10. Discussion

10.1 The task of considering the adequacy of the response to the emergence of BSE has required us to carry out a critical review of the *Southwood Report* and the work of the Southwood Working Party – as indeed of the work of the other scientific committees which provided assistance to the Government in dealing with the BSE crisis. A primary task of the Working Party was to evaluate the risk to human and to animal health posed by BSE and we have considered the basis of that evaluation. The Working Party were also asked to advise on measures to counter those risks. We have considered both their evaluation of risk and whether the measures that they advised were appropriate and adequate.

10.2 We wish to record at the outset that each member of the Working Party agreed, when asked, to serve on it without remuneration. We are conscious that to have been subjected to the demands of this Inquiry some ten years later has been a poor reward.

10.3 The Working Party are to be commended for important recommendations that they made after their first meeting, and for the promptness with which they made them. We have referred at paragraph 2.4 above to the four recommendations which were made at that stage. As to the first (the establishment of an expert group on research), the experience of the members of the Working Party rightly led them to appreciate from the outset that research could not be left to the parochial enthusiasm of MAFF and the CVL. A review of research could have been said to fall within the wide terms of reference of the Working Party, but we believe that they were right to conclude that this task could better be performed by a separate expert committee.

10.4 As to the second recommendation, the setting up of scrapie-into-cattle transmission tests seems an obvious thing to suggest. It was not, however, implemented and we consider why this was in vol. 2: *Science*.

10.5 The third recommendation emphasised the importance of checking to see whether BSE was vertically transmissible. Mr Wilesmith had made a start in this direction by recording on the computer database the identity of offspring of BSE-infected cattle which had been retained or were to be retained within the adult herd.

10.6 The Working Party did not expressly spell out the reasoning behind their fourth recommendation, the destruction of the carcasses of animals suffering from BSE. It was implicit from it that they considered that both the head and other parts of an animal affected by BSE might be capable of transmitting infection. They did not explain what led them to this conclusion, although the phrase ‘at this stage of knowledge’ gave the hint that it was a precautionary measure dictated by uncertainty.
10.7 When giving evidence to us, the Working Party emphasised the strength of their reaction on being informed that, although the heads of animals affected by BSE were removed for laboratory inspection, the remainder of the carcasses went into the human food chain. In his written statement to the Inquiry Sir Richard said that all the Working Party were horrified at this.\(^{112}\) In oral evidence he elaborated:

> We were mostly horrified to think that the spinal cord and the rest of the animal was still going into the animal food chain. That was the most horrifying . . . The idea that these animal bits which were from infected animals, which might have had the disease for three months, which could therefore have a very high titre – that was our guess; and I think it has been proved right – of the material, were going into the food chain for either humans or pets caused us considerable concern. We felt it was our job to stop that happening . . . Immediately.\(^{113}\)

10.8 Sir Anthony Epstein said: ‘. . . just to take the heads off and put the rest into the food chain is what was so shocking.’\(^{114}\)

10.9 It seems to us that the reasoning of the Working Party followed the same course as that of Mr Cruickshank and Mr Andrews, and was reasoning that would be shared by any scientist, or indeed intelligent layman, who was informed of what was and what was not known about TSEs and BSE. Cattle were succumbing to a fatal disease transmitted by their feed. No precedent existed that gave firm reassurance that infected tissue from cattle so affected could be eaten with impunity by animals of other species. Reactions of horror on the part of the Working Party on learning that carcasses of affected cattle were being fed to humans were appropriate, as was their immediate recommendation that this practice must stop. The decisiveness with which that recommendation was made was commendable.

10.10 The recommendation that carcasses of affected animals should be destroyed was also designed to protect pets by preventing the incorporation of potentially infective material in their food.

10.11 Question 18 of the Key Questions (see paragraph 1.25 and the Annex) had asked what steps it would be prudent to take in respect of clinically affected animals covering, among other things, the use of meat offal and meat products for human consumption and for pet food. Mr Wilesmith had answered:

> Given the difficulties in abattoirs of identifying parts of the given carcass it may be prudent to condemn, for any use, the whole carcass of affected animals.

10.12 Dr Pickles, for DH, had responded to the question simply and tersely: ‘Not acceptable.’

10.13 It is regrettable that MAFF and DH had not reached and implemented a similar accord in March 1988, rather than deferring the decision. (The reasons for this are explained in vol. 3: The Early Years, 1986–88.) Happily the Southwood Working Party lost no time in giving the advice that was so urgently needed on this point.

\(^{112}\) S1 Southwood para.10  
\(^{113}\) T3 pp. 128–9  
\(^{114}\) T3 p. 119
10.14 The Working Party, through Dr Pickles, also lost no time in drawing to
the attention of the DH Medicines Division and the HSE the need to address the
potential risks posed by BSE. At the end of 1988 Sir Richard wrote also to Dr Little
of the VPC about the potential risk of using bovine sources for veterinary
products.115

10.15 The Working Party were perceptive in urging, after their second meeting,
that the ruminant feed ban should be indefinitely extended. Its original imposition
for a limited period and its renewal for a further limited period may, as a matter of
presentation, have made the ban more acceptable to those affected by it, but may
also have diminished their appreciation of the importance of complying with it.116
The Working Party appreciated this danger and were right in judging that there
was no realistic prospect that it would be safe to lift the ruminant feed ban in the
foreseeable future.

10.16 Another recommendation they made after their second meeting – that milk
from cattle suspected of being affected by BSE should be destroyed – represented
an appropriate application of ‘ALARP’ – an approach to risk analysis (see
paragraphs 10.38–10.40).

10.17 Having been responsible for the setting up of the Tyrrell Committee to advise
on research, the Working Party drew attention to a number of areas where research
was needed for further consideration by that Committee. They emphasised,
repeatedly, the importance of the study of offspring of affected cattle in order to
check for maternal transmission. They recommended the monitoring of CJD cases
– the achievement of the CJD Surveillance Unit under Dr Robert Will in identifying
the emergence of variant CJD demonstrated the wisdom of this recommendation
(see vol. 8: Variant CJD).

10.18 It is right that these benefits of the work of the Southwood Working Party
should be recognised. It is also right that we should record that, when the Southwood
Report was published, it was generally well received. In particular:

• Sir Donald Acheson advised his Minister that he regarded the Report as
  ‘a thorough study of the problem with sound and balanced conclusions’.117

• ‘The International Round Table’, a group of experts in spongiform
  encephalopathies, met in June 1989 to carry out a critical analysis of the
  Southwood Report and unanimously found the Report ‘to be scientifically
  sound in observations, conservative and sound in conclusions, and
  understandable to both scientific and non-scientific audiences’.118

• On reading the Report, Professor W B Matthews, a leading authority on
  spongiform encephalopathies, thought it ‘an impressive piece of work’.119

115 YB88/12.20/2.1
116 S24C Reed (UKASTA)
117 YB89/2.9/9.1
119 S317 Matthews W B para.10
We have, however, had to carry out our own appraisal and we have given particular consideration to the following questions:

i. On what basis did the Working Party assess the risks posed by BSE to human health as remote?

ii. Why did the Working Party advise that manufacturers should exclude certain bovine offals from baby food?

iii. Why did the Working Party make no other recommendation in relation to the risks posed by oral ingestion of tissues from cattle subclinically infected with BSE?

iv. Did the Working Party adequately address the risks posed by the use of bovine matter in the production of medicinal products?

v. Did the Working Party adequately address occupational risks posed by BSE?

vi. Did the Working Party adequately address the risks posed by BSE to animals?

