At the meeting on 25th June 1994 (YB 94/06.25/4.1-4.5) SEAC members present had received information about a single case in an experiment and the true significance of that case was not then understood. We acknowledged in the written record that a definitive answer to the questions posed of us in relation to amending the SBO ban could not be given, that there was a theoretical risk, and that the Government could extend the SBO ban. We asked for the situation to be carefully monitored. It was against that background, which was known or should have been known to the recipients of the advice, that we said no further action was necessary on the basis of the scientific evidence.

176. In the event, the issue was considered at the seventeenth meeting of SEAC on 30th August 1994 (**YB 94/08.30/2.1-2.15**) when amendments were made to the note of the meeting on 25th June 1994 (**YB 94/06.25/4.1-4.5**). At that meeting Dr M McGovern, a Department of Health observer, is recorded in paragraph 8 the minutes of the 30th August 1994 Meeting as explaining:

“Dr McGovern explained that the Government’s decision in this case was taken not on scientific grounds alone, but in a wider context”.

The members of SEAC understood that to mean that the policy decisions to be taken by the Government took into account matters other than those which were within the remit of SEAC.

J. ADVICE TO MAFF/DH ON RISKS FROM MUTANT SCRAPIE OR TRANSMISSION OF BSE TO SHEEP

177. At the fifth meeting of SEAC members on 19th September 1990 (**YB 90/09.19/2.1-2.5**) the minutes show:

“F. Scrapie

17. Mr Bradley tabled document RB238, providing a preliminary account of an investigation of possible changes in the neuropathology of sheep with scrapie. The work suggested that if there were any abnormalities appearing in scrapie lesions in the field, they were very rare, and that the neuropathology of field scrapie was very different from that of animals infected with BSE with the notable exception of only one animal to date. The Chairman requested that some thought be given to a study of neuropathology (sic) material to see if it could produce a classification breakdown of the BSE agent.

18. Professor Barlow and Mr Bradley were asked to produce a paper for the next meeting summarising the evidence relating to possible changes in the agent and its recycling through different species. This might lead to a study reviewing the neuropathological findings”.

178. Mr Bradley was present at that meeting as an observer from MAFF.

179. At the sixth meeting of SEAC members on 1st November 1990 (**YB 90/11.01/7.1-7.9 at 7.8**) the minute shows:

“G. Changes in the Scrapie Agent

18. The Committee considered Professor Barlow’s paper. This mainly reflected the fact that data simply were not available on which to draw clear conclusions. The current requirement was for general indications of developments rather than for highly detailed data. The paper’s proposals for information gathering would conflict with the much higher priority task of securing enough sheeps’ brains for inactivation

studies. For the time being at least the best approach might be to consider ways of improving the ad-hoc provision of information about possible changes in the agent”.

180. SEAC members recognised the possibility of a mutant strain of scrapie, which might have a different host range, might be or become pathogenic to man and which might become endemic in sheep.
181. The preliminary attempt to identify new strains of scrapie by the study of pathology in sheep did not support the idea that a common variant was present. However, SEAC members knew that the techniques for identifying different strains of scrapie with different properties in sheep were not as well developed as they had been in mice. Therefore the best approach to looking for a new strain that was BSE in sheep was, first, to identify the properties of different sources of BSE after transmission to mice. The second stage was then to show that BSE agent which had been transmitted from cattle to sheep could still be identified after transmission to mice. These studies were completed in 1993.
182. However, no explanation has yet been given as to how the researcher would identify whether it was BSE which had been returned to sheep, rather than the source of BSE.
183. There was no clinical evidence of BSE in sheep between 1990 and March 1996.

K. SEAC INVOLVEMENT IN SBO BAN FOR ANIMALS

184. Advice was not sought from SEAC on extending the specified bovine offal ban to animal feedstuffs until June 1990, and the topic was considered in September 1990.
185. MAFF prepared a paper for SEAC and a preliminary meeting of SEAC took place on 7th September 1990 (**YB 90/09.07/1.1-1.4**). Not all members were present. In the minutes of the meeting on 19th September 1990 (**YB 90/09.19/2.1-2.5**) the following is recorded:

“11. The Committee approved a report from the preliminary meeting held on 7th September (**YB 90/09.07/1.1-1.4**) (SEAC 5/1 (**SEAC 5 Tab 1**) Revised as amended) and an opinion to be conveyed to the MAFF and Department of Health (SEAC 5/7 (**SEAC 5 Tab 7**), as amended)”.
186. In consequence SEAC recommended that the SBOs should be excluded from animal feed.
187. It was the rapid increase in the BSE epidemic, the occurrence of more cases of FSE and the results of the pig transmission experiment which led SEAC to give the advice we did on the extension of the SBO ban. Before then (September 1990), we were not asked to advise on the extension of the SBO ban.

