14. Lessons to be learned

1260 We have reached the final chapter of this volume – consideration of the lessons to be learned from the events that we have been considering. First we summarise lessons from particular episodes of the story and then lessons to be learned about five topics which run right through the story: the use of advisory committees; dealing with uncertainty; legislative loopholes; crisis management; and the experience of the victims of vCJD and their families.

1261 Aspects of this Inquiry make this an unusual and not entirely satisfactory exercise. The BSE story is an ongoing story. We have looked at a substantial section of the story, but one that ended over four-and-a-half years ago. We have conducted a particularly public Inquiry and believe that, while it has been proceeding, many lessons have already been learned from the BSE experience and acted upon. The scenery has shifted very considerably from that with which we have made ourselves familiar. The most significant changes have been the creation of the Food Standards Agency and the devolution of powers to a Scottish Parliament and Welsh Assembly. We have also been informed of the creation of a large number of interdepartmental bodies, covering areas which include zoonoses, animal disease surveillance and Transmissible Spongiform Encephalopathy (TSE) research.

1262 The Office of Science and Technology has addressed the questions of the Government’s use of science, the Government’s use of expert committees and the Government’s approach to risk. These topics have also received consideration by a number of other institutions.

1263 It is not part of our remit to assess how well all these developments are now working. That is for others, including the Government, press and public. We propose to confine ourselves strictly to the lessons to be learned from the BSE experience up to 20 March 1996. If some of these lessons have already been learned, others may bear repeating.

Episodes in the BSE story

Lessons from the fact that BSE emerged

Commentary

1264 The fact that the origin of the BSE epidemic is unknown leaves many questions unanswered. In particular it raises the possibility that rare cases of autosomal genetic mutation may give rise to sporadic TSE in cattle, and possibly in other animals.
Lessons

- BSE is a novel and alarming zoonosis. There is much about it that is not yet understood. Precautionary measures need to be applied to reduce the potential risk to as low as is reasonably practicable.
- TSEs may occur in species in which they have previously been unknown.
- It is possible that TSEs develop sporadically in other animal species as they do in humans.
- If TSEs develop sporadically and rarely in farm animals, as they do in humans, they may well pass undetected. This is particularly the case where farm animals are slaughtered for consumption when young and thus before clinical signs normally develop.

Lessons from the transmissions of BSE

Commentary

1265 We have now learned much about the capacity of BSE to transmit to other animals, both naturally and experimentally. The lessons learned provide valuable data for risk management.

Lessons

- TSEs may be transmissible between the same species and between different species.
- TSEs may be transmissible within animal feed and human food.
- Tissues in an animal incubating a TSE may be infectious before the animal has developed clinical signs of the disease.
- It is possible to distinguish between the level of infectivity, or titre, likely to be found in the different tissues of an animal incubating a TSE. The brain and spinal cord, in the later stages of incubation, are the highest risk tissues.
- A very small quantity of infective material may be sufficient to transmit a TSE by the oral route.
- Risk of oral transmission of a TSE will be greatly reduced if high risk tissues are removed from the food chain.

Lessons from the spread of the BSE epidemic

Commentary

1266 What turned the initial case or cases of BSE from an incident into a catastrophe was the wide, and latent recycling consequent upon the practice of using meat and bone meal (MBM) as an ingredient of animal feed.
Lessons

- The process of rendering animal parts to produce MBM, which is then incorporated in animal feed, will result in the pooling of material from many animals and the wide dissemination of infection from a single infective animal.

- The rendering process cannot be relied upon to inactivate TSEs.

- Recycling animal protein carries a greater risk of spreading infection with a TSE when it is carried out within the same species.

- Recycling animal protein carries a greater risk of spreading infection with a TSE where the protein is derived from high-risk tissues.

- Where a TSE has a lengthy incubation period, recycling may spread the disease very widely before its emergence is detected.

Lessons from the identification of BSE

Commentary

1267 The identification of the emergence of a new animal TSE was of critical importance as the first step towards addressing the implications of the disease. The importance of a surveillance system that will identify the emergence of new animal diseases was demonstrated. The efficacy of the passive surveillance system depends upon farmers and their veterinarians drawing incidents of animal disease to the attention of the State Veterinary Service (SVS). When a new disease is identified, early publication of information about its characteristics will be desirable in order to encourage reporting of similar cases.

1268 We note with satisfaction the consideration currently being given to surveillance by the circulation of a consultation document: Veterinary Surveillance in England and Wales – A Review, April 2000. We emphasise the importance of pursuing this initiative.

Lessons

- An effective system of animal disease surveillance is a prerequisite to the effective control of animal diseases.

- An effective system of passive surveillance will depend upon farmers and their veterinarians having the incentive and the facility for drawing instances of animal disease to the attention of the SVS.

- Research into methods of diagnosis should form an integral part of an animal disease surveillance system.

- The proximity of the nearest veterinary centre of investigation to the farm where the disease occurs will be an important factor in determining whether or not a casualty is referred for pathological examination.

- The identification of BSE demonstrated the importance of the animal disease surveillance system of the SVS and of the close links that existed between
the Veterinary Investigation Centres (VICs) and the Central Veterinary Laboratory (CVL).

- It is important that details of a new disease which may have implications for human and animal health should be disseminated within the State and private veterinary systems in order to encourage the reporting of similar cases.

Lessons from the consideration of the nature and implications of BSE

Commentary

1269 When BSE was identified as a new disease by the CVL in December 1986, it was at once appreciated that two important questions needed to be answered. Was it indeed a TSE? And did it have implications for human health? It was the greatest good fortune that, as a result of the joint initiatives of the Agricultural and Food Research Council (AFRC) and the Medical Research Council (MRC), there existed in the form of the Neuropathogenesis Unit (NPU) a world-renowned centre of expertise in TSEs. We have criticised the delay in seeking the collaboration of the NPU in answering the first important question. We have also criticised the more substantial delay in involving DH in the consideration of the second question.

