6. TSE research: planning, funding and implementation

Introduction

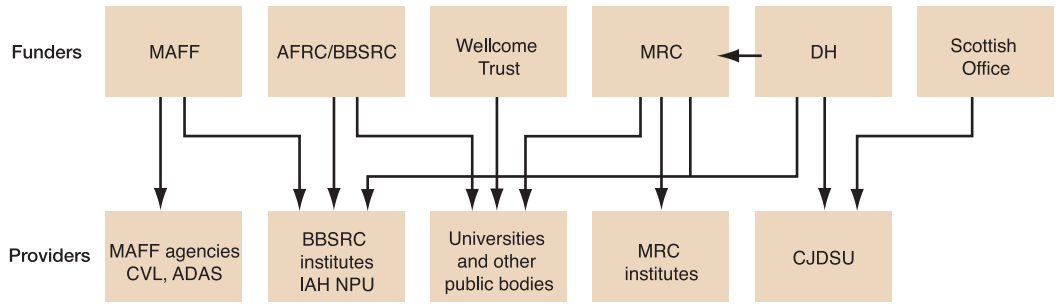
6.1 The establishment and implementation of an appropriate research programme was one of the key elements of the Government's response to the emergence of BSE. Our assessment of the adequacy of this element is given in Chapter 7.

6.2 This chapter describes how government research was organised and implemented, and how the funders and providers – more usually known as 'customers' and 'contractors', for reasons explained below – worked together.

6.3 Between 1986/87 and 1995/96, the Government spent well over £60 million on research into BSE and other TSEs.[673] Of this, £37.9 million came from MAFF; £1.6 million from the Department of Health (DH),[674] including funding for the CJD surveillance programme, further details of which are given in vol. 8: *Variant CJD*; and £27.4 million was provided by the Research Councils. In addition, between 1986 and 1998, TSE research funded by a private medical charity, the Wellcome Trust, amounted to just under £6 million.[675]

6.4 So although there was a shared objective – to find out more about the newly identified disease, BSE, and other similar diseases – the research was funded from several different sources and the work was done in a number of different places. Figure 6.1 below shows which organisations were involved.

Figure 6.1: Funders and providers of BSE- and CJD-related research



Note: EU-funded research is not included in this figure

6.5 Part 1 of this chapter outlines the principles that underpinned publicly funded research in 1986, including the system of Research Councils at arm's length from Government Departments, and the machinery for directing and overseeing this system. Part 2 describes the Public Expenditure Survey (PES) system – the means by which Departments obtained funds from Parliament; considers the two key

673 Between 1986/87 and 1998/99 around £110 million was spent by government
674 Before July 1988, the Department of Health and Social Security (DHSS)
675 M11 tab 7

policy considerations that impacted upon animal disease research from the early 1980s; and looks at the main protagonists – the Agricultural and Food Research Council (AFRC),[676] the Medical Research Council (MRC), the jointly funded Neuropathogenesis Unit (NPU), MAFF and the Central Veterinary Laboratory (CVL), and DH.

6.6 Part 3 describes the establishment of MAFF's TSE research programme, focusing on the early research undertaken by the CVL, and how this programme developed in the light of advice from the Southwood Working Party, the Tyrrell Consultative Committee on Research (the Tyrrell Committee), and the Spongiform Encephalopathy Advisory Committee (SEAC). We conclude with a brief account of the research programmes put in place by other funders.

PART 1: HOW RESEARCH WAS COMMISSIONED AND FUNDED

Before 1986 – background

The 'arm's-length' principle – the Research Councils

6.7 The idea that civilian Government Departments needed scientific support for their work dated back many years. A Medical Research Committee, the direct ancestor of the present Medical Research Council, and an Advisory Council for Research were established in 1913. These and the Research Councils established later remained outside and at arm's-length from Departments. As the Dainton Report of 1971[677] put it:

> For many years past it has been evident that Government departments need scientific knowledge . . . and in some cases large scientific establishments to enable them to carry out their functions. But departments also need to be able to obtain help and independent advice from those who are engaged in strategic and basic science which underpins the work of several departments. It is essential that the advice and information from this source should be free from considerations of administrative and political convenience; but it does not mean that policies for strategic and basic science should be devised without proper regard for public policy.[678]