Assessment of the risk of transmission of BSE to humans

We have referred above to passages in the Report dealing with the risk posed by BSE to humans, ie:

5.3.5. In these, as in other circumstances, the risk of transmission of BSE to humans appears remote.

8.2. . . . Although the risks appear remote.

9.2. It is . . . most unlikely that BSE will have any implications for human health.

The Report does not expressly explain the basis upon which the terms ‘remote’ and ‘most unlikely’ are used to describe the risks to human health.

We asked the Working Party for clarification of their assessment of risk. Their starting point was to explain the significance of the word ‘remote’ when used to qualify 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 considered that the risk that BSE would prove transmissible to humans by eating beef or bovine products was remote. The slaughter and compensation policy and the advice in relation to baby food were precautions that they considered it reasonable to take to guard against this remote risk.

The risk from eating bovine tissue was seen as lower than that from other potential methods of transmission. An injection of a medicinal product derived from infective bovine tissue, or infection of an open wound as a result of occupational hazard, posed a more serious risk than that from oral ingestion. Before writing their
Report, the Working Party had taken steps to see that the responsible authorities had addressed the medicinal and occupational risks. It seems that it was on the assumption that appropriate precautions were being taken that the Working Party had described those risks as ‘remote’ in their Report (see paragraphs 10.83–10.109 below).

10.24 We explored with the Working Party why it was that they concluded that the risk of transmission from eating bovine tissues was remote. They confirmed our understanding that this conclusion was based on the premise that BSE was likely to behave like scrapie.

The scrapie experience

10.25 Sections 3.5 to 3.7 of the Report consider whether there is any evidence of an association between scrapie and CJD. The Report concludes that there is not. Chapter 4 of the Report was written by Mr Wilesmith. It sets out in detail the epidemiological basis for Mr Wilesmith’s conclusion that BSE had resulted from infection by the scrapie agent. That conclusion is set out in the Summary at 10.2 as follows:

The epidemiological evidence suggests this new disease has appeared as a result of contamination of meat and bone meal derived partly from sheep offal and fed to British cattle from the early 1980s. Contamination had arisen because modern rendering practices failed to destroy the agent of scrapie, the endemic spongiform encephalopathy of sheep.

10.26 In paragraph 6.3 of the Report the Working Party state:

It cannot automatically be assumed that animals and man will react to BSE agent exposure as they have done to scrapie, which in the human case has not led to any clear association with disease. The BSE agent may, for example, be an adapted or particularly virulent form of scrapie agent although the results of the epidemiological study indicate otherwise.

10.27 We think that the inference from the Report is that, because BSE is probably scrapie in cattle, it is likely to behave in the same way as scrapie in sheep and thus not to transmit to humans or to animals that have not proved susceptible to scrapie. The Working Party have confirmed to us that this was indeed the basis of their approach to risk:

There was no, or virtually no scientific knowledge concerning BSE available at this time. We worked on the basis that scrapie was the most likely cause of the BSE epidemic; we had to base our advice on the science relating to scrapie at that time . . . Our assessment of the likelihood of the risk posed by BSE followed from this and recognised that BSE might be more hazardous to man than scrapie had been; our recommendations were made on this basis.121

10.28 In the period up to March 1996, the theory that BSE was scrapie in cattle underpinned the belief of many that BSE did not involve a risk to human health.

121 S483 Southwood para. 42
With the benefit of hindsight it is now generally accepted – and acknowledged by Mr Wilesmith – that some of his provisional conclusions, which were adopted by the Working Party, were probably not correct. The affected animals recorded at the time of the Southwood Report were not all index cases that had succumbed to a common source of infection, namely scrapie. It is more probable that they were infected as a consequence of the recycling of earlier cases of BSE which had gone undetected. The initial source of infection is unknown and may never be known, but there are difficulties in the way of the theory that it was scrapie. These matters are dealt with in detail in vol. 2: *Science* in an analysis which would not have been possible with the limited knowledge at the time of the Southwood Report. We feel, nonetheless, that had the Working Party subjected Mr Wilesmith’s theory to a rigorous assessment they might have concluded that it was not easy to accept that scrapie had always been capable of infecting cattle but had, until 1982, been inactivated by rendering. We do not, however, consider that the Working Party are to be criticised for accepting Mr Wilesmith’s conclusions as to the probable source of BSE. They had been provided with Mr Wilesmith’s assistance as an epidemiology expert adviser and could not be expected to attempt a peer review of his work. They emphasised to us: ‘. . . we were not a peer group review body. It was not our role to re-examine the specialised epidemiological data presented by Mr Wilesmith.’

Mr Wilesmith’s conclusions were almost universally accepted at the time and are still considered by some to be a plausible explanation of the emergence of BSE. Nevertheless, the Report did not make it plain that Chapter 4, which dealt with the cause of BSE, and Chapter 6, which dealt with the future course of the disease, were written by and expressed the opinions of Mr Wilesmith, opinions which the Working Party had not felt able to peer review. We believe they should have done.

10.29 The view that BSE was unlikely to be transmissible to humans was shared by both Dr Hope and Dr Kimberlin. It was later endorsed by the Scientific Veterinary Committee of the European Commission and by the Spongiform Encephalopathy Advisory Committee (SEAC). The latter, in its *Summary of Present Knowledge and Research* into TSEs, published in September 1994, observed:

Our conclusion therefore is that, as the Southwood Working Party determined, taking all the available evidence together, the risk to man from BSE is remote.

10.30 SEAC went on to refer to the advice that had nonetheless been given aimed at reducing exposure to BSE agents. It ended this report:

Our scientific assessment is that the risk to man and other species from BSE is remote because the control measures now in place are adequate to eliminate or reduce any risk to a negligible level. We do, however, point out that any species exposed already and before any bans were effective could be incubating disease, and therefore continuous monitoring is very important until any possible incubation period has been exceeded.

10.31 The conclusion that BSE would probably prove no more transmissible to humans than scrapie was not founded on a scientific understanding of the factors
governing transmission of TSEs in general or scrapie in particular. That some factor prevented the oral transmission of scrapie to man whereas it could be transmitted orally to other animals seemed clear from epidemiological studies. That kuru had probably been transmitted orally from one human to another was known. What was not known was the mechanism by which the TSE agent in one animal infected another, or even the biological nature of that agent. What created a ‘species barrier’ to the transmission of scrapie from one animal to another was not known. The conclusion that BSE would behave in the same way as scrapie was essentially a matter of judgement in the face of uncertainties, or an ‘educated guess’. This was not something that the Working Party sought to conceal, as is clear from private correspondence which Sir Richard had with a number of scientists about BSE. In a letter to a Mr J Granger (a veterinary surgeon) on 25 October 1988, Sir Richard wrote:

I have to say that it is my view that the risk of transmission of BSE to man is relatively small, but this view is based entirely on drawing a parallel with scrapie... there’s clearly a formidable barrier to its transmission to man. On the other hand as the agent has crossed apparently from sheep to cattle, we must be concerned that it would pass to another species.124

10.32 The other members of the Working Party confirmed that the view expressed by Sir Richard was one which they shared.125

10.33 To Dr E Poole (of the Radcliffe Infirmary in Oxford) Sir Richard wrote on 9 August 1988:

... 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 CJ disease.126

10.34 To Dr David Doyle, a consultant neuropathologist, he wrote on 8 September 1988, again in a private letter:

Against this rather comforting scenario one could argue that the agent causing BSE has already crossed one species boundary and may be a more ‘virulent’ strain – whatever this means in the context of scrapie agents.127

10.35 We consider that it was reasonable for the Working Party to conclude by way of judgement, or educated guess, on the basis of the scrapie experience, that BSE was unlikely to be transmissible to humans and that the risk of transmission by oral ingestion was remote, giving that word the rather technical meaning it has in the medical context (see paragraph 10.22 above). Similar conclusions were reached by some of those most experienced in the field of TSEs. The Report did not, however, spell out the crude basis upon which this assessment of risk had been made.