Lessons

- Where animal or public health is at stake, resort should be had to the best source of scientific advice, wherever it is to be found, without delay.
- Collaboration between MAFF and DH, and between the Chief Veterinary Officer (CVO) and the Chief Medical Officer (CMO), must be maintained in considering the potential for animal diseases to threaten human health and the steps that should be taken in response to any potential zoonosis. Consideration should be given to whether a formal structure is the best means of achieving this.
- Advantage should be taken of the expertise and resources of the Public Health Laboratory Service (PHLS) whenever the possibility of a potential zoonosis exists.
- Lead responsibility must be clearly established for coordinating the scientific response to a new disease or a new outbreak of disease.
- Consideration should be given to combining in the same laboratory research on scientific issues that have common application to human and animal health by scientists practising in each field.

Lessons from the investigation of the cause of BSE

Commentary

1270 The investigation of the cause of the cases of BSE that were being reported in 1987 and 1988 was carried out by Mr Wilesmith. He was the only veterinarian
on the staff of the SVS who had a postgraduate qualification in medical epidemiology. He told us of the dearth of veterinarians trained in epidemiology and of the absence of any training courses in veterinary epidemiology. Dr Tyrrell told us of the initial impossibility of finding a veterinary epidemiologist of high calibre to serve on the Spongiform Encephalopathy Advisory Committee (SEAC).

1271 The result was that the burden of the epidemiological investigation of BSE was shouldered by Mr Wilesmith, with the help of his subordinate staff, throughout the period with which we are concerned. The data on which he worked were not readily available to others interested in the epidemiology of the disease.

1272 Mr Wilesmith quickly and correctly identified MBM as the vector of BSE. His tentative conclusions as to why the MBM was infective proved to be erroneous. They were reasonable on the data available to him, but could profitably have been subject to epidemiological review as more data became available to which modelling could be applied.

Lessons

- Provision should be made for training veterinarians in epidemiology. Joint postgraduate training programmes in epidemiology for trainees in veterinary medicine and public health medicine should be encouraged.
- Epidemiologists, particularly those in the public sector, should make available the data upon which their conclusions are based.

Lessons from the introduction of the ruminant feed ban

Commentary

1273 When the ruminant feed ban was introduced, it was not appreciated that there was any need to be concerned about the amount of cross-contamination of cattle feed likely to occur in feedmills from the production of pig and poultry feed containing MBM. This was because it was assumed that the quantity involved would not be sufficient to result in transmission. There was a general impression that a large quantity of contaminated material had to be eaten in order to transmit this disease. There was no basis for this assumption, which should not have been made. Had rigorous thought been given to the matter, this would have involved seeking the views of the experts, who would have advised that a small quantity might suffice to infect.

Lessons

- When a precautionary measure is introduced, rigorous thought must be given to every aspect of its operation with a view to ensuring that it is watertight.
- Reliance on a trade association or other body to communicate the importance of a precautionary measure is not always appropriate.
Lessons from the introduction of slaughter with compensation

Commentary

1274 The decision that cattle showing clinical signs of BSE should be compulsorily destroyed was too long delayed. One reason was that DH was not involved until a very late stage. We have already referred to the need to maintain joint MAFF/DH involvement in dealing with potential zoonoses. Another cause of delay was the reference to a Working Party of the question of how to respond to BSE when the input of the Working Party was not essential to the decision on compulsory slaughter.

Lessons

- Where policy decisions turn on risks to human health, DH should be involved in the formulation of policy from the outset.
- Reference to outside expert committees involves delay. It should be avoided, where possible, in a situation of urgency.
- Uncertainty can justify action.

Lessons from the Southwood Report

Commentary

1275 We have drawn attention in Chapter 4 to certain aspects of the Southwood Report which detracted from its overall merit. We shall deal in due course in more detail with lessons to be learned in relation to the use of expert committees generally. We set out here those derived specifically from the Southwood Report.

Lessons

- An advisory committee should draw a clear distinction between any information provided by others, which it has not reviewed, and its own conclusions.
- An advisory committee should explain the reasoning on which its advice is based.
- When giving advice, an advisory committee should make it clear what principles, if any, of risk management are being applied.
- An advisory committee should not water down its formulated assessment of risk out of anxiety not to cause public alarm.
Lessons from the introduction of the animal SBO ban

Commentary

1276 The animal SBO Order suffered from fundamental defects which rendered it unenforceable. It was prepared in haste and without consultation. It was also prepared without the rigorous thought that should have been given to the need to introduce Regulations that were enforceable and the manner in which the Regulations should have achieved this.

Lessons

• Where a precautionary measure is introduced, rigorous thought must be given to every aspect of its operation with a view to ensuring that it is fully effective.

• If this cannot be done before the measure is introduced, it should be done as soon as possible afterwards.

Lessons from the implementation and enforcement of the animal SBO ban

Commentary

1277 The widespread disregard, both deliberate and accidental, of the animal SBO ban, was due in part to defects in the Regulations, in part to lack of enthusiasm among local authority inspectors and in part to lack of rigour by the Veterinary Field Service (VFS) in monitoring enforcement. We believe that the VFS’s lack of rigour was in part a consequence of the fact that it had no statutory monitoring function and no right of access to slaughterhouses.

Lessons

• When Regulations that have implications for human or animal health fall to be enforced by local authorities: 107
  – clear guidance should be given to the local authorities as to the importance of the Regulations and the manner of their enforcement;
  – there should be statutory provision enabling central government to monitor the standards of compliance and enforcement.

