4. The Southwood Working Party and other scientific advisory committees

The Southwood Working Party

248 The Southwood Working Party24 consisted of Sir Richard Southwood, Professor of Zoology at Oxford University; Professor Anthony Epstein FRS,25 a virologist; Professor Sir John Walton,26 a neurologist; and Dr William Martin, a veterinarian who had just retired from the Directorship of the Moredun Research Institute in Edinburgh. Sir Richard emphasised to us that they were not experts in the narrow sense of having particular expertise in TSEs. Each was, however, a scientist of the highest standing in his field and together they were well placed to consider the available data and to give a considered view as to what implications these suggested that BSE might have for human health.

249 This was precisely the task that Sir Donald Acheson wanted the Working Party to perform. When writing to Sir Richard on 8 April 1988, he suggested a first meeting of the group as soon as possible, a small number of additional meetings at the end of the summer and ‘a very brief note with recommendations’. In the event a substantial report was delivered in February 1989. The Working Party’s wide terms of reference were:

To advise on the implications of Bovine Spongiform Encephalopathy and matters relating thereto.

250 The Report addressed both human and animal health. The original reason for this had been to ‘play down the human health issue’. Sir Richard had, however, been anxious from the outset to have broad terms of reference and he had also been determined that the Report should be published. Happily the breadth of the terms of reference did not inhibit MAFF officials from recommending, before the Working Party had been fully constituted, that a ruminant feed ban should be introduced.

251 The Working Party were served by a joint secretariat, consisting of Mr Alan Lawrence, an official in MAFF’s Animal Health Division who was given special responsibility for BSE, and Dr Hilary Pickles, a Principal Medical Officer whom Sir Donald Acheson appointed to take the lead in DH in relation to BSE.

252 Although the Working Party took longer than had been hoped to produce a Report, they lost no time in making important interim recommendations. They had asked what happened to material from affected animals and been told that these animals would usually go to be slaughtered for human food, in the same way as healthy animals. They told us that they were horrified by this and felt it was their

24 Who are the subject of Volume 4 of this Report
25 Now Sir Anthony Epstein
26 Now Lord Walton
job to stop it happening immediately. In consequence, after their first meeting on 20 June 1988, Sir Richard wrote to Mr Andrews recommending that carcasses of clinically affected animals be destroyed by incineration or a comparable method. The removal of the head was not an adequate safeguard as that was not the only source of infection. This recommendation was accepted and implemented. The measure proved of crucial importance in protecting humans, and also animals, from the risk of infection with BSE. The Working Party are to be commended for their prompt and decisive action.

253 The Working Party made further immediate recommendations: that an expert working party should be set up to advise on the research in hand and the research required in relation to BSE; that priority should be given to a study to see whether BSE transmitted from cow to calf; and that tests be carried out to see whether scrapie could be transmitted to cattle. This was further wise advice promptly given. It led to the setting up of the Tyrrell Committee on research.

254 The Working Party were not to meet again until November. In the meantime, the two secretaries, and Mr Wilesmith, who had been asked to act as expert adviser to the Working Party, set about drafting sections of the Report.

255 The second meeting of the Southwood Working Party on 10 November 1988 led to interim recommendations that the ruminant feed ban, which was due to expire at the end of the year, be extended indefinitely, and that milk from cows affected with BSE be destroyed. Dr Richard Kimberlin, who had retired from being Acting Director of the Neuropathogenesis Unit (NPU), Edinburgh, to run his own consultancy in TSEs, attended this meeting. Experiments at the NPU had recently demonstrated that BSE could be transmitted to mice, and there was discussion about the likelihood of transmission from cow to calf. There was also discussion about whether it was safe to eat ox brain. The Working Party decided that it would not be appropriate to ban the eating of UK ox brain but that it was worth consideration whether products containing brain should be required to be labelled, leaving the consumer to make his or her own choice. The Working Party subsequently dropped the idea of labelling as they were informed that this would involve complications under European law.

256 It was agreed at the second meeting that those responsible for occupational health and for the safety of medicines should have their attention drawn to the need to address potential risks posed by BSE. Again, the Working Party are to be commended for taking action to safeguard human health in advance of delivering their Report. We shall consider the response to their action when we come to consider the topics in question.

257 The Working Party met again on 16 December and had a final meeting on 3 February 1989. The contents of their Report were considered in detail on both occasions, and we shall now consider these.