10.36 Is this a matter for criticism? We have concluded that it is. The evaluation of risk was the primary task that the Working Party had undertaken to perform. Each member was a scientist of high distinction. Their Report was to be published, and their reasoning would need to be understood at the time and reassessed in the future.
as new information came to light. Their position required them to use the greatest care in the manner in which they communicated their assessment of risk. It does not seem to us that they did so. In our view the Working Party should have set out the reasoning which led them to use the term ‘remote’, and explained what they meant by that term. It was certainly possible to do so. We can illustrate this by quoting from an article on ‘Transmissible Encephalopathies in Animals’ which Dr Kimberlin submitted for publication in the *Canadian Journal of Veterinary Research* in June 1989.\textsuperscript{128}

> A final question concerns the public health risks posed by BSE. On the one hand, there is the evidence that scrapie can infect other species to produce diseases such as TME and BSE; on the other, the absence of an epidemiological link between scrapie and CJD suggests that even if scrapie could infect humans, usually it does not. For this reason alone, BSE is unlikely to be a major threat to humans.

The article went on to refer to the possibility of a change in the agent on crossing the species barrier. Dr Kimberlin concluded:

> It is therefore possible that the transmission of scrapie from sheep to cattle may alter the population of scrapie strains to which humans are exposed. If the strains selected by cattle have a greater pathogenicity for humans than sheep strains, the risks to humans would be increased accordingly.

From a practical standpoint, it is virtually impossible to quantify these risks. Strain typing is a protracted exercise and even if a selection of scrapie strains in cattle was demonstrated, there is no way of evaluating directly their increased or decreased pathogenicity for humans. Neither are there diagnostic tests of infection (other than bioassay) to measure the level of human exposure. And the long incubation periods of these diseases mean that it could be at least a decade before an actual risk revealed itself by an increased incidence of CJD. Because of these difficulties there is no alternative but to assume that BSE poses a real risk, however small, and take precautionary steps to reduce it to an absolute minimum.

10.37 We do not understand Dr Kimberlin’s conclusions to differ from those that had been reached by the Working Party. They are, however, expressed with a clarity lacking in the *Southwood Report*. They are not alarmist but at the same time leave no room for complacency.

**The approach to risk**

10.38 The Working Party were asked not merely to advise whether BSE posed a risk to man but to advise upon the appropriate precautionary measures should they conclude that a risk existed. So far as the latter is concerned, the Working Party explained to us:

> 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

\textsuperscript{128} This was finally published as: Richard H Kimberlin, ‘Transmissible Encephalopathies in Animals’, *Canadian Journal of Veterinary Research*, vol. 54, 1990, pp. 30–7
steps for its reduction. The magnitude of a risk comprises both its likelihood and the scale of the danger.129

10.39 This approach to risk is sometimes described 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. As the Working Party observed, in the case of BSE this was a difficult exercise:

If the homology with scrapie was complete, then there was no risk. But we judged that there was a possibility that BSE might be more dangerous to man than scrapie. This was a particularly difficult situation to evaluate, for though the likelihood of the risk was very low, the magnitude of the danger should it prove to be real was very great.130

10.40 The Working Party did not proceed upon the basis that it was certain that BSE was caused by the scrapie agent nor on the basis that it was certain that BSE would behave as scrapie behaved. They proceeded on the basis that while it was likely that BSE would prove no more transmissible than scrapie, precautions needed to be taken to guard against the possibility that this would prove not to be the case. As they pointed out, the implications of that possibility were extremely serious. We believe that this was a proper approach to be adopted by the Working Party.

10.41 We now propose to consider the recommendations made by the Working Party in relation to risk management, dealing first with the risk from eating BSE-infected tissues, then the risk from medicinal products, then occupational risk and finally the risk to animal health.

The baby food recommendation

10.42 What we have described as ‘the baby food recommendation’ is strictly a misnomer. The Working Party made no recommendation in respect of baby food; they dealt with it in the body of the Report, at paragraph 5.3.5. After observing that clinically affected cattle were being slaughtered and destroyed, they gave this advice:

We consider that manufacturers of baby foods should avoid the use of ruminant offal and thymus; the latter can currently be described on food labels as meat.

10.43 The Working Party’s discussion in relation to the baby food recommendation was recorded by Dr Pickles as follows:

Research on offal in baby food was presented, including specimens in cans/jars. It appeared that, contrary to the impression given recently in the Guardian, a magazine article and a recently published book, if offal were included it would have to be labelled either as ‘offal’ or more specifically.
However, these regulations permitted thymus to be included as ‘meat’ and this tissue is known to be infected in scrapie. However, it appeared the scrapie agent has also been isolated from liver and kidney, and unlike other offal these organs are often included in baby food. Since the evidence of risk was slight and indirect it was agreed that in the body of the report there was to be a remark that manufacturers should avoid offal and thymus in baby food and note that thymus can currently be described as meat, but there would be no direct comment about liver or kidney (which can also be labelled as ‘meat’, although specific labelling is more usual). No remarks about baby food were to be included in the summary.131

10.44 Neither this record nor the terms of the recommendation in the body of the Report made it plain whether it was the Working Party’s wish to prevent or at least discourage the incorporation of liver and kidney in baby foods. As to this, Sir Richard told us:

. . . I think after the meeting was over, as was very customary, we would all rush away and look things up and discuss things, and we reached the conclusion that that bit about liver and kidney was erroneous. So I was able to advise the Chief Medical Officer that we were not concerned about liver and kidney. We were concerned about brain and lymphatic tissue. I remember making that point very much to the Minister when we met him subsequently.132

10.45 Thus MAFF and Ministers were told that the Working Party had clarified this recommendation by explaining that they intended ‘offal’ to have the meaning ascribed to that term by the Meat Products and Spreadable Fish Products Regulations 1984: that is, brain, spinal cord and lymphoid tissue, but not liver and kidney.133

10.46 The baby food recommendation shows that the Working Party considered that:

i. There was a possibility that certain tissues in cattle infected with BSE but not yet showing clinical symptoms of the disease (‘subclinically infected animals’) might be infective.

ii. The tissues most likely to carry a risk of infectivity were those which had been shown experimentally to be infective in sheep infected with scrapie.

iii. The risk was sufficient to justify attempting to prevent the incorporation of these tissues in baby food.

iv. The appropriate means of doing this was advice to manufacturers in the body of the Report without any recommendation in the Summary.

v. Inferentially, oral ingestion of these tissues by humans other than babies did not pose sufficient risk to justify any precautionary measures. Labelling of products containing brain and spleen had already been expressly stated to be unjustified.