• Measures that depend on particular slaughterhouse procedures being followed need to be based on informed understanding of practical working conditions.

107 This lesson is derived equally from the enforcement of the human SBO ban
Lessons from the introduction of the human SBO ban

Commentary

1278 We have been critical of the fact that the merit of the introduction of this precautionary measure was diminished by:

i. the delay in appreciating that it was desirable to introduce a ban, consequent upon failure adequately to review the Southwood Report;

ii. the public presentation of the reason for the ban, which suggested that it was not an important public health measure; and

iii. the failure to identify that the practice of mechanical recovery of meat called for special consideration.

Lessons

- Government Departments must retain ‘in house’ sufficient scientific expertise to enable them to understand and review advice given by advisory committees.

- Government Departments must review advice given by advisory committees to ensure that the reasons for it are understood and appear to be sound.

- Where a precautionary measure is introduced, rigorous thought must be given to every aspect of its operation with a view to ensuring that it is fully effective and its purpose and application understood by those concerned.

- Government Departments should clearly tell both the public and those responsible for enforcement the reasons for, and the importance of, any precautionary measures that they introduce.

Lessons from the final months

Commentary

1279 The Government was taken by surprise and wrong-footed by the announcement by SEAC that a new variant of CJD had been identified which was probably linked to BSE. It should not have been. The growing apprehension that this might be the case had been expressed by Dr Will and other members of SEAC at its meetings on 5 January 1996 and, more forcibly, 1 February. Representatives of MAFF and DH present at those meetings did not put their colleagues on the alert that SEAC might be moving towards this conclusion. The possibility of this should nonetheless have been appreciated by those who received the reports of the SEAC meetings. They did not, however, consider any contingency plans. There were no interdepartmental discussions about the gathering storm. Everyone waited to see what SEAC had to say.
Lessons

- Departmental representatives attending meetings of advisory committees in the capacity of secretariat or observers should see that their Departments are promptly informed of any matters which may require a response from government.

- Contingency planning is a vital part of government. The existence of advisory committees is not an alternative to this. The advisory committees should, where their advice will be of value, be asked to assist in contingency planning.

Lessons in respect of Wales, Scotland and Northern Ireland

Commentary

1280 An outbreak of an infectious animal disease may pose threats over a wide geographical area and the effectiveness of the response must not be inhibited by purely administrative boundaries. BSE proved to be a UK-wide problem and the lessons to be learned are those which relate to such a problem.

1281 It will usually be desirable where there is a problem common to the UK threatening animal health, or both animal and human health, that a common solution should be found, that the same legislative measures should be introduced at the same time and that enforcement standards should be similar.

1282 When BSE emerged, the Territories were, in general, content to follow the lead of MAFF and DH. Under devolution a similar attitude cannot be relied upon. SEAC’s advice was the critical element in the formulation of policy, but SEAC reported only to MAFF and DH. We do not consider that this was the most satisfactory arrangement then and it certainly would not be satisfactory today. Moreover, information and expertise existed in the Territories that might usefully have informed UK policy-making. It is important that advice and information should be shared by all those who are responsible for animal and human health in the United Kingdom.

Lessons

- Arrangements need to be in place which will facilitate a synchronised approach throughout the United Kingdom to common problems of animal health, or animal and human health.

- Advisory committees set up to advise on problems of animal health, or animal and human health, which are common throughout the United Kingdom should report to the appropriate Departments both in England and in the Territories.

- So far as animal diseases, particularly those which may involve risk to human health, are concerned, a clear understanding should exist as to:
  i. the identification of those areas where a uniform and synchronised policy and/or implementation is required and who is to take the lead;
ii. the sharing of resources and information;
iii. a structure for consultation and joint decision-making that minimises unnecessary delay.

Lessons from the emergence of vCJD

Commentary

1283 The transmission of BSE to humans was considered most unlikely, but it has happened. The normal incubation period is not yet known, though if that of kuru is any guide, it is likely to be long. It is too early to estimate the number of people who are at present incubating the disease.

Lessons

- Although likelihood of a risk to human life may appear remote, where there is uncertainty all reasonably practicable precautions should be taken.
- Precautionary measures should be strictly enforced even if the risk that they address appears to be remote.
- All pathways by which vCJD may be transmitted between humans must be identified and all reasonably practicable measures taken to block them.
- The needs of victims of vCJD and their families have special features. Consideration should be given to how best the health and welfare services can meet them. Patients for whom a care plan has been carefully arranged have received better management than those for whom this is lacking.

Lessons from the handling of non-food routes of transmission to humans

Commentary

1284 The widespread use of bovine material for a whole range of food and non-food purposes created a large number of potential pathways of infection of BSE to man. The same is true of any potentially zoonotic disease. Handling of the risks to humans calls for the identification of all such pathways, availability of appropriate powers to address the risks and clear allocation of responsibility for doing so.

Lessons

- A comprehensive review to identify all the potential pathways of infection to humans, including those from waste disposal, for a potentially zoonotic disease should be undertaken as a basis for taking steps to prevent transmission. This review should involve all relevant Departments and draw on outside expertise as necessary.
Lessons to be learned

An overall handling plan with consistent objectives and a timetable should be drawn up and lead responsibility for dealing with each pathway clearly allocated.

The legislation applicable to different types of product may provide differing and sometimes inconsistent powers for dealing with similar risks or raw materials. Consideration should be given to the need for a power to cut off supply of a widely used but potentially toxic raw material at source.

Occupational health risks should be considered in relation to each of those pathways and advice or warnings be promptly provided.

Lessons from the approach to BSE and medicines

Commentary

A potential zoonosis with a long incubation period throws up particular problems for the systems that exist to ensure the safety of human and veterinary medicinal products. While Medicines Act licensing decisions need to be insulated from undue pressures, they also need to be taken on a fully accountable basis.