**Epidemiology**

258 The first eight pages of the Report consisted of a history of BSE and an account of what was known about TSEs. These were largely written by Mr Wilesmith, Mr Lawrence and Dr Pickles, the latter topic being a summary of a substantial
number of published papers, with which members of the Working Party would have made themselves familiar. There then followed a chapter on ‘the cause of BSE: the epidemiological evidence’. This had been written by Mr Wilesmith. It set out the tentative conclusions that we have detailed in the previous chapter, including the following:

- the epidemiology was typical of an extended common source epidemic;
- all affected animals appeared to be index cases;
- the common feature was the use of commercial concentrates in feed;
- a possible explanation for the emergence of BSE was a change in the exposure of cattle to ovine-derived protein and the scrapie agent due to
  i. more scrapie-infected material going to be rendered;
  ii. changes in the rendering processes.

259 A subsequent chapter, also written by Mr Wilesmith, dealt with ‘the Future Course of the Disease’. This stated that the effect of recycling of BSE was impossible to quantify and possibly minimal and undetectable, in which case a constant incidence of 350–400 cases a month could be expected. The possibility of maternal transmission was recognised, but it was observed that this would be unlikely to sustain BSE in the national cattle population.

260 The Working Party did not see it as their role to conduct a critical review of Mr Wilesmith’s conclusions. We do not suggest that they should have done. The Report did nothing, however, to dispel the impression that the conclusions in question had been reached, or endorsed, by the members of the Working Party. In a covering letter to Ministers, published with the Report, the Working Party thanked Mr Wilesmith and others for their assistance and added, ‘The Report, however, remains our own.’ We think that the Working Party should have made it plain that the section of the Report dealing with epidemiology had been provided by Mr Wilesmith and was based on data which they had not been able to review. In the event their Report added weight to a number of epidemiological conclusions which subsequently proved to be fallacious, the most significant being that the cases of BSE were index cases of cattle infected with scrapie. It was this theory which gave so many the false reassurance that it was very unlikely that BSE was transmissible to humans.

**Risk to humans**

261 In the most important part of their Report, the Working Party set out their views on the possibility that BSE might be transmissible to humans. These were, in summary:

- Humans were susceptible to spongiform encephalopathies.
- Neural and, to a lesser extent, lymphoid tissue carried the infection, while the risk was far less with other tissues.
- Parenteral inoculation was more efficient in transmitting disease than oral or topical exposure.
The greatest risk in theory would be from parenteral injection of material derived from bovine brain or lymphoid tissue.

Medicinal products for injection or surgical implantation using bovine tissues might be capable of transmitting infectious agents.

Direct inoculation of bovine tissue could arise accidentally in certain occupations.

In these and in other circumstances the risk of transmission of BSE to humans appeared remote.

The Working Party commented that because the risk of transmission of BSE to humans could not be entirely ruled out, action had been taken to remove known affected cattle from the human food chain. The Medicines Licensing Authority had been alerted to potential concern about BSE in medicinal products and would ensure that scrutiny of source materials and manufacturing processes now took account of the BSE agent. The Health and Safety Executive had also been alerted to potential concern about BSE.

The Working Party had this to say about possible risks from eating animals incubating BSE but not yet showing clinical signs:

It has been suggested, although clinically affected animals are being slaughtered and destroyed, that consideration should be given to products containing brain and spleen being so labelled, to enable the consumer to make an informed choice. The Working Party believes that risks as at present perceived would not justify this measure.

They went on to state, however:

We consider that manufacturers of baby foods should avoid the use of ruminant offal and thymus.

We shall from now on describe this piece of advice as ‘the baby food recommendation’.

There were a number of matters which the Working Party did not explain in their Report:

- What did they mean when they said that the risk of transmission of BSE to humans appeared ‘remote’?
- Why did they consider that the risk appeared remote?
- Why did they recommend that affected cattle should be slaughtered and destroyed?
- Why did they make the baby food recommendation?
- Why did they not recommend any other precautions to protect human food from subclinically infected animals?

All these matters we raised with the members of the Working Party.
They explained that they intended the word ‘remote’ to bear the meaning that this word has when used to describe a risk in a medical context. In that context a remote risk is one that is highly unlikely to prove significant, but which it is unreasonable to ignore. Reasonable precautions should be taken to try to prevent a remote risk. The Working Party set out to advise what those precautions should be. They told us that in doing so:

Our approach to risk was in accord with the then developing application of analysis to public risk which involved the balancing of the perceived magnitude of the risk against the practicability or achievability of successive steps for its reduction. The magnitude of a risk comprises both its likelihood and the scale of the danger.