6.8 In 1965, the existing Research Councils were reconstituted and new ones were set up, making a total of five.[679] Established by Royal Charter, their purpose was 'to foster research and training in the fields specified in their Charters'.[680]

6.9 The Research Councils were 'non-departmental public bodies' and their staff (ie, scientific administrators and scientists employed by them at their headquarters

676 Before 1983, the Agricultural Research Council. In April 1994 the AFRC merged with the biotechnology and biological sciences programmes of the former Science and Engineering Research Council to form a new Biotechnology and Biological Sciences Research Council (BBSRC)
677 *The Future of the Research Council System: report of a CSP [Council for Scientific Policy] Working Group under the chairmanship of Sir Frederick Dainton* (published as an appendix to Government Green Paper Cm 4814, *A Framework for Government Research and Development*, November 1971) (M19 tab 2B), p. 4 para. 13 (hereafter *Dainton Report*)
678 *Dainton Report* (M19 tab 2B), p. 12 para. 35
679 Including the Agricultural Research Council, founded in 1931, and the Medical Research Council, founded in 1920
680 *Dainton Report* (M19 tab 2B), p. 5 para. 14

and in the research units and institutes which they supported) were therefore civil servants. They developed research programmes in two main ways:

i. 'Response-mode' support – proposals, usually but not always short-term, were invited from scientists and universities and similar institutions on any topic within the Research Council's remit. These were subjected to peer review and supported, in descending order of merit, until the available funds had been deployed. The resulting portfolio of research projects was analysed against regular assessments of the needs of the stakeholder and of emerging research opportunities. This could lead to adjustments in the proportion of the budget allocated to different areas of science.

ii. Specific initiatives might be taken to try to develop work in a particular area – for example where a new need had to be addressed early. These would normally be worked up by committees of scientists with relevant expertise, attended by officials from other relevant agencies (eg, other Research Councils and Government Departments).

6.10 Until 1972 the Research Councils were funded almost entirely from the Science Vote held by what was then the Department of Education and Science (DES) and were autonomous in respect of their research programmes – in other words, they decided what work to do without formal involvement or direction by government.

The 'customer/contractor' principle

6.11 Significant changes to this system were introduced from 1972, following the Rothschild Report.[681] Lord Rothschild was critical of the autonomy of the Research Councils in respect of 'applied' research,[682] concluding that:

> This is wrong. However distinguished, intelligent and practical scientists may be, they cannot be so well qualified to decide what the needs of the nation are, and their priorities, as those responsible for ensuring that those needs are met. This is why applied R&D must have a customer.[683]

6.12 He proposed that such research 'must be done on a customer/contractor basis', whereby:

> The customer says what he wants; the contractor does it (if he can); and the customer pays.[684]

A customer department might commission research for its own purposes,[685] or on behalf of others whose interests it represented or sponsored (eg, a particular industry, or particular groups in society, or the public generally).[686] The customer would be responsible for determining:

[681] *The Organisation and Management of Government R&D*, by Lord Rothschild, the then head of the Government's Central Policy Review Staff, published as an appendix to the Green Paper *A Framework for Government Research and Development* (Cm 4814 November 1971) (M19 tab 2A)(hereafter cited as *Rothschild Report*)
[682] That is, R&D with a practical application as its objective, as opposed to basic, fundamental or pure research – see *Rothschild Report* (M19 tab 2A), para. 6
[683] *Rothschild Report* (M19 tab 2A) p. 4 para. 8
[684] *Rothschild Report* (M19 tab 2A) p. 3 para. 6
[685] For example, the Navy commissioning work leading to the development of a new torpedo – M19 tab 2A p. 4 para. 9
[686] For example, the Department of the Environment commissioning R&D work on roads on behalf of the motorist – M19 tab 2A p. 4 para. 9

i. that research was needed to achieve a specified objective;

ii. how much should be spent on that research; and

iii. the relative priorities of different research programmes.