Lessons

- Reliance on reported adverse reactions will not result in the timely identification of problems arising from a disease with a long incubation period. A database of concerns other than those resulting from adverse reactions should be considered.

- The licensing authorities, their advisory committees and others involved in the medicines licensing system each have information and expertise in relation to potential zoonoses that will be of use to the other. Effective action in respect of such diseases depends on this being shared. MAFF, DH and the Medicines Commission should consider what improvements might be needed to existing collaborative arrangements.

- It is not always clear in practice where responsibility rests as between Ministers, officials and advisory committees for advising, determining policy and taking key decisions on medicines. This should be clarified, so as to ensure that important policy decisions are taken by, or approved by, Ministers, whether those decisions are to take action or to take no action.

- The extent of the requirements of confidentiality in relation to the licensing of medicines should be reviewed.

- Medicines Advisory Committees should make clear what is a scientific assessment and what is a value judgement, so that value judgements are not treated as expert assessments of risk.

- Ring-fencing of medicines decisions to insulate them from outside pressures can reduce accountability. There should be properly reasoned and recorded decision-taking, and the criteria being applied should be made openly available.
• Thought should be given to ways of ensuring that those licensing animal-derived medicinal products are properly informed about the sources and collection of materials.

**Lesson from the approach to BSE and cosmetics**

**Commentary**

1286 Addressing the possible risks posed by BSE in relation to cosmetics was impeded by lack of knowledge about the cosmetic products available, their composition and uses.

**Lesson**

• DTI should review the need to maintain data on products which offer a potential pathway of infection.

**Lesson from the approach to BSE and occupational risk**

**Commentary**

1287 Delays in drafting and issuing guidance in respect of occupational risks posed by BSE were inordinate.

**Lesson**

• The Health and Safety Executive (HSE) should consider means of ensuring that the issue of guidance in respect of risks impacting on different occupations is carried out in a manner which is coordinated and expeditious.

**Lesson in relation to pollution and waste control**

**Commentary**

1288 The pathways by which the BSE agent might come into contact with humans and animals as a consequence of the disposal of waste did not receive adequate consideration prior to March 1996.

**Lesson**

• The disposal of waste from any processing of material that may contain the BSE agent should be reviewed to ensure that it does not involve risk of infection of humans or animals.
Lessons in relation to research

Commentary

We have noted the very large number of research projects that were undertaken in response to BSE. We have also drawn attention to a number of areas where, with hindsight, we can see that research could profitably have been started earlier or pursued with more vigour. Had an improved structure for research coordination been in place, many of these deficiencies might have been avoided.

Lessons

- Where a problem in animal and human health arises that leads to demands for research of the scale and diversity required by BSE, it is desirable that Government Departments and Agencies coordinate their efforts.
- Coordination of the research effort is desirable in order to achieve:
  - identification of gaps in research;
  - determination of research priorities;
  - identification of the best sources of expert assistance;
  - a well-constructed plan for funding from the outset;
  - competition for research projects;
  - peer review of projects; and
  - efficient arrangements for provision of clinical material to researchers.
- The progress of research and the implications of any new developments must be kept under continuous and open review.
- Our conclusion that BSE was probably present in the cattle herd in the 1970s may have implications for past and current assessments of risk which have assumed that the earliest date of infection was around 1980. This illustrates the importance of setting out assumptions and keeping them under review.
- What is now known about the relative sensitivity of mouse bioassay compared with calf bioassay may have implications for the conclusions drawn from mouse bioassays. These need to be reconsidered systematically.

The use of scientific advisory committees

Commentary

Volume 4 of our Report deals in detail with the assistance provided by the Southwood Working Party and Volume 11 with the assistance provided by the
Tyrrell Committee and SEAC. The Government relied heavily on the advice of SEAC during most of the period with which we are concerned, and in Volume 11 we discuss, with commentary, the lessons to be learned from the use of this Committee. We shall not repeat that commentary here, but briefly itemise the lessons which apply to such committees.

Lessons

Setting up the committee

- The areas of advice that are required from the advisory committee should be identified as precisely as possible before the committee is set up.
- The terms of reference should specify with as much precision as possible the role of the committee.
- The composition of the committee should include experts in the areas of the advice that is likely to be required.
- Those invited to join a committee should be given a realistic estimate of the commitment required.
- A lay member can play a valuable role on an expert committee.108
- Government should seek advice from the professional or other body best qualified to advise on suitable candidates for membership.
- Potential conflicts of interest should not preclude selection of those members otherwise best qualified, but conflicts of interest should be declared and registered.
- Where any item of business involves an apparent conflict of interest on the part of a member, that should be declared.
- Where the workload of a committee is considerable, it is reasonable that members who are not public servants should be remunerated.
- It will often be desirable to draw the secretariat from the commissioning Department(s) in order to provide a two-way channel of communication.
- In such cases, as in all cases, the secretariat must be careful to respect the independence of the committee.

The role of the committee in relation to policy

- Where a policy decision is urgent, consideration should be given to whether delaying the decision pending advice from an advisory committee is the best course.
- Consideration should be given at the outset to the manner in which the committee will contribute to deciding policy.
- Government should recognise that if a committee is asked to advise which policy option to adopt, there may be little alternative but to follow the advice given.

---

108 See the section below on ‘Dealing with uncertainty and the communication of risk’
Where the policy decision involves the balancing of considerations which fall outside the expertise of the committee, it will normally not be appropriate to ask the committee to advise which policy option to adopt.

It may be appropriate to ask the committee to set out a range of policy options, together with the implications of each.