This approach is sometimes known as ALARP (As Low As Reasonably Practicable). It requires an exercise in proportionality. When deciding whether a precaution is ‘reasonably practicable’ it is necessary to weigh the cost and consequences of introducing the precaution against the risk which the precaution is intended to obviate.

Why was the risk considered remote? Our reading of the Report led us to conclude that the Working Party had drawn comfort from the way that scrapie behaves. Sheep infected with scrapie have been slaughtered for human food for hundreds of years, without doing any harm. If BSE was the scrapie agent in cattle, it was likely that it would behave in the same way.

The Working Party confirmed to us that this was indeed their reasoning. But they emphasised that they did not assume that BSE would behave like scrapie. They recognised the possibility that, whether or not scrapie was the source of the infection, BSE in cattle might behave more virulently than scrapie in sheep. Because of this possibility, reasonable precautions needed to be taken against the possible risk from eating BSE-infected meat.

The Working Party concluded that reasonable precautions against the risk from eating BSE-infected meat involved taking sick animals out of the food chain, but that no precautions were needed in respect of subclinically infected animals, other than the baby food recommendation.

We have a number of criticisms to make of this part of the Working Party’s Report. In the first place they did not make it clear that, in describing the risk as remote, they were intending to indicate that steps should be taken to reduce the risk as low as reasonably practicable. We think that they should have done.

In the second place, we do not consider that the Working Party correctly applied the ALARP principle. Animals with BSE that had developed clinical signs of the disease were to be slaughtered and destroyed. No steps were to be taken, however, to protect anyone other than babies from the risk of eating potentially infective parts of animals infected with BSE but not yet showing signs. It is true that infectivity of the most infective tissues – the brain and spinal cord – rises significantly shortly before clinical signs begin to show. It is also true that there were reasons to think that babies might be more susceptible to infection than adults. But we do not consider that these differences justified an approach that treated the
risk from eating brain or spinal cord from an animal incubating BSE as one in respect of which there were no reasonably practical precautions that need be taken.

274 We believe that part of the Working Party’s problem was that they were in no position to reach an informed view of how the ALARP principle should apply. They were not aware of the practice of mechanical recovery of meat, which sucked from the spinal column the residue left attached after removal of meat – a residue likely to include portions of spinal cord. Nor, so we believe, did they have in mind that it was reasonably practicable to identify and remove the potentially infective tissues in the course of the slaughterhouse processes.

275 In these circumstances, we do not criticise the Working Party for failing to recommend the precautionary measure that MAFF was subsequently to put in place – the SBO ban. What we feel they should have done was to point out that cattle subclinically infected with BSE were entering the human food chain, that some tissues of such cattle were potentially infective, and that consideration should be given to identifying such steps as were reasonably practicable to prevent their being eaten, not just by babies, but by everyone.

276 There is a further aspect of the way the Southwood Report dealt with risk that caused us concern. The Working Party said of the risk of transmission of BSE through the use of medicinal products:

> Although the risks appear remote the Working Party recommended that the attention of the Licensing Authority, the Committee on Safety of Medicines, the Committee on Dental and Surgical Materials and the Veterinary Products Committee be drawn to the emergence of BSE so that they can take appropriate action.

277 The Working Party told us that they had described these risks as remote only because of the action that they had been assured was being taken to address them. They had initially considered that some medicinal products sourced from bovine materials, which were injected, might carry a relatively high risk of transmission. With the assistance of Dr Pickles they had taken all proper steps to get those responsible for the safety of medicines to start taking action to address this risk. They had intended to include in their Report details of some of the steps that could be considered to prevent the BSE agent entering into pharmaceutical manufacture. However, as we describe in paragraphs 901–906 below, in response to concerns expressed by officials responsible for medicines licensing, they had been persuaded to tone down their Report and make no mention of these by the assurance that action was being taken.