6.13 For such a system to work, Government Departments had to be capable of acting as 'intelligent customers' when commissioning research:

> Subject to certain reservations . . . the executive departments should themselves ensure that they get what they want from the Research Councils.[687]

To do this, they needed to ensure that they had access to specialist advice and to set up internal systems for identifying and assessing needs, determining relative priorities, allocating funds, and monitoring expenditure and outcomes. The *Rothschild Report* envisaged that Chief Scientists would advise and support units within their Departments in fulfilling their function as customers, while Departments would have Controllers of Research and Development (R&D) who acted as 'the chief executive of the R&D function, the contractor providing an R&D service for the customer'.[688]

6.14 Lord Rothschild recommended that the customer/contractor principle should be reflected in the funding system: ie, that a significant proportion of the Science Vote should be transferred from the DES to the relevant Departments to enhance their ability to commission research from wherever they wished.[689] This recommendation was accepted by the Government.[690] Funds were transferred to, among others, MAFF[691] (around 50 per cent of the Agricultural Research Council's budget), and to the then Department of Health and Social Security (DHSS) and the Scottish Home and Health Department (SHHD) (around 25 per cent of the Medical Research Council's budget).

6.15 However, as a result of:

> . . . strict constraints on administrative and staff costs, [DHSS] has not felt justified in . . . developing expertise for a full commissioning role in the biomedical area.[692]

6.16 The original transfer of funds from MRC to the Department of Health (DH) was therefore reversed in 1981.[693] DH did not undertake or commission basic biomedical research itself – the customer/contractor relationship with the MRC envisaged by the *Rothschild Report* was replaced by less formal arrangements set out in a Concordat, which was updated as appropriate.[694] The terms of the Concordat are described later in this chapter.

687 *Rothschild Report* (M19 tab 2A) p. 11 para. 30
688 *Rothschild Report* (M19 tab 2A) p. 6 para. 12
689 That is, to MAFF, DHSS and the Scottish Home and Health Department, the Department of the Environment and the Scottish Development Department, and the Department of Trade and Industry (Rothschild Report, p. 12, Table 4). Funds were also transferred to the Department of Employment – see *Framework for Government Research and Development*, London, HMSO, July 1972 (M19 tab 3), p. 13 para. 50
690 The resulting switches of funds were sometimes described as 'Rothschild transfers' – for example, by Professor Sir Tom Blundell in oral evidence to the Inquiry (T30 p. 19)
691 Acting on behalf of the Welsh Office Agriculture Department (WOAD) as well. The Department of Agriculture and Fisheries for Scotland (DAFS) also funded some agricultural and fisheries research.
692 *Review of the Framework for Government Research and Development (Cm 5046)* (Cm 7499 March 1979) (M19 tab 5), pp. 12–13 para. 37
693 OST Memorandum (DO01 tab 1), p. 4 para. 9
694 Research on BSE funded by the Department of Health: BSE Memorandum DH4/98 (DH01 tab 5), p. 2 para. 8. The 1991 edition of the Concordat is on M11F at tab 2

6.17 Lord Rothschild's other recommendations were also endorsed, and differing structures for commissioning and funding research evolved across Whitehall. Those in place in MAFF and DH between 1986 and 1996 are described below. There were equivalent arrangements in the Scottish Office and the Department of Agriculture for Northern Ireland (DANI); these are outlined briefly in vol. 9: *Wales, Scotland and Northern Ireland*, but played no part in the BSE/vCJD story.

'Near-market research'

6.18 Chapter 6 of vol. 15: *Government and Public Administration* describes how the 1980s and 1990s witnessed an increasing emphasis on value-for-money in the use of resources by Government Departments. Activities were scrutinised to determine whether they needed to be done at all and, if so, whether they should continue to be done by government. In relation to scientific research, the Government concluded that:

> . . . the balance of existing policies should be changed in order to move away from near-market R&D support.[695]

In other words, it withdrew from commissioning and funding research from which industry gained direct benefit.

6.19 The impact of this policy change was particularly significant in the field of agricultural and food research, an issue described below in paragraphs 6.43ff of this chapter.

Overseeing the system (1): the machinery

6.20 The Government's endorsement of Lord Rothschild's recommendations brought with it greater scrutiny of the activities of scientists and a need for them to justify more clearly their demands on public resources, within a generally tougher financial environment.[696] Existing machinery within Departments and across government was developed to manage and control the system, in three respects:

i. oversight of the Research Councils:

ii. liaison between Government Departments, the Research Councils and other organisations involved in research and development; and

iii. scientific advice to and support for the Government.