Where advice is sought on the implications of policy options, this may best be achieved by dialogue between government and the committee.

Where advice is required only on those ingredients of a policy decision which fall within the particular expertise of the committee, questions should be formulated with precision to achieve that result.

Where a Department has concerns about the practical implications of advice that a committee may give, these should be placed openly before the committee.

Where a committee is asked to advise on risk management, it will normally be helpful for the committee to follow a formal structure based on recognised principles of risk assessment.

**The form of the advice**

- Advice should normally be given in writing.
- Advice should be in terms that can be understood by a layperson.
- Advice should clearly state the reasons for conclusions.
- Assumptions underlying advice should be made clear.
- Advice should identify the nature and extent of any areas of uncertainty.
- Where appropriate, the advice should set out the different policy options and the implications of each.

**Communication of the advice**

- The advice of the committee, together with any papers necessary for the full understanding of that advice, should be circulated to all within government with responsibility for policy decisions in respect of which the advice is relevant.
- The advice of the committee should normally be made public by the committee.
- The proceedings of the committee should be as open as is compatible with the requirements of confidentiality.
Review of the advice

- Departments should retain ‘in house’ sufficient expertise to ensure that the advice of advisory committees, and the reasoning behind it, can be understood and evaluated.

- Advice given by a committee should be reviewed by those to whom it is given to ensure that the reasons for the advice are understood and appear sound.

- Where the reasoning of the advice of a committee is unclear, clarification should be obtained from the committee.

Dealing with uncertainty and the communication of risk

Commentary

1291 Some argue that it is not the task of government to protect the public against risk in circumstances where the individual can accept or avoid the risk by making his or her own informed choice. Where the hazard is transparent and one that the individual can readily avoid, this argument has force. Most people believe, however, that government has an important role to play in reducing the extent to which the consumer is exposed to hazard. They believe, for instance, that the Government should do all that is reasonably practicable to see that the food that they eat and the medicines that they take are reasonably safe.

1292 The Government adopted this approach in seeking to protect the public from the possibility that BSE might pose a hazard to human health. We have already considered the extent to which the way that it set about achieving that objective was an adequate response to the emergence of BSE. At this point we are concerned with the lessons to be learned from one aspect of the response that proved particularly unsatisfactory – communication of risk to the public. Although we have made a number of individual criticisms in respect of risk communication, the lessons to be learned are based on hindsight and relate to the overall approach of reassurance that was adopted. We do not consider that individuals should be criticised for following that approach.

1293 The problem is not an easy one. The public are anxious to understand the basis upon which the Government’s decisions on risk management are taken. The Government does not set out to achieve zero risk, but to reduce risk to a level which should be acceptable to the reasonable consumer. The individual consumer wishes to be satisfied that the Government has drawn the line in the right place. How can the Government best satisfy the public that this aim has been achieved? We discussed this question with a number of witnesses.

1294 Throughout the BSE story, the approach to communication of risk was shaped by a consuming fear of provoking an irrational public scare. This applied not merely to the Government, but to advisory committees, to those responsible for the safety of medicines, to Chief Medical Officers and to the Meat and Livestock Commission. All witnesses agreed that information should not be withheld from the public, but some spoke of the need to control the manner of its release. Mr Meldrum spoke of the desirability of releasing information ‘in an orderly fashion’ – of
ensuring that the whole package of information was put together, taking care in the process not to ‘rock the boat’.

1295 Mr Brian Dickinson, who was a member of MAFF’s Food Safety Group, put the matter in this way:

Given the strength of public debate on the matter at the time one was aware of slightly leaning into the wind. You could not just stand upright and give a totally impartial, objective view of what was the situation. There was a stronger danger of being misinterpreted one way rather than the other, and we tended to make more reassuring sounding statements than might ideally have been said.

1296 We felt that this was an accurate description of the general approach to risk communication. We have seen that it provoked increasing scepticism and, on 20 March 1996, the reaction that the Government had been deceiving the public.

1297 In discussing this topic with us, Sir Robert May, Chief Scientific Adviser, expressed the following view:

You can see the temptation on occasion to wish to hold the facts close so that you can have internal discussion and the formation of a consensus so that a simple message can be taken out into the market place. My view is strongly that that temptation must be resisted, and that the full messy process whereby scientific understanding is arrived at with all its problems has to be spilled out into the open.

1298 This view received strong support from representatives of the consumer organisations. They emphasised the need for open scientific debate. Ms Sheila McKechnie, the Director of the Consumers’ Association, emphasised the need to develop a culture of trust. She commented that:

There is nothing more nanny-ish than withholding information from people on the ground that they may react irrationally to that information.

1299 She made the point that organisations build up credibility by openness. She expressed the hope that the Food Standards Agency would achieve this.

1300 Everyone agreed that the Government had a problem with credibility. A number of Government Ministers told us that they had lost credibility with the public, so that it was necessary to get independent experts to lend credibility to public pronouncements about risk. Mrs Bottomley spoke of the need for the public to receive information free of ‘political overtones’. She told us that she did all that she could to promote the Chief Medical Officer as an independent expert who could be trusted by the nation.

1301 Our experience over this lengthy Inquiry has led us to the firm conclusion that a policy of openness is the correct approach. When responding to public or media demand for advice, the Government must resist the temptation of attempting to appear to have all the answers in a situation of uncertainty. We believe that food scares and vaccine scares thrive on a belief that the Government is withholding information. If doubts are openly expressed and publicly explored, the public are
capable of responding rationally and are more likely to accept reassurance and advice if and when it comes. We note, by way of example, that SEAC and MAFF have made public the fact that an investigation is being carried out into the question of whether BSE has passed into sheep. We do not understand that this has led to a boycott of lamb.