278 The action taken by the Working Party, assisted by Dr Pickles, to galvanise those responsible for the safety of medicines was praiseworthy. The Working Party told us that they were anxious to avoid raising, by their Report, concerns about the safety of vaccines that would lead to a vaccine scare which could result in children being exposed to much greater risk than that posed by BSE. We sympathise with their anxiety. It led, however, to their Report giving the reader a false impression of their assessment of the risk relating to medicinal products. The Working Party should not have allowed this. They could have avoided doing so, without creating a vaccine scare, simply by saying that they had had concerns about the implications that BSE might have for certain medicinal products and had referred those concerns
to the Committee on Safety of Medicines and the Veterinary Products Committee, which had undertaken to address them. Unfortunately, the wording of the Report was to give some who were responsible for dealing with medicinal products, both human and veterinary, the impression that these would involve no more than a remote risk, even if no remedial measures were taken.

279 Similarly, the sections of the Report that dealt with occupational safety gave the impression that occupational risks were remote whether or not steps were taken to address them. The Working Party had commendably taken steps before publication of their Report to ensure that occupational risks were addressed. Dr Pickles had written to, and met with, the Health and Safety Executive (HSE) on their behalf. Their Report recommended that the HSE consider whether further guidance should be given. However, it seemed to us that the effect of this recommendation was likely to be uncertain, given the indications in the body of the Report that the risk was remote and that no specific additional guidance on BSE was thought necessary. As with medicines, we consider that the Working Party should not have used words that conveyed the impression that the risks were, even in the absence of precautionary measures, remote.

280 By the time that the Working Party came to finalise their Report, their interim recommendation that an expert committee be set up to advise on research had been implemented. The Tyrrell Committee had been established. In their Report the Working Party drew attention to a number of areas where research was needed for further consideration by that Committee. They also recommended the monitoring of CJD cases, since any human cases of BSE would probably present as CJD. The achievement of the CJD Surveillance Unit in identifying in 1996 the emergence of variant CJD demonstrated the wisdom of this recommendation.

281 The draft of the Working Party’s Report had a sting in its tail. It referred to the fact that BSE had resulted from the practice of feeding animal protein to herbivores, and noted that this practice opened up new pathways for infection. It continued:

We believe that the inevitable risks are such that it would be prudent to change agricultural practice so as to eliminate these novel pathways for pathogens.

282 When MAFF officials learned that this was to be included in the Report they were horrified, as they read it as an attack on the practice of incorporating MBM in animal feed. Animal Health Division commented to the Permanent Secretary that the rendering industry processed over 100,000 tonnes of raw material every month, thus providing a source of animal feed and industrial raw material, and also a ‘waste disposal’ service for the slaughtering industry. A paper setting out those implications was quickly prepared and sent to the Working Party. Dr Martin also wrote to Sir Richard, urging restraint on this topic. Restraint there was, for an amendment was made to the draft which was intended to make clear something that Sir Richard later confirmed. The Working Party was not recommending that the practice of rendering animal protein should cease, but that its continuance should depend upon finding a rendering process capable of destroying all pathogens.

283 We have criticised some aspects of the Southwood Report, but those criticisms should not obscure the vital benefit that the Working Party provided in putting an immediate stop to the practice of eating BSE-diseased animals, in bringing
immediate pressure to bear on those responsible for the safety of human medicines and occupational health to address the risks posed by BSE, and in giving wise advice about research. When the Report was published, it was generally well received by those who were expert in the field. Nonetheless a number of experts raised, at the time, the question of the risk posed by subclinical animals, and many more, when giving evidence to us, claimed to have identified the need to address this problem at the time. Pressure to do so was soon to build up and lead to the decision to introduce the SBO ban.

284 The Working Party’s risk assessment had, necessarily, been based on very limited data. In August 1988 Sir Richard, replying to a medical correspondent, wrote:

My colleagues and I have made various recommendations based, I have to admit, largely on guesswork and drawing parallels from the existing knowledge of scrapie and CJD.

In a summary section of their Report, the Working Party wrote:

Our deliberations have been limited by the paucity of the available evidence. Further research work in this area is essential.

In their General Conclusions, after observing that it was most unlikely that BSE would have any implications for human health, the Working Party added this warning:

Nevertheless, if our assessment of these likelihoods are incorrect, the implications would be extremely serious.

285 Unfortunately, this warning and the tentative nature of the Working Party’s conclusions were not appreciated or were lost sight of. Right up to 1996 the Southwood Report was cited as if it demonstrated as a matter of scientific certainty, rather than provisional opinion, that any risk to humans from BSE was remote.