6.21 During the period with which the Inquiry is concerned, these functions were exercised by, respectively:

i. from 1986 to 1994, the Advisory Board for the Research Councils (ABRC),[697] and thereafter by the Director-General of the Research Councils (DGRC);

[695] White Paper DTI – *the department for Enterprise* (Cm 278 January 1988), p. 33 para. 8.2. 'Near-market research' was R&D aimed at developing a marketable product or process – see OST Memorandum (DO01 tab 1), p. 5 para. 16
[696] OST Memorandum (DO01 tab 1), p. 3 para. 6
[697] As mentioned above, the successor from 1972 to the Council for Scientific Policy

ii. from 1976 to 1987, the Advisory Council for Applied Research and Development (ACARD); from 1987 to 1993, the Advisory Council on Science and Technology (ACOST); and from 1993 the Council for Science and Technology; and

iii. the Government's Chief Scientific Adviser (CSA), supported initially by a Science and Technology Group in the Cabinet Office, and from 1992 by a new Office of Science and Technology (OST).

6.22 Initially, the 'arm's-length' principle was retained, in that the overseeing bodies included independent members from academic institutions and industry as well as representatives from Government Departments and public sector research bodies. However, as described below, this began to change in 1993/94.

6.23 Advice on the allocation of the Science Vote among the Research Councils and other bodies and on the structure of the Research Council system was provided by the ABRC.

6.24 From 1982 to 1987, ACARD[698] coordinated all applied R&D and basic research in collaboration with the ABRC.[699] Then, ACARD was absorbed into a new body, ACOST. This had an independent chairman and its role was to advise the Government on the priorities for and the application of science and technology (S&T),[700] the coordination of S&T activities in collaboration with departmental advisory bodies,[701] and the nature and extent of UK participation in international collaboration in S&T.[702] ACOST's secretariat reported to the CSA, who was a member of ACOST.

6.25 This system was changed significantly in the early 1990s. Firstly, in 1992, responsibility for S&T was moved from the Department of Education and Science (DES) to a Cabinet Minister, the Chancellor of the Duchy of Lancaster, who headed the Office of Public Service and Science (OPSS) within the Cabinet Office. Within the OPSS, a new Office of Science and Technology (OST) was formed, headed by the Chief Scientific Adviser to the Government. The OST's role was to:

- advise the Government on all aspects of S&T;
- promote the effective use of S&T resources;
- develop and coordinate S&T policy;
- maximise the contribution of government S&T expenditure on national quality of life and economic performance;
- assist with taking of decisions on S&T priorities in the Public Expenditure Survey (PES) and the Ministerial Committee on S&T;[703] and
- enable the resolution of cross-departmental S&T issues.

6.26 The OST also became responsible for the Science Budget and for the work of the Research Councils. In 1995 it was transferred from the Cabinet Office to the

698 Set up in 1976 to improve 'the interface between Government and organisations outside it on applied R&D' – see OST Memorandum (DO01 tab 1), p. 4 para. 8
699 OST Memorandum (DO01 tab 1), p. 5 para. 13
700 For the 'benefit of both the public and the private sectors in accordance with national needs'
701 Which included ABRC
702 *Civil Research and Development: Government response to the First Report of the House of Lords Select Committee on Science and Technology, 1986–87* (Cm 185 July 1987) (M19A tab 13), para. 8
703 Chaired by the Prime Minister

Department of Trade and Industry, whose Cabinet Minister, the President of the Board of Trade, assumed responsibility for science.[704]

6.27 Secondly, in the autumn of 1993, ACOST was replaced by a Council for Science and Technology (CST).[705] Chaired by the CSA, the CST was seen as a development of ACOST, drawing on the Technology Foresight programme (a joint exercise between industry and the science and engineering communities) and seeking to ensure that government research spending priorities were informed by outside independent and expert advice.[706] In his oral evidence to the Inquiry, Professor Roy Anderson, who had been a member of ACOST, expressed the view that the CST:

> . . . much to the horror of the scientific community, is less independent of Government [than its predecessor, ACOST].[707]