**Lessons**

- To establish credibility it is necessary to generate trust.
- Trust can only be generated by openness.
- Openness requires recognition of uncertainty, where it exists.
- The importance of precautionary measures should not be played down on the grounds that the risk is unproved.
- The public should be trusted to respond rationally to openness.
- Scientific investigation of risk should be open and transparent.
- The advice and the reasoning of advisory committees should be made public.
- The trust that the public has in Chief Medical Officers is precious and should not be put at risk.
- Any advice given by a CMO or advisory committee should be, and be seen to be, objective and independent of government.
- The role, if any, of the Chief Veterinary Officer in making public statements in relation to risk to human health from a zoonosis or potential zoonosis should be clarified.
- The activities of the Meat and Livestock Commission (MLC) in the period up to 20 March 1996 do not appear to have represented all its statutory objectives. The MLC has submitted to us proposals in relation to its future role. We recommend that these receive consideration in the light of our Report.

**The legislative framework**

**Commentary**

1302 The Government’s response to BSE adopted different approaches to dealing with the risk that the BSE agent in cattle incubating the disease or showing signs of it might be transmitted to other animals or to humans.

- Cattle showing clinical signs were compulsorily slaughtered and destroyed.
- The incorporation of high-risk tissues from apparently healthy cattle in human food was forbidden.
- The incorporation of ruminant protein in feed for ruminant animals was banned.
- The incorporation of high-risk tissues from apparently healthy cattle in animal feed was banned.
The disposal of high-risk tissues was regulated so that, in effect, they could only be disposed of as waste.

The use of bovine products or by-products of UK origin in the manufacture of medicinal products was phased out in compliance with guidelines.

Recovery of mechanically recovered meat (MRM) from the spinal column of cattle was forbidden.

The problem

1303 The statutory powers relied on in adopting these measures were enacted in order to deal with known hazards. However, while it was established that BSE was a major disease threat to cattle, it was for several years unknown whether it was a hazard to human beings and other animals, and if so, how great a risk it posed. The generally held belief of the Government’s scientific and veterinary advisers was that BSE probably did not pose a risk to human beings, pigs or poultry. Moreover, even the risk to cattle was not fully established; it was unknown whether BSE could infect cattle other than by some form of ingestion. Thus an unusual feature of the BSE story was that the Government imposed Regulations to address risks that scientists believed probably did not exist, or at least could not confirm as probably existing.

1304 The Government had to take action on BSE in the face of two other significant uncertainties. First, in the absence of a diagnostic test for BSE in live animals, it was impossible to know which animals might be incubating the disease. It could be statistically demonstrated, in the case of any individual animal at the time of slaughter, that that animal was very unlikely to be incubating BSE. Second, it was probable that not all parts of an infected animal might carry infectivity sufficient to transmit the disease to other animals of its own or other species.

1305 The evidence disclosed a number of occasions on which lawyers in MAFF’s Legal Department expressed concern as to whether precautionary measures which were being proposed fell within the powers conferred by the legislation under which they were to be introduced. We consider it desirable that legislation should clearly empower Ministers to take precautionary measures in a situation where the existence of a hazard is uncertain. We believe that there are areas where this may not be the case. We have not attempted a detailed analysis of the law in these areas, for this is not part of our task. We draw attention to them so that they may receive further consideration.

Power to order the slaughter of animals

1306 Section 32(1) of the Animal Health Act gives the Minister power, if he thinks fit, to order the slaughter of ‘any animal which is affected or suspected of being affected with any disease to which this section applies, or has been exposed to the infection of any such disease’.

1307 Mr MacGregor used this power when introducing the slaughter and compensation scheme in August 1988. The primary reason why he did so was in order to address what was considered to be the remote possibility that BSE was transmissible to humans.
MAFF lawyers expressed doubts as to whether s.32(1) could be used in these circumstances. We do not know whether these doubts were resolved or, if they were, on what basis. We consider that there was certainly scope for doubt as to the extent of the Minister’s powers under s.32(1), having particular regard to the fact that:

i. scientists considered it unlikely that BSE was transmissible to humans; and

ii. BSE had not at that time been designated a zoonosis under S.29 of the Act.

Consideration was given to a policy of slaughtering animals in the same herd as a BSE victim, or slaughtering the offspring of BSE victims, because of the possibility that BSE might be vertically or horizontally transmissible. Again we think that there would have been some doubt as to the power of the Minister to introduce such a policy under s.32(1) of the Act, having regard to the uncertainty as to the manner in which BSE might be transmitted.

An animal which was not showing clinical signs of BSE would not, ordinarily, be said to be ‘affected with the disease’. Furthermore, even if the word ‘affected’ in section 32(1) included pre-clinical infection, it would be difficult to say of any such animal that it was ‘suspected of being affected with BSE’, since statistically this would be highly improbable in the case of any individual animal. Nor is it clear that an animal could properly be described as ‘exposed to infection’ in circumstances where it was uncertain whether transmission of infection was possible.

**Power to order the destruction of parts of an animal**

Section 1 of the Animal Health Act 1981 gives Ministers power to make ‘such orders as they think fit . . . for the purpose of in any manner preventing the spread of disease’, and section 8 gives them power to make ‘such orders as they think fit’ for prohibiting and regulating the removal of ‘carcasses, fodder, litter, dung and other things’. Section 35(1) of the Act also gives Ministers power to order the seizure, and impose requirements for the destruction, burial, disposal or treatment, of ‘anything, whether animate or inanimate, by or by means of which it appears to them that any disease to which this subsection applies might be carried or transmitted’.

The powers under section 35(1) were used in 1991 to give MAFF the power to seize, destroy and dispose of the carcasses of animals suspected of having died from BSE. The powers under sections 1 and 8 were used to protect human health by ordering the destruction of milk from cows affected by BSE, after BSE had been designated a zoonosis.