10.47 The possibility that tissues of subclinically infected animals might be infective was addressed both by the baby food recommendation and by the concern

---

131 YB92/2.03/2.2
132 T106 p. 103
133 L11 tab 6
shown by the Working Party in relation to medicinal products of bovine origin. We consider that the Working Party are to be commended for identifying these tissues as a potential hazard. Experimental work in relation to scrapie had demonstrated a development of infectivity in certain tissues in sheep before clinical symptoms became apparent, and it was logical to anticipate that if BSE were transmissible to humans, the same tissues in cattle might prove infective. Our concern has been to explore, first, whether it was reasonable to conclude that babies might be particularly at risk of infection; second, whether it was reasonable to conclude that precautionary measures should be taken in relation to baby food rather than measures designed to protect all humans; and finally, and more generally, whether the Working Party was in a position to form a reliable conclusion as to which measures were appropriate to meet this risk.

Susceptibility of babies

10.48 On 24 March 1996, SEAC, at the request of the Government, considered whether susceptibility to the BSE agent was likely to be age-related. It had wide-ranging discussion of the changes in the physiology of the human gastrointestinal tract and host defences during life. It was assisted in these discussions by three leading experts covering the fields of paediatrics, gastroenterology, and infection and immunity. They considered what was known of TSEs in natural infections and animal model systems. They concluded that there were no data to support the suggestion that children were more likely to be susceptible to infection by the BSE agent than adults.  

10.49 The Southwood Working Party, when considering baby food nearly seven years earlier, did not have the benefit of the knowledge that had accumulated by 1996 of TSEs in general and BSE in particular. They were addressing what seemed to be no more than an unlikely possibility that the BSE agent, whose nature was uncertain, might be transmissible to humans. They explained to us the factors that led them, in these circumstances, to conclude that there was an enhanced risk that BSE might be transmissible to babies as a result of the ingestion of baby food:

i. An article by Hadlow and others suggested to the Working Party that lambs exposed from birth were more readily infected with scrapie than lambs first exposed after weaning.  

ii. Wilesmith’s epidemiological work had indicated that calves had an ‘effective exposure’ that was 30 times as high as that of adult cattle (see Annex, answer to question 7).

iii. The Regulations permitted any part of the animal that was fit for human consumption to be incorporated in baby food.

iv. Baby food was largely homogenised and might contain offal without this being apparent.

v. There are many infections to which the young are more susceptible than adults. Also infants have lesions in their gums which could provide an easier entry.

vi. There had been a fashion, at least in the 1930s, to feed sheep brains to infants.

134 YB96/3.24/2.1–2.14  
136 S483 Southwood paras 77–86
10.50 Bearing in mind the limitations of the scientific data available to the Southwood Working Party, their conclusion that the risk of infection by oral ingestion of food containing potentially infective bovine tissues might be greater in the case of babies than for the rest of the population was, in our view, reasonable.

10.51 When discussing this recommendation at the meeting with Mr John MacGregor on 14 February, Sir Richard commented that the likelihood of problems arising through the use of these products in baby food was very low indeed and the suggestion was a course of ‘extreme prudence’. 137

10.52 The Working Party considered that the enhanced risk to babies was sufficient to justify advising the exclusion from manufactured baby food of potentially infective tissues. This contrasted with their attitude to the risk posed to humans other than babies from the ingestion of these tissues, which they considered to be so slight as not to justify any precautionary measures. We now turn to examine the latter conclusion.

The risk from the tissues of subclinically infected animals

10.53 The Working Party’s vigorous reaction against the entry into the human food chain of any part of an animal showing clinical symptoms of BSE contrasts with their attitude to animals infected with BSE that were slaughtered before clinical symptoms had developed. This was a matter which they considered at their second meeting on 10 November 1988. Before that meeting Dr Pickles had circulated a first attempt at drafting some of the sections of the Report. This included the following suggestions of possible precautions in addition to the exclusion from the human food chain of affected cattle:

Ox-brain would carry more BSE agent than other edible parts. It is eaten rarely in this country and it could be questioned whether restricting ox-brain for human use to imports from overseas would create any opposition, and be seen as a sensible further move. Brain and lymphoid tissue could be omitted from meat pies without any important consequences for the industry and certainly without any culinary loss. Temperatures in meat pie manufacture are not always high enough to destroy agents such as scrapie. 138

10.54 At their second meeting the Working Party rejected the idea of a ban on United Kingdom ox-brain for human consumption, but proposed to suggest that there was a case for labelling to indicate whether processed food contained brain in order to enable an informed customer to make his or her own choice. It was observed that, if accepted, this course was likely to cause the meat pie industry to find alternatives to brain rather than to include it with labelling. 139 Subsequently, after Mr Cockbill had advised that certain technical hurdles would have to be surmounted under European Community Regulations before brains could be labelled, the suggestion of labelling was abandoned. In the event the only recommendation made by the Report in relation to the oral ingestion of tissues from

---

137 YB89/2.14/5.2
138 YB88/11.07/1.4
139 YB88/11.11/1.1–1.2
subclinically infected animals was the baby food recommendation. The Working Party explained to us in some detail why they decided that no precautions, other than the baby food recommendation, were justified in this area:

Based on the scientific evidence known to us as at 20 June 1988 we viewed the risk posed to human health by tissues and fluids from asymptomatic infected cattle as sufficiently low for the highlighting of a potential risk to human health to be unnecessary. Later in our deliberations we identified good reasons to reach a different conclusion for the very young.

...the evidence before us was that the titre of infective material in certain tissues such as brain and spinal cord of asymptomatic animals only reached high levels shortly before clinical signs developed. On the evidence available to us the potential risks posed to the adult human population by asymptomatic cattle through the oral route of transmission were minimal.\(^{140}\)

10.55 They summarised their reasons for not recommending the banning of ox-brain as follows:

(i) We had already requested removal of symptomatic cattle from the human food chain.

(ii) Scrapie was the model on which we had to rely for taking action.

(iii) The titre of tissues, including brain, in subclinical scrapie is generally low. (Hadlow et al.)

(iv) Comparatively small numbers of cattle were being notified as affected (1,365 at the end of October 1988 [0.01% of the national herd]).

(v) Epidemiological information supplied to the Working Party suggested that the outbreak was plateauing.

(vi) The mean incubation period we were informed was 4 years, ie, after calves (up to 6 months) and prime cattle (12–30 months) are killed and before the majority of dairy cows are slaughtered (6–7 years).

(vii) Brains of cattle are generally destroyed during the process of killing.

(viii) Consumption of brains was low and if used they were required to be cooked.

(ix) Banning consumption of brains would require EC approval and could be difficult.

(x) The greatest estimated danger was to certain occupations (vets, slaughtermen, etc) or by pharmaceutical preparations given by injection.

(xi) The majority of affected cows were dairy stock.\(^{141}\)

\(^{140}\) S483 Southwood paras 37 and 38

\(^{141}\) S483 Southwood para. 66. Paragraph 41 of this statement notes: ‘...we were aware that there were infected but asymptomatic cattle but we were not in a position to estimate how many’.
We observe that a number of these reasons were equally applicable to other tissues.