6.28 A further significant change was made from January 1994, when oversight of the Research Councils was brought within central government. The ABRC was replaced by a Director-General of the Research Councils (DGRC) located within the OST.[708] The DGRC's role was to support and advise the Minister responsible for science on 'securing the successful operation of the seven Research Councils in pursuit of their missions'. This included advising on the allocation of the Science Budget and setting out a broad framework reflecting government and other priorities, within which the Research Councils could decide what science to fund and how.[709]

6.29 At ministerial level, scientific issues were discussed by the Cabinet Committee on Economic Affairs. This was supported by a committee of officials, including the Chief Scientists of Departments, chaired by the CSA and with a joint Cabinet Office and OST secretariat.[710] The committee of officials provided the main forum for the discussion of S&T issues of cross-government interest.[711]

Overseeing the system (2): the role of the Government's Chief Scientific Adviser (CSA)

6.30 There had been a Chief Scientific Adviser (CSA) to the Government since 1964.[712] In 1976 he operated with his own team from the Cabinet Office and from 1992 as Head of the OST.[713] Apart from being responsible for interdepartmental coordination, the CSA was also expected to advise on the way in which the customer/contractor arrangements were working.[714]

6.31 By 1987 the CSA was stated to be:

704 It also had training and technology transfer responsibilities – see OST Memorandum (DO01 tab 1), p. 7 paras 24–6.
705 White Paper, *Realising our potential: a strategy for science, engineering and technology* (Cm 2250 May 1993) (M19 tab 7), para 1.18 (3) (hereafter cited as 'SET White Paper')
706 SET White Paper (M19 tab 7), para 1.18 (3)
707 T4 p. 90
708 SET White Paper (M19 tab 7), para 1.18 (7)
709 *BSE Inquiry: preliminary evidence relating to the Office of Science and Technology (and its predecessors) and the Government's Chief Scientific Adviser* (OST, 26 February 1998) (DO01 tab 3), para. 10
710 T70 pp. 16–17
711 S185B May
712 The post had originated during the Second World War
713 OST Memorandum (DO01 tab1), paras 10 and 22. T70 p. 9
714 Framework for Government Research and Development (Cm 5046 July 1972) (M19 tab 3), p. 5 para. 10

> . . . responsible for providing, or organising the provision of, advice to the Prime Minister and the Cabinet Office on scientific and technological matters, or scientific and technological aspects of other issues . . . [was] concerned to influence positively the economic contribution from Government spending [on] science and technology . . . [and sat] on the principal interdepartmental committees which [dealt] with the scientific and technological issues that [came] before Government.[715]

6.32 The CSA chaired the committee of officials providing S&T advice and support to the Cabinet Committee on Economic Affairs, and was a member of ACOST, of ABRC, and of other UK scientific advisory bodies. The post also carried international responsibilities.[716] As head of the OST, the CSA was responsible for:

i. advising the Science Minister and other Ministers on government S&T expenditure and programmes; and

ii. coordinating the Government's S&T strategy, its use of S&T in policy-making, and S&T input to key policy issues.[717]

Overseeing the system (3): the role of departmental Chief Scientists

6.33 The proper functioning of the customer/contractor system in government depended upon Departments being able to act as 'intelligent customers'. The 1972 White Paper recognised that:

> . . . each Department must also have its own central scientific staff, who are responsible for advice on scientific aspects of departmental policy. They will participate fully in the discussions [with contractors] and ensure that the customer is able to take all ideas into account in stating his needs.[718]

6.34 Some Departments already had Chief Scientists, but DH and MAFF did not. The White Paper announced their intention to create such posts, which were to be supported by 'small' staffs. How this developed is described later in this chapter.