These sections of the Animal Health Act are in very wide terms. The question arises of whether they could have been used to order the destruction of SBO as a precautionary measure to safeguard human health, whether through foodstuffs or any other consumer product. We consider that had such a course been adopted, a challenge might have been anticipated on the grounds that:
i. it was statistically highly unlikely that any individual animal was incubating the disease; and

ii. scientists believed it unlikely that tissues from an animal incubating the disease posed any risk to humans.

We do not suggest that such a challenge would necessarily have succeeded.

**Power to ban the use of material for specified purposes**

Apart from the slaughter and compensation policy, which related only to cattle diagnosed as showing clinical signs of BSE, and the power to seize and destroy carcasses of animals suspected of having died of BSE, the Government did not order the compulsory destruction and removal from circulation of any animals, parts of animals or material derived from or connected with animals which might have been incubating or exposed to BSE. Instead, the Government adopted the alternative approach of banning the use of potentially infective material for particular purposes. Thus the ruminant feed ban prohibited the use of ruminant protein in feed for ruminants; the human and animal SBO bans prohibited the use of particular bovine tissues in food for human and animal consumption, and subsequently prohibited the movement of MBM derived from SBO material to any unlicensed destination; and MRM derived from bovine vertebral columns was banned from use in human food. The question arises whether Ministers had adequate powers to adopt the approach of banning suspect material for particular purposes in the face of the uncertainties about BSE which we have outlined above.

Under a range of different statutes, Ministers had power to take action to block potential routes of transmission of animal diseases by imposing requirements as to the manufacture, sale or supply of products which might incorporate animal material. Thus:

- the Animal Health Act, the Food Act 1984 and its successor, the Food Safety Act 1990, gave the relevant Ministers power in certain circumstances to ban animals and animal tissues from incorporation in food for animal and human consumption;

- the Consumer Protection Act 1987 gave the Secretary of State for Trade and Industry power to make provisions for the purpose of securing that goods were safe, and for the purpose of securing that goods which were unsafe were not made available to persons generally;

- the Environmental Protection Act 1990 gave power to regulate the release of harmful substances into the environment; and

- the Medicines Act 1968 gave the licensing authorities power to impose requirements as to methods of manufacture or as to product ingredients as a condition of granting product licences for human and veterinary medicines.

In the case of the powers granted by each of these statutes, questions were liable to arise as to whether they empowered action on a precautionary basis in circumstances where the existence of risk was not merely uncertain, but considered very unlikely. Thus, when it was proposed to introduce the human SBO ban in June 1989, MAFF lawyers advised the administrators that ‘given that it is not possible to
prove that the offal to be banned is in fact “unfit” for human consumption, it will be necessary to be able to justify the reasonableness of provisions made as to use’. They recognised the possibility of a challenge to a ban introduced under the Food Act in order to protect humans from a risk which was far from established, and in fact considered to be remote.

### Legislative constraints in relation to medicines

1318 The Food Act 1984 and the Food Safety Act 1990 contained powers to prohibit the sale or use of any specified substance or any substance of a specified class in or as food intended for sale for human consumption. As MAFF lawyers pointed out when the provisions of the human SBO ban were being considered, this power did not enable prohibition of the use of these substances in or in the production of medicines. The legislative scheme for regulating the safety of medicines was very different.

1319 In granting or renewing any product licence under the licensing regime established by the Medicines Act, the licensing authorities could have made it a condition that material from BSE-affected cattle, and SBO from any cattle, should not be used in the manufacture of a product. However, it does not appear that the licensing authorities could have made this a general requirement to cover all human and veterinary medicinal products. They could only have acted on a case-by-case basis by including such a requirement in every licence for a product which might include such material, as and when an application was made for the grant or renewal of a product licence.

1320 As for existing licences, the statutory power to suspend, revoke or vary a licence was subject to a requirement that the licence holder should be given notice of the intention to revoke or vary the licence and afforded an opportunity to appear before the relevant section 4 committee or to make representations in writing as to the proposed revocation or variation. While the licensing authority had power to suspend an individual licence with immediate effect in the interests of safety, such suspension could not exceed a period of three months pending consideration as to whether the licence should be varied or revoked, and the licence holder was entitled to appear before the relevant committee and to make representations on the matter.

1321 If, in response to BSE, the licensing authority had wished to use its statutory powers to ensure that UK bovine material was not used in the manufacture of medicinal products, it seems that it would have had to revoke or vary every relevant product licence (possibly after a suspension of up to three months), and in doing so it would have had to give each current licence holder or applicant the opportunity to appear before the relevant section 4 committee to argue against the proposed revocation or variation. This would have been an administrative nightmare. In these circumstances it is not surprising that the decision was taken to issue guidelines rather than attempt to use formal statutory powers.

1322 We consider that it might be of value if licensing authorities had a statutory power under the Medicines Act to impose a general prohibition on the use of substances which are considered to be unsafe in the manufacture of any human and

---

109 YB89/6.12/3.1
110 Section 29 and schedule 2, paras 1–14
veterinary medicines. We appreciate, however, that this suggestion may not be compatible with a regulatory regime which is now governed by European law.

**Legislative constraints in relation to cosmetics**

1323 Cosmetics is another area where the regulatory regime is governed by European law. The Cosmetic Products (Safety) Regulations 1989 give effect to the 1976 EC Cosmetics Directive. Little scope is left for independent regulatory action by the UK Government, and effecting changes to European Regulations can be a lengthy business.

1324 In these circumstances we were told that in practice the regulation of the cosmetics industry operated on an informal and voluntary basis, under which guidance was given to and implemented by the industry. This was the course adopted in relation to BSE. It does not seem to us that this regulatory regime caters satisfactorily for a situation such as the emergence of BSE.