The conclusions of the Southwood Working Party

10.56 The Working Party gave no explanation in their Report for their conclusion that the risk from eating brain and other possibly infective tissues of subclinical cases of BSE did not call for any general precautionary measures. This was unfortunate, for it made it impossible to carry out a reasoned review of their conclusion. Had they set out in their Report the factors that they enumerated to us, the validity of each could have been considered. The subsequent escalation of the epidemic, which they had not anticipated, would of itself have demonstrated that their Report could no longer be treated as valid scientific guidance on precautionary measures. More fundamentally, we do not consider that the factors enumerated by the Working Party justify the conclusion that they based upon them.

10.57 On 13 November 1989 the first Specified Bovine Offal (SBO) ban was introduced, taking out of the human food chain those bovine tissues that might, in subclinical cases of BSE, carry infectivity. The question arises why, if the Working Party applied the ALARP principle, they did not recommend general measures of this type to deal with the risk posed by subclinical BSE cases.

What was reasonably practicable?

10.58 With hindsight it is clear that the human SBO ban was a desirable and proportionate measure to address the risk posed by subclinical animals. In a letter to Dr Reimer Böge of the European Parliament dated 20 December 1996, Sir Richard said:

> Although there is as yet no evidence that the titre of the agent in the specified offal is sufficient to infect humans orally I believe that their removal is a precaution that should have been taken in 1988, rather than the next year. But I must stress that this is because the precautionary aspect must now be weighed more heavily as since last April we believe that the agent may be transferred, presumably if present at a sufficiently high titre, to humans.¹⁴³

10.59 Members of the Tyrrell Committee told us that when they began their duties in March 1989, they had concerns about subclinical BSE cases. Thus Dr David Tyrrell, while paying tribute to the Report, added:

> I would have given more emphasis to the probable large numbers of infected cattle which would be by now around, and what we were going to do about them¹⁴⁴ ... Having read Richard Kimberlin’s papers, I was aware that there could be large amounts of infectivity in tissues of animals which were healthy, and if these were not removed in some way or another, then they would also expose human beings to risk.¹⁴⁵

10.60 Dr Kimberlin commented:

---

¹⁴² The Bovine Offal (Prohibition) Regulations 1989 banned the use of the brain, spinal cord, spleen, thymus, tonsils and intestines of any bovine animal over six months old slaughtered in the UK for human consumption

¹⁴³ YB96/12.20/1.2

¹⁴⁴ T6 p. 36

¹⁴⁵ T6 p. 49
I think what Southwood did in the short space of time that he had available to him was admirable, and he did the obvious easy things, and that was fine, but it became very clear to some of us anyway that that would not be enough.146

10.61 Dr Will said:

. . . we were aware that the specified bovine offals ban was going to be introduced, I think, around that time . . . June . . . That to me was an absolutely critical measure to protect public health, because it would remove CNS [central nervous system] tissues from infected cattle which could not be identified clinically, in addition to the removal of affected cattle that were identified . . .147

10.62 Insofar as these statements purported to reflect views at the time that the Southwood Report was published, we treat them with caution. Witnesses are not immune from the temptation to be wise after the event. There were, however, some who expressed concern about the risk posed by tissues of subclinical animals at the time.

10.63 By the time of the Working Party’s second meeting, Dr Timothy Holt and Ms Julie Phillips had published a perceptive article in the British Medical Journal drawing attention to the potential risks of products derived from the brains of asymptomatic victims of BSE.148

10.64 On 1 November 1988 Dr Fraser, Head of Experimental Pathology at the Neuropathogenesis Unit (NPU), wrote to Dr Holt inviting him to discuss his concerns about preclinical animals with the NPU:

Our work on scrapie highlights our lack of knowledge on BSE such as the levels of infection in healthy cattle incubating the disease. The incorporation of lymphoreticular tissue such as spleen into meat products is just one example of a policy which may be difficult to sustain.149

10.65 On 2 March 1989 the Guardian published a letter from Dr Helen Grant, an experienced neuropathologist at the Middlesex and Charing Cross hospitals, expressing concern about animals incubating BSE. Shortly afterwards she wrote to Sir Richard:

The report of your working party is quite first class both as to the collecting of factual material and as to recommendations. The only criticism I would be inclined to level is that the ominous problem of the incubation period is not given enough emphasis. Since it is impossible by testing them to reveal which animals are infected (as opposed to ‘affected’) the long incubation period is potentially very sinister because these animals continue to reach our food.150

10.66 Sir Richard replied on 13 March:
As you can imagine, in this Report it was extremely difficult to steer the proper course between causing excessive alarm and undue complacency. The evidence to date seems to indicate that the BSE agent is very similar to scrapie, and of course we have lived with scrapie for two hundred years, and most of us have at some time or other eaten sheep offal – though the incidence of CJD remains low. It was this line of argument that finally convinced us not to press the point that you have made in your letter any more strongly.\textsuperscript{151}

10.67 We believe that had the Southwood Working Party correctly applied the ALARP principle, and had they been informed of the measures that were available to reduce risk and their practical implications, they would have recommended the precautionary measures that were subsequently adopted under the SBO ban. This conclusion is based upon knowledge available at the time.

10.68 When speaking of their reaction to affected animals entering the food chain, Sir Richard quoted one of his colleagues as saying: ‘Good gracious, a lot of the CNS system must still be left in the spinal column, and that must go in the food chain getting into mechanically recovered meat and so on.’\textsuperscript{152} The same was true of the subclinical animal.

10.69 Later he added, in relation to ox-brain:

We continued to be concerned because, I think I can remember Sir Anthony saying, what about the animals that are not showing symptoms but will obviously have some of the agent in their brain and nervous core; and we all thought: ‘What can we do about this? But it is the whole British cattle herd. How were we going to deal with that? Was there some way we could find the part of that which was at most danger and somehow exclude it from the human food chain?’ It might well be it may still be true that the titre would not be sufficient to cause a disease certainly ingested, that we do not know even today. We did explore it. Those are the minutes written in the way you saw. We accepted the minutes. We obviously continued to worry about this, particularly in relation to baby food, and you will have before you the paper from Mr Cockbill dated on 12 December, which I did not have available when I prepared my memorandum initially, but then I was able to incorporate it.

In some paragraphs, I refer to the problems of the EC and so on, all of which were produced as reasons why it would be difficult to label food as containing ox-brains. In general, I think the message we got was [that it was] going to be a very difficult procedure to follow. We continued to worry away at that right the way through to the end.\textsuperscript{153}

10.70 It was, or should have been, plain that there were substantial numbers of asymptomatic infected animals being slaughtered for food. The Working Party, rightly, were not convinced that the outbreak was plateauing. The CNS tissues of sheep clinically affected with scrapie had been demonstrated to have higher titres of infectivity than those of asymptomatic infected sheep. In contrast, the level of infectivity in the lymphoreticular system reached its maximum about a year before

\textsuperscript{151} YB89/3.13/1.1
\textsuperscript{152} T3 p. 116
\textsuperscript{153} T3 pp. 134–5
clinical symptoms appeared. There was no sound basis for concluding that either type of tissue would be incapable of infecting, even if it were safe to conclude that experience in relation to sheep could be applied to cattle. The Working Party could not, however, be confident of that. As Sir Richard said to us:

What we, of course, were also very concerned to know is: how did the titre of the agent build up in those particular tissues during the progression of the infection over five years in a cow, because that is absolutely fundamental to the extent of the risk that existed after 1988 . . . it has been six or seven years before we really got any information of that sort.154

10.71 The Working Party concluded, and rightly concluded, that it was not safe to proceed on the basis that it was certain that BSE would not transmit orally to humans. They concluded that action was called for to meet the risk that BSE would not behave like scrapie. They were driven to that conclusion by uncertainty.