Other scientific advisory committees

The Consultative Committee on Research into SEs (The Tyrrell Committee)27

286 One of the first recommendations to be made by the Southwood Working Party in June 1988 was that an expert Consultative Committee on research should be set up. In February 1989 it was announced that, following this recommendation, a Consultative Committee had been set up, chaired by Dr David Tyrrell.28 The other members were Dr Watson,29 Professor John Bourne,30 Dr Robert Will,31 and Dr Richard Kimberlin.32 The terms of reference were:

27 Detailed consideration of the work of The Tyrrell Committee appears in vol. 11: Scientists After Southwood
28 A microbiologist who was Director of the MRC Common Cold Unit
29 Director of the Central Veterinary Laboratory
30 Director of the Institute for Animal Health
31 Consultant Neurologist at the Western General Hospital Edinburgh
32 Ex-Acting Director of the NPU, who had retired to set up an independent consultancy, advising on TSEs
To advise the Ministry of Agriculture, Fisheries and Food and Department of Health on research on transmissible spongiform encephalopathies including:

(a) work already in progress or proposed;

(b) any additional work required;

(c) priorities for future relevant research.

In the context of these terms of reference, transmissible spongiform encephalopathies include those affecting both domestic and wild ruminants and man.

287 The Committee moved fast. After three meetings it presented an ‘Interim Report’ to the Government on 10 June 1989. This identified a number of research questions that needed to be answered about BSE under the headings: epidemiology, pathology and molecular studies. Research studies needed to answer these questions were identified and graded with three stars for highest priority, two stars for medium priority and one star for low priority. We consider the adequacy of the research carried out into BSE in Chapter 12 below.

288 In commenting on the research questions, the Committee observed:

We need to be sure that the disease really came from sheep and to know whether it is likely to establish itself long-term in bovines.

289 In their conclusions the Committee stressed that more research was needed:

If the preliminary studies and arguments-by-analogy used to determine our present control policies turn out to be incorrect, it will be essential to have well-documented facts available so that current policies can be effectively revised.

290 The Report was produced in haste as an interim one because the Committee was anxious that there should be no delay in seeking provision of resources for essential research and getting the projects under way. The Committee emphasised the importance of having the projects peer-reviewed and suggested that:

A standard mechanism may be needed to oversee this co-operation and co-ordination beyond the lifetime of our Committee.

291 The Committee asked for guidance as to whether they were expected to have a continuing role in peer review and project coordination.

292 Mr Gummer decided that the Government should respond to the Tyrrell Report by initiating all research projects falling within the top two of the Tyrrell Committee’s priority categories, and Mr Roger Freeman, Parliamentary Under-Secretary at DH, conveyed to him his Department’s agreement with this response. Delay then occurred in ensuring that the necessary funding was in place. This was not achieved until January 1990, when the Government published the Report and announced that work was in hand to implement the projects recommended by the
Tyrrell Committee as urgent and of high priority, some of which were already in progress. It is creditworthy that Mr Gummer, in accordance with the advice of his officials, proffered by Mr Andrews, and with the support of DH, decided that all these projects should be pursued.

The Spongiform Encephalopathy Advisory Committee (SEAC)

No further assistance was sought from the Tyrrell Committee. Officials at MAFF and DH agreed that it was desirable that a new expert standing committee should be formed to meet from time to time to advise on questions about BSE, but that this new committee should not publish reports. Its role would include having a general overview of research. Dr Tyrrell was invited, and agreed, to chair this new committee. Mr Gummer announced the setting up of SEAC on 3 April 1990. Its terms of reference were:

To advise the Ministry of Agriculture, Fisheries and Food and the Department of Health on matters relating to spongiform encephalopathies.

A detailed account of the setting up, membership and activities of SEAC appears in Volume 11, together with discussion on its role. In this volume we shall refer from time to time in the course of the narrative to questions asked of, and advice given by, SEAC. Contrary to the expectation, and to some extent the wishes, of its members, SEAC found itself given the role of providing policy advice on almost every decision that the Government was faced with in handling BSE.

We should record our respect for the dedication of the members of both the Tyrrell Committee and SEAC. Members of the latter found themselves called upon to provide much more assistance than they had been led to believe would be the case. Independent scientists in this country have an admirable tradition of agreeing to serve on committees performing functions in the public interest. Members of SEAC, who exemplified this tradition, found that it involved a considerable burden.