**General constraints of European law**

1325 When a manufacturer of MRM sought judicial review of the Specified Bovine Offal (Amendment) Order 1995, one of the arguments put forward was that once definitive measures for a relevant outbreak of disease had been adopted by the European Commission at the EU level, individual Member States were no longer entitled to adopt unilateral measures to deal with the risks posed by the disease.

1326 The High Court granted leave to seek a judicial review of the Order, thereby indicating that it considered the matter to be at least reasonably arguable. However, the judicial review was abandoned after 20 March 1996, and so this argument was not tested at the time. It may well remain open to those who object to actions taken by the Government to deal with zoonoses generally, and BSE in particular, where those actions go beyond EU measures taken under Directives 89/662/EEC and 90/425/EEC.

1327 If the argument is correct, the consequences are worrying. First of all, it calls into question the lawfulness of the Specified Bovine Offal (Amendment) Order 1995. The Government decided to act speedily to ban the use of bovine vertebral columns in the manufacture of MRM on the advice of SEAC. We believe that such action was clearly desirable in the interests of human health. However, this important measure could have been open to challenge under European law, at least until it was adopted by the Commission in July 1997 by Decision 97/534.

1328 The argument also has implications for the future handling of other zoonoses or potential zoonoses. It suggests that in matters governed by the Directives we have cited, the Government may not be able to take unilateral action in the event of a reassessment of the risks associated with a particular disease outbreak.

1329 We understand that a similar point is currently before the European Court of Justice. We expect that this issue will be reviewed by MAFF when the decision of the Court is known. If, in the light of that decision, there remains any danger that measures for the protection of human or animal health may be readily susceptible to challenge, consideration will need to be given to steps to minimise this danger.
Lessons

- Where an animal disease is identified, which could be transmitted to animals or humans via a range of possible routes, powers under UK and European law which enable Ministers to order the slaughter of animals, and the destruction of animal tissues or anything which might carry infection, should not be restricted merely because it cannot be established as a reasonable probability, as opposed to a mere possibility:
  
  i. that the disease is transmissible; or
  
  ii. that a particular animal may be infected by the disease in question; or
  
  iii. that particular organs or tissues in an animal may carry infection.

- Similarly, any powers under UK and European law which enable Ministers to adopt an alternative approach of banning the use of any substances for particular purposes in order to protect human or animal health should not be restricted merely because one or more of the matters referred to above cannot be established as a reasonable probability, as opposed to a mere possibility.

- Current medicines and consumer protection legislation should be reviewed with a view to giving the Government power to act swiftly and comprehensively to ban the use of any substances or processes which might pose a risk to human or animal health.

- The Government should review and clarify its powers under European law to introduce emergency measures for the protection of public and animal health in relation to outbreaks of disease where measures have previously been taken by the European Commission.

The experience of vCJD victims and their families

Commentary

1330 Members of the families of 15 young victims of vCJD came to tell us of what they had experienced. Many more provided us with statements. The description of the clinical treatment of the disease that has been set out in Volume 8 does not fully bring home the horror of what in each case was a harrowing personal tragedy. It is particularly hideous to see young people struck down by a destructive neurological disease of the kind that more usually strikes those who have enjoyed something close to a full life-span.

1331 The start of the nightmare is an inexplicable change of personality. A happy, outgoing and confident young person develops mood swings, depression and lapses of short-term memory. Worried parents or relatives consult their GP, who can find no clinical signs and prescribes an anti-depressant. As the symptoms worsen a referral to a psychiatrist follows.

1332 The psychiatrist finds no sign of organic disease and treats the patient for psychiatric illness, sometimes as an inpatient in a psychiatric ward, where both the environment and the treatment are inappropriate. No improvement follows. For the victim and the relatives this is a time of acute anxiety, but worse is to follow. Neurological symptoms supervene: pins and needles and pains in the limbs,
unsteadiness of gait, failures of muscle coordination. A referral is made to a neurologist. A neurological condition is diagnosed – the nature of it may not be. There are other conditions that have similar signs and symptoms to those of vCJD.

1333 Different tests are carried out, some invasive and unpleasant. Sometimes vCJD is suspected, sometimes it is not. The symptoms worsen: speech difficulties, impairment of intellect, involuntary movements, incontinence, progressive immobility until the victim is bedridden. It becomes plain that there will be no recovery.

1334 Some families want to care for their loved one at home until the end comes. Others seek a suitable hospital or hospice. In either case their anxiety is that the patient’s final days should be spent in a caring, secure and comfortable environment.

1335 The victims of vCJD and their families have special needs. Degenerative neurological diseases of the young are rare. The structure of the health service makes no special provision for them. Hospital facilities for the elderly who are terminally ill are seldom the place for young people. Hospices that care for those whose days can be numbered may be reluctant to accept patients for whom it is impossible to predict when the end will come.

1336 The evidence that we received showed widely varying standards of management and care of victims of vCJD and of support for their families.

Lessons

1337 What is needed includes:

- as speedy as possible a diagnosis of vCJD;
- informed and sympathetic advice to relatives about the future course of the disease and the needs of the patient;
- speedy assistance for those who wish to care for the victim at home. Needs often include aids for the care of the disabled, modification to the home, financial assistance and respite care;
- a coordinated care package which addresses the needs of the victims and their families; and, if requested;
- a suitable institutional environment for a young person, incapacitated and terminally ill.

1338 It should occasion neither surprise nor individual criticism that these needs were frequently not met in the early days of the disease. We are now able to look back with hindsight. The lesson is clear: the needs of vCJD victims call for a different approach by the health service and the social services departments of local authorities.