10.72 Just as there was uncertainty as to whether BSE would behave like scrapie, there was uncertainty about the nature and transmission of TSEs. In August 1987 Dr David Taylor of the NPU wrote to advise Mr John Sloggem of DH’s Medicines Division, who was concerned about the risk of a proposed oral medicine that incorporated bovine brain extract. Having given examples of natural oral transmission of TSEs (kuru and TME) and experimental oral transmission (scrapie into mice; and kuru, CJD and scrapie into squirrel monkeys), Dr Taylor concluded:

Oral transmission has not been studied experimentally to anything like the extent that the intraneural route has, and so we know little of the efficiency of the route for infection or how agent gets from the gut to the brain. One would think instinctively of it being a less efficient route, but it is impossible to quantify this on the basis of existing data.155

10.73 In our judgement this uncertainty should have precluded the nice distinctions the Working Party made between the risk to babies and the risk to other humans.

10.74 Mr Meldrum commended the Southwood Report. He said, however, that when he came to reflect on it he detected an illogicality. That perceived illogicality was remedied by Mr John MacGregor’s decision to introduce the SBO ban, which Mr Meldrum described as ‘inspirational’.156

10.75 We agree with Mr Meldrum that the Southwood Report had an illogicality. If slaughter and destruction of animals showing symptoms of BSE was, as we believe it was, a reasonable response to the possibility, albeit seen as remote, that BSE might be transmissible to humans, it was illogical not to remove the potentially infective offal from cattle not showing symptoms.

10.76 In this context we should refer again to the conclusions of the International Round Table (see paragraph 10.18). It is significant that, while endorsing the Southwood Report, this body commented that: ‘Until additional information is obtained, tissues, with the exception of nervous tissue ((brain, spinal cord) and perhaps some of the major lymphoreticular organs from unaffected animals of the same herd, are not believed to be a source of any further danger than that already

154 T3 pp. 109–10
155 YB87/8.31/1.1
156 T120 pp.197
incurred by allowing scrapie-infected sheep or goat tissues to enter the human food chain.’ (Emphasis added.)

10.77 In written submissions addressing the question of whether they should have recommended precautionary measures that went further than the baby food recommendation, the Working Party said:

... it was reasonably practicable for the limited number of manufacturers of baby food to control the ingredients of their products. We judged it was neither necessary nor reasonably practicable to go further. Any recommendation for older individuals would have had to read along the lines ‘butchers and others should not incorporate offals in their products or sell the same’. As so many outlets would be involved this would have required a regulation and we were advised that this would involve many difficulties (ie, was not reasonably practicable) (see Mr Cockbill’s letters to us – RFA 1 paragraph [391], 12 December 1988. It would almost certainly have created a crisis in the beef industry such as that which we have subsequently observed. Given that we and others were agreed that the scrapie analogy was the most reliable guide to the risk to humans and that we understood that the ‘dose’ (if any) to adults would be less, then such a further recommendation was not necessary and, we believe, would have been regarded at the time as highly irresponsible.

10.78 We would comment on this submission as follows:

i. the SBO ban provided a practicable means of removing high risk tissues from general consumption;

ii. the SBO ban did not create a crisis in the beef industry. On the contrary, it was considered desirable to introduce the measure as a reassurance to consumers of beef;

iii. there would have been nothing irresponsible about recommending an SBO ban; but

iv. the reality was that the possibility of this precautionary measure was not drawn to the attention of the Working Party.

10.79 The Working Party told us that, when considering measures to deal with BSE, they considered the slaughter of the entire herd and concluded that that would be disproportionate. We do not believe that they considered the possibility of an SBO ban of the kind that the Government introduced later, although they did consider a ban on the consumption of brain. Sir Richard said of the SBO ban that ‘the Ministry had found a way of dealing with the whole cattle herd other than slaughtering it’, and that he in no way resisted that ban being introduced.

The role of the Working Party

10.80 We do not believe that the Working Party was an appropriate body to make detailed recommendations about an SBO ban. They did not have the expertise or the
data needed to take the policy decisions. Practical decisions could not properly be taken without reliable knowledge of the routes by which and the extent to which the various parts of the cow entered the human food chain. They could not be taken without detailed scientific advice, beyond the expertise of the Working Party, as to the likely infectivity of the various tissues. They could not be taken without knowledge of the practicability of removing those tissues from the human food chain and the financial implications of so doing. On 12 April 1989, in a note to Dr Watson, Mr Raymond Bradley (Head of the CVL’s Pathology Department) advised:

It is quite clear that in an infected animal in the late preclinical phase . . . lympho-reticular tissues and certain other tissues, including some endocrines . . . plus CNS, are highly likely to be infected to a high titre of significance to humans if the agent is transmissible to them . . . It is a big step to take to try to eliminate certain items from the food chain. However, it would be relatively simple to reduce risks considerably by sending for rendering or incinerating specified easily identified organs and ensuring the necessary training and adjusted slaughter and butchering procedures to reduce cross-contamination. Spleen, uterine . . . all endocrines, heads (unopened but after removal of muscular tissue) and spinal cord from sheep over 1 year and cattle over 2½ years could be designated unsaleable for human consumption.\(^{161}\)

10.81 Considerations such as these were not discussed by the Working Party, and we do not suggest that they should have been. What we believe that the Working Party could and should have done was to advise that cattle infected with BSE, that were entering the human food chain, had tissues which 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.

10.82 The failure of the Southwood Working Party to make such a recommendation in relation to the risk of transmission posed by asymptomatic cattle was a shortcoming which should not overshadow the credit due to the Working Party for a series of prompt and valuable recommendations. Happily, the baby food recommendation focused attention on the problem of the subclinically infected animal, and led to precautionary measures being put in place that went beyond those recommended by the Working Party.