188. It was important to consider humans before other animals. It should be remembered that prior to the results of the pig transmission experiment, pigs and poultry were not known to be susceptible to TSEs. Breeding pigs, in particular, were thought to have received a very high exposure to the same type of contaminated MBM as cattle but without any evidence of the occurrence of TSE. The issue of symptom-less hosts was considered very carefully because it could apply to all domestic and farmed animal species.

L. TRANSMISSION STUDIES ON MARMOSETS

189. At an informal meeting on 27th February 1992 Dr Ridley and Mr Wells described to some of the SEAC members, including me, the results of the work on four marmosets, two of which had been inoculated with scrapie, and two with BSE (**YB 92/02.27/3.1-3.5**). Dr Ridley's conclusion, recorded at paragraph 4 in the minute was:

“There was no doubt that scrapie and BSE had been transmitted to marmosets. Although the small number of animals involved made it difficult to draw conclusions, the separation between incubation periods were striking, as illustrated by the diagram... The Committee agreed that while this might be significant, it was not possible to draw firm conclusions” (**YB 92/02.27/3.2**).

190. Paragraph 7 of the minutes records:

“They (meaning the members of SEAC) noted the MRC's intention to wind down the use of marmosets in the field of SE's and their view that the way forward was to develop transgenic models. The Committee would want to reflect upon this further” (**YB 92/02.27/3.3**).

191. Paragraph 6 of the minutes was the adoption of Annex II. Annex II said:

“3. Although marmosets have not previously been infected with BSE, they have been infected with SE's including scrapie using similar methods so the results of this experiment are not surprising” (**YB 92/02.27/3.5**).

192. The findings were expected given what was already known.

193. The matter was considered at the twelfth meeting of SEAC on 28th April 1992 (**YB 92/04.28/2.1-2.8**) which was attended by myself and others. The relevant minute (**YB 92/04.28/2.2**) reads:

“D. Meeting on marmosets

5. The Committee noted the report of the informal meeting on 27th February. There had been some criticisms that the work had been unnecessary but the responses already published had been adequate”.

194. Oral transmission with brain homogenate had been established in other species. Demonstrating oral transmission in marmosets would not have been a surprise because I, and other members of SEAC, thought it could probably be done in the light of our other knowledge. It is worth noting that with (i) the reduced possibility of transmission because BSE was given orally; and, (ii) the incubation period shown for the intra-cerebral inoculation, the experiment could take years to produce a result. Furthermore, the value of any such studies in assessing the risks of BSE in humans was considered dubious because, although humans and marmosets are both species of primates, they could not be regarded as having the same susceptibility to BSE, any more than mice and hamsters can. Studies with transgenic mice containing the human PrP gene offered a better way forward.

M. SEAC ADVICE ON BREEDING OFFSPRING OF BSE INFECTED CATTLE.

195. The issue of breeding from the offspring of BSE infected cattle was considered by Ministers and officials prior to the first meeting of SEAC on 1st May 1990 (YB 90/05.01/2.1-2.4) and a paper was prepared by MAFF officials in early 1990. Prior to the creation of SEAC it appears that on 14th March 1990 (YB 90/03.14/3.1) Ministers considered that the advice of the Tyrrell Committee should be sought. At that point, the former Consultative Committee was not meeting and SEAC had yet to have its first meeting.
196. At the first meeting of SEAC on 1st May 1990, papers prepared by MAFF officials on transmission and epidemiology and cattle to cattle transmission were dealt with in a specific minute of that meeting (YB 90/05.01/2.4). Item 4 of the minutes reads:

“The Committee had several reservations about the line proposed by MAFF concerning advice against the use for breeding of animals which were offspring of BSE cows. There was thought to be a bias against such breeding in any case. The incidence of sub-clinical infection invalidated any action proposed. Any advice against breeding from BSE offspring might imply breeding from other cows was acceptable, and yet this was not necessarily the case since these animals could have silent infection. The evidence with natural scrapie suggested there was no association with birth order, so even young cows might be capable of passing infection on to offspring. With the proposed measures, there would be incentives to cheat, perhaps even leading to an increase in infection as farmers offload suspect animals, with difficulties in buying in replacement cows at appropriate ages. There could be disposal of certain useful genes if BSE-offspring were not used for breeding. It was possible infectious but resistant genotypes would be selected, leading to further problems. The effect on the public and the meat trade was thought important: if all these offspring could be properly identified then there would be difficulty in finding buyers for them, but if not properly identified there would be presentational difficulties and little chance such measures would have any effect. In view of the expected elimination of the disease

eventually in any case (barring horizontal transmission), at best new measures might be able to accelerate this slightly. At worst, new measures could conceivably make the epidemic worse, although minimal effect was most likely. Introduction of new measures now would lead to suspicion of something unpleasant being concealed.

Proper modelling would be very valuable in formulating advice here and the Committee reiterated how important it was this was undertaken.

Whilst not persuaded that the BVA's advice should be endorsed, for all the above reasons, the Committee supported obtaining more accurate breeding records and noted MAFF's intention of strengthening the legislation in this area".

197. The matter was considered at the emergency meeting of SEAC on 17th May 1990 (**YB 90/05.17/1.1-1.4**). The minutes show that the first item on the agenda was a request to SEAC to amplify the advice given previously on breeding which was the advice set out in the minute reproduced earlier.
198. At the meeting of SEAC on 13th June 1990 (**YB 90/06.13/1.1-1.5**) the members of SEAC considered a paper labelled 3/2 (**SEAC 3 Tab 2**) in detail together with an alternative draft. No agreement was reached at that meeting.
199. The matter was considered again by the members of the Committee at the meeting on 2nd July 1990 (**YB 90/07.02/3.1-3.4**) and finally approved on 19th September 1990 (**YB 90/09.19/2.1-2.5**). The approved document made it plain what the considerations were which led to the conclusion that they:

“could not advise the Government to take measures to limit the use of offspring of cattle suffering from BSE from breeding”. (**SEAC 4 Tab 1, para 13**).
200. Further:

“Such measures would either not be necessary, or not be adequate, as a national control policy for dealing with BSE” (**SEAC 4 Tab1, para 13**).
201. It was in the context of careful reasoning, set out in a written document, that the members of SEAC gave their advice that

“Nevertheless, individual farmers might well find such measures appropriate. Farmers who knew that their animals had never been given feed containing meat and bone meal, for example, would no doubt want to avoid buying in breeding replacements from a herd where BSE had occurred. Some farmers might choose to fatten the offspring of BSE cattle rather than to breed from them but such decisions would depend on the farming practices of the individuals and the advice of their veterinary surgeons” (**SEAC 4 Tab 1, para 13**).

202. In the Annex to the letter dated 24th June 1990 (YB 90/07.24/3.1-3.12) the members of SEAC said:

“There is no scientific evidence currently available to support official advice against the use for breeding of the offspring of cows suffering from BSE, even if infection can pass down from calf to calf, a possibility that cannot be excluded at present”.

203. That statement is heavily qualified. First, it makes it plain that it is given on the basis of the scientific evidence then available. Secondly, it accepts the possibility that infection could pass from cow to calf.

204. The Annex went on to say:

“Because the likely origin of the epidemic has been eliminated, the outbreak in cattle will be self-limiting unless infection can be spread freely between cattle – in which case restricting breeding would be pointless. So at best, restricting the use of the offspring of BSE cattle would accelerate the decline that was likely in any case. Because of the possibility that sub-clinically infected animals might infect their offspring, not all potentially infected calves might be identified, which would reduce any benefit. Other possible consequences might even be unhelpful, since it could lead to the increased dispersal of infected animals to other herds, and to the loss of valuable genetic material. We support MAFF’s intention to impose more stringent requirements to secure better records of cattle, their offspring and their movements. In any case, vertical transmission, if this is found to occur, would make no different to the remoteness of the hazards for humans. This viewpoint may need to be revised in the light of new scientific information”.

205. Maternal transmission of BSE had not been established. However, the statement of SEAC accepted the possibility that restricting the use of offspring of BSE would accelerate the decline of the epidemic.

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Dr D.A.J. Tyrrell

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