The risk in relation to medicinal products

10.83 The Working Party were, from the outset, concerned about the risks posed by medicinal products, and in particular products that were administered by injection, that had been sourced from, or produced by, a process which involved the use of bovine tissues and fluids. They lost no time in urging those responsible for the safety of medicines to take steps to address those risks, and they continued to do so throughout the period that they were working on their Report. They emphasised that action was necessary both in respect of future application for licences, and in relation to ‘existing products’, which phrase they intended to cover products

\(^{161}\) YB89/4.12/1.3
manufactured under existing licences, including vaccines held in stock. Sir Richard told us:

We really thought the medical problem was severe. I would not have written all the letters I did to Professor Asscher if I had not felt the problem was severe and if my colleagues had not agreed with me totally.\(^{162}\)

10.84 We were concerned as to why the risks from medicinal products were described as ‘remote’ in paragraphs 5.3.5. and 8.2 of the Report. As to this, the following response was given to us on behalf of the Working Party:

We do not consider that there was anything misleading in these statements. This is not because the potential risk was remote. On the contrary the potential risk was relatively high. The evidence before the Working Party at the time of its Report was that the Licensing Authorities had been fully alerted to the risks and had indicated that they were taking appropriate action to prevent transmission. Professor Asscher said in his letter of 26 January 1989 to Sir Richard that ‘I want to reassure you that CSM intends to take appropriate action in regard of products within its remit’.\(^{163}\)

10.85 Sir Richard confirmed that this was the position in his oral evidence.\(^{164}\) It was not clear that Lord Walton agreed with this. His oral evidence suggested at one point that he thought that the risks from medicinal products were remote, even before any action was taken to deal with them, ‘though not as remote as the risk from oral products.’\(^{165}\) This followed a passage in which he had explained:

But we had to walk a very difficult tightrope between . . . not producing a report which was alarmist and might have had a serious effect on the vaccination programme, and nevertheless on the other hand giving advice to the Committee on Safety of Medicines and other organisations. I think the most important phrase is that we gave advice so that those bodies could ‘take appropriate action’. That was our intention.\(^{166}\)

10.86 Sir Anthony Epstein said that he had been ‘really happy with this phrase that you are dissecting’ because, on 26 January 1989, Professor Asscher had written saying: ‘I want to reassure you that the CSM intends to take appropriate action.’\(^{167}\)

10.87 Sir Richard commented that this assurance moved what had originally ‘stood out as a very serious problem’ into the remote category.\(^{168}\)

10.88 During this hearing, the Working Party were referred to an extract from a paper discussed by the CSM’s BSE Working Group on 6 September 1989 which purported to quote the *Southwood Report* as finding that ‘the risk to man of infection via medicinal products was remote’. Sir Richard said that this incorrectly stated the Working Party’s view and failed to take account of all the warnings they had given. Sir Anthony agreed.\(^{169}\)

---

\(^{162}\) T106 p. 73  
\(^{163}\) S483 Southwood para. 89  
\(^{164}\) T106 pp. 64, 68  
\(^{165}\) T106 p. 76  
\(^{166}\) T106 pp. 74–5, incorporating revisions proposed in S483B Southwood  
\(^{167}\) T106 p. 77  
\(^{168}\) T106 p. 79  
\(^{169}\) T106 pp. 81–2
It appears from this evidence that the Working Party considered that the risk from medicinal products – in particular those administered by injection – would not have been remote in the absence of appropriate precautionary measures. This was not apparent to Mr Lawrence. He stated:

My clear recollection is that the Southwood Working Party concluded, on the basis of the evidence available to them at the time, that the risk of BSE to man was remote, even before any measures were taken. This is certainly confirmed by the passages of the Southwood Report at (eg) paras 5.3.5, 8.2, 9.2 and 10.4. The measures I am referring to are the measures recommended by Southwood, which were more extensive than simply the slaughter and compensation policy and any action by the Licensing Authority.

I am also asked whether any members of the Working Party said anything to me to suggest, or otherwise, to give me the impression that the assessments only referred to the position after the slaughter with compensation policy was introduced and after action was taken by the Licensing Authority under the Medicines Act. The answer, to the best of my recollection, is ‘no’.

Dr Pickles also understood that from December 1988 onwards it was the Working Party’s view that:

...the risk through medicinal products in the UK pharmacopoeia appeared remote, even in advance of the further steps which the Working Party believed were to be taken by the relevant bodies.

This was because the initial review by DH’s Medicines Division showed that there were no products with bovine neural or lymphoid tissue as a major ingredient, although there was incomplete information on products where bovine material had been used in the production process.

We are in no doubt that the Report conveyed the message that the Working Party considered the risk from medicinal products to be remote even before any remedial measures were taken. This is not a conclusion based on construing the Report like a legal document. It is to give the wording of the Report its natural meaning, in the way that Mr Lawrence has done. We can understand the anxiety of the Working Party not to include in their Report anything likely to provoke a boycott of vaccines with the inevitable adverse consequences which would follow. This, we think, could have been achieved by a simple statement that the Working Party had been concerned at the implications that BSE might have for certain medicinal products and had referred those concerns to the CSM, which had undertaken to address them. It was not, however, satisfactory, whether by oversight or by design, to include in the Report passages which gave the reader a false appreciation of the Working Party’s assessment of the risk, and they should not have done so. This shortcoming was the more serious given their failure to explain what they meant by the word ‘remote’.

We have set out in detail the considerable lengths to which the Working Party went, assisted by Dr Pickles, to ensure that the CSM secured appropriate action to meet the risks posed by medicinal products. These actions went beyond the duties...
that the Working Party had undertaken and were praiseworthy. We sympathise with the reassurance that the Working Party felt on receipt of Professor Asscher’s letter of 26 January 1989.

10.93 In these circumstances we sympathise, too, with the following comment made to us by Sir Richard:

I cannot believe that the CSM and those other bodies, who were after all more expert in this field than ourselves, would have been so lulled into a sense of security by a particular two words in our Report.¹⁷³

Unfortunately this is what appears to have occurred.

10.94 The Report gave some who were responsible for dealing with medicinal products the impression that the Working Party had concluded that these constituted no more than a remote potential risk even if no precautionary measures were taken. The CMO received a draft minute to the Secretary of State prepared by Dr Pickles, which contained the following passage:

In Sir Richard’s view the risk to human health is minimal. Nevertheless, he has alerted the Licensing Authority and the Health and Safety Executive to potential problems in their areas of responsibility. At the present time, we cannot give any complete guarantee of safety for human medicines that use bovine materials in manufacture, such as most vaccines. However, appropriate action is being taken by Medicines Division following advice from the Committee on Safety of Medicines, the Committee on Review of Medicines, the Committee on Dental and Surgical Materials and defensive briefing is being prepared for when the report becomes public.¹⁷⁴

10.95 On 9 February the CMO wrote to his deputy, Dr Ed Harris, as follows:

My attention has been drawn to a sentence in Dr Pickles’s draft of a submission to the Secretary of State on this matter. It reads: ‘At the present time we can’t give any complete guarantee of safety for human medicines that use bovine materials in manufacture such as most vaccines.’ Having looked at the Report I am not able to find any statement which supports this statement of concern. I have, however, therefore spoken to Dr Pickles on the telephone and she reports to me that for some considerable time she has had serious concern about the safety of bovine-based vaccines in the light of the fact it has been discovered that contamination with placental material (which is known to be heavily infected with the BSE particle) is a distinct possibility in the preparation of material for human vaccines derived from foetal serum. This matter as described to me by Dr Pickles gives me sufficient cause for concern to ask you to look into it urgently together with Medicines Division.¹⁷⁵

10.96 The steps taken consequent upon this initiative on the part of the CMO, which he described as ‘quite contrary to my normal practice’,¹⁷⁶ are described in vol. 7: Medicines and Cosmetics. We note that the initiative was stimulated by

¹⁷³ T106 p. 79
¹⁷⁴ YB89/2.00/8.1–8.2
¹⁷⁵ YB89/2.09/7.1
¹⁷⁶ T79 p. 100
Dr Pickles rather than by the wording of the Report. Subsequently it appears that the Report, which had at the request of the meeting of 1 February been toned down so as not to risk alarming the public, provided unwarranted reassurance to those whose actions the Working Party were relying upon when describing the risk as remote. Thus the minutes of a meeting of the Human and Veterinary Medicines Briefing Group (HVMBG) on BSE on 22 February 1989 record that:

The slight theoretical risk of BSE being transferred to humans was considered to be more likely from products used parenterally or by implantation than by the oral route.\(^\text{177}\)

10.97 The CSM met on the next day. A note of the meeting records that the CSM:

\[\ldots\] agreed with the Southwood Working Party that the risk to man of infection via medicinal products is remote \[\ldots\] It was agreed that no special action was required on any existing products.\(^\text{178}\)

10.98 A Position Statement by the CSM and Licensing Authority on the implications of BSE for human medicinal products was produced which stated:

The Committee on Safety of Medicines (CSM) has considered the safety of human medicines in the light of the report of the Working Party on Bovine Spongiform Encephalopathy (BSE) – the *Southwood Report*. The CSM agrees with the Southwood Working Party that the risk to man of infection via medicinal products is remote. As a precautionary measure, and for the sole aim of seeking to guard against what is no more than a theoretical risk to man, the CSM and the Veterinary Products Committee (VPC) have agreed joint guidelines on good manufacturing practice for the manufacturers of human and veterinary medicines who use bovine, or other animal, materials either as an ingredient or in the production process.\(^\text{179}\)

10.99 A Q&A briefing prepared at the same time included:

3. Are the risks greater with some medicines than with others?

Theoretically, injectable ((parenteral) products might seem to pose a greater risk than oral medicinal products, but the CSM agreed that the risk from either is remote.

6. Are existing stocks safe?

The CSM agreed with the Southwood Working Party that the risk of transmission of BSE via medicinal products to man is remote and there is therefore no reason to question the safety of existing products.\(^\text{180}\)

10.100 In his statement to the Inquiry Dr Martin commented:

\[\ldots\] I attended, on behalf of the Working Party, a meeting of the ‘Human and Veterinary Medicines Briefing Group Re. BSE’ chaired by Professor Gerry
Collee on 23.2.89. I was left with the impression that those on the human medicine side regarded BSE as an animal problem and that we, on your Working Party, were being excessively apprehensive.\(^{181}\)

10.101 We noted, with interest and surprise, the following statement in the minutes of the HVMBG meeting on 22 February 1989:

Normally, in matters where there is as little knowledge as there is in the case of BSE, CSM would have been advised to take no action but to monitor the situation. Due to the publication of the *Southwood Report*, this option is not open.\(^{182}\)

10.102 It seems to us that the Working Party, Dr Pickles and the CMO together stimulated a reaction from the DH Medicines Division and the relevant Committees to the emergence of BSE that might otherwise have been long delayed.

10.103 The terms of the Report also appear to have deceived those responsible for veterinary medicines as to the Working Party’s assessment of risk in relation to these. Mr Alastair Kidd who, when the Veterinary Medicines Directorate was established at the CVL in March 1989, became Director of Licensing, told us that, in respect of veterinary medicines:

... manufacturers were advised to change the sources of supply of bovine and ovine materials as quickly as possible, where necessary, to minimise the risk of contamination of products. However, manufacturers were allowed to exhaust existing stocks as the *Southwood Report* and the VPC and CVL specialists in BSE had considered that the risk of BSE transmission by medicinal products appeared remote.\(^{183}\)

10.104 The steps taken to address the risks posed by BSE in relation to human and veterinary medicinal products are set out in vol. 7: *Medicines and Cosmetics*.

**Occupational risks**

10.105 We have set out the passage in the Report dealing with occupational risks above (at paragraph 9.5). The Report referred to the danger of direct inoculation of bovine tissue occurring accidentally in certain occupations. It said that the HSE had been alerted to the potential concern about BSE and in particular to the possible infectivity of placentae. No specific additional guidance on BSE was thought appropriate at the time, but the Report emphasised that adherence to recommended procedures in handling animals and animal products was clearly very important.

10.106 Health and safety issues were considered at the third meeting of the Working Party on 16 December 1988. The minutes record: ‘It was considered that [the HSE’s] current line was appropriate.’\(^{184}\)
10.107 The Report recommended at paragraph 8.3 that ‘the potential problems caused by BSE are brought to the attention of the HSE who can consider whether further guidance should be given’ (see paragraph 9.14 above). It seems to us that the effect of this recommendation was likely to be uncertain having particular regard to the statement in the body of the Report that the risk was remote and that no specific additional guidance on BSE was thought appropriate. Once again this indicated that occupational risks were remote whether or not steps were taken to address them, and we consider that the Working Party should not have used words that conveyed that impression.

10.108 We have, however, at paragraphs 3.5 and 3.6 above, described steps taken before publication of the Southwood Report to ensure that occupational risks were addressed. Those steps were commendable. Nevertheless, it remains an unfortunate fact that, just as in the case of medicinal risks, the Report was to be quoted in a manner which tended to dilute enthusiasm which might otherwise have been applied to the implementation of the precautionary principle. Thus the ‘Guidance for Veterinary Surgeons handling known or suspected cases of BSE’ published by MAFF in January 1990 stated:

Although the Southwood Report stated that it is ‘most unlikely that BSE will have any implications for human health’ some guidelines are considered necessary for those who must inevitably come into close contact with the disease. The offering of such guidelines does not imply knowledge of a risk to humans from BSE and, indeed, if BSE does behave like scrapie, there will be no threat whatsoever to human health other than through physical danger.  

10.109 There is a lesson to be learned here. When drafting a Report dealing with risk, it is not safe or satisfactory to rely on private communications or assurances that have been made or received and, as a result, play down the need for precaution in the Report.

The risk to animals

10.110 At an early stage the Working Party concluded that there was no early prospect of identifying a rendering method that would entirely inactivate the BSE agent. They recommended that the ruminant feed ban should be extended indefinitely. The Government initially extended the ban for a further year, but subsequently made the ban indefinite. This was the single most important measure taken to eliminate BSE. Indirectly, of course, it was also a measure calculated to eliminate risk to human health.

10.111 At their first meeting the Working Party gave consideration to recommending that the ruminant feed ban be extended to pigs and poultry, but decided that the risk was so small that such a move was not warranted. They had, nonetheless, some concern as to the possibility that BSE might be transmissible to other species and recommended in their Report that if a specific test were to be developed, research on the agents of spongiform encephalopathies in non-
mammals, including poultry, should be undertaken. Moreover, the Working Party
drew attention to the more general dangers of infection inherent in the practice of
recycling animal waste.\textsuperscript{187}

10.112 It was, of course, possible that pigs and poultry had been infected with
TSEs, but never lived long enough to develop clinical symptoms. This would have
been of no moment unless they risked infecting humans or other animals. These
were possibilities that were considered later in the story. We do not consider that the
Working Party is open to criticism for failing to reflect them in their Report, having
regard to the state of knowledge and the material facts then prevailing.

10.113 The Working Party considered the possibility of transmission of BSE to
cats and dogs and recommended that the surveillance of the health of domestic pets
should be brought to the attention of the Consultative Committee on Research
(the Tyrrell Committee) and the veterinary profession.\textsuperscript{188}

10.114 We consider that the Working Party did all that could be expected of them
in relation to risks to animal health.

\textsuperscript{187} IBD1 tab 2 paras 5.2.3 and 9.4
\textsuperscript{188} IBD1 tab 2 para. 5.2.4