6.35 In 1988 the Government's Chief Scientific Adviser issued 'Criteria for judging the adequacy of arrangements for providing scientific advice'.[719] These described the role and functions of departmental Chief Scientists,[720] which were perceived as threefold:

i. to act as a focus for their Department's requirements for scientific and technological advice and take a strategic view of the content and balance of its research and development programmes to meet those needs;

715 *BSE Inquiry: preliminary evidence relating to the Office of Science and Technology (and its predecessors) and the Government's Chief Scientific Adviser* (OST, 26 February 1998) (DO01 tab 3), para. 2
716 M19A tab 13 Annex A
717 DO01 tab 3 para. 4
718 *Framework for Government Research and Development* (Cm 5046 July 1972) (M19 tab 3), p. 4 para. 8
719 The 'Fairclough Guidelines', quoted as Annex 1 to *Commissioning and funding research in MAFF* (M32 tab 7)
720 Or their equivalents if the scale of the research requirement and/or the size of the Department did not justify such a post

ii. to ensure effective strategic research to support the Department's future policy, and normally to hold or have discretion over a budget to fund strategic research; and

iii. to oversee policy divisions' role as 'intelligent customers', to maintain the quality and consistency with which that function was performed, and to input specialist advice as appropriate.

6.36 The Criteria also stated that departmental Chief Scientists should hold the highest possible professional credentials, have access to Ministers and the Permanent Secretary, and be an integral part of the Department's top management. However, they added that Departments should have access to independent advice of the highest calibre in order to complement internal advice, balance internally generated views, and introduce a wider perspective, especially where the Chief Scientist was a career civil servant.

Summary

6.37 In summary, Government Departments acted as 'customers', commissioning research from a range of 'contractors' including their own in-house laboratories (if they had such facilities), the Research Councils, universities and private sector Research Institutes. DH exercised its 'customer' role less formally than MAFF,[721] through a process of consultation with the MRC governed by a Concordat. Departmental Chief Scientists played an important role in developing their Departments' ability to act as intelligent customers. Government research was overseen at a strategic level by the Chief Scientific Adviser and, at ministerial level, by the Cabinet Committee on Economic Affairs. Oversight of the Research Councils, and of relations between them, Departments and other bodies, was exercised by a number of committees, with extensive cross-representation to facilitate the dissemination of information.

PART 2: COMMISSIONING AND FUNDING OF RESEARCH, 1986–96

Introduction

6.38 The main funders and providers of research into TSEs are shown in Figure 6.1, at the start of this chapter. During the late 1980s, the relationship between these began to change. A key development was the separation of many government executive functions, including those responsible for research, such as MAFF's Central Veterinary Laboratory (CVL),[722] from the policy-making parts of Departments, and their reconstitution as Executive Agencies. As Chapter 6 of vol. 15: *Government and Public Administration* explains, these Agencies operated at arm's-length from their parent Departments, were headed by chief executives

[721] Part 2 of this chapter notes that MAFF's research budget was much larger than DH's, and it therefore commissioned much more research directly

[722] In the late 1980s, the CVL was part of the State Veterinary Service, which was part of ADAS (Agricultural Development and Advisory Service). In 1990 the State Veterinary Service was transferred to MAFF's Food Safety Directorate, and the CVL was set up as an Executive Agency of MAFF. ADAS became an Executive Agency in 1992

who were directly accountable to Ministers, and were financially self-sufficient. Other changes, less obvious, are described here.

Funding – the PES system

6.39 As explained in volume 15, the Treasury was guardian of the public finances and therefore had to agree all departmental spending plans. The annual Public Expenditure Survey (PES) was the mechanism by which the Government planned its expenditure (including on research) for the forthcoming financial year and the two years following (which was known as 'the PES period'). The Government's financial year ran from 1 April to 31 March.

6.40 In the spring of each calendar year, Departments sent the Treasury their expenditure bids for the next PES period. These bids were based on the expenditure levels agreed during earlier PES rounds and, where deemed necessary, proposed additional expenditure on top of these. So bids put forward in, for example, the spring of 1986 would have been for proposed expenditure during the financial years 1987/88, 1988/89 and 1989/90.

6.41 During the following months, these bids were discussed in detail with the Treasury at official level. Next came bilateral discussions between each spending Minister and the Chief Secretary to the Treasury. The bids had to be consistent with the overall figures for public expenditure during the PES period agreed earlier by the Cabinet, and were themselves put to the Cabinet for final agreement in the autumn. When this agreement had been obtained, Departments' budgets were fixed for the following three years. Detailed expenditure 'Estimates' were then presented to Parliament, which voted funds accordingly.[723] Expenditure programmes were funded from specified Votes (in the case of science and technology, the 'Science Vote'), and transfers between these required approval by Parliament, and thus by the Treasury.

6.42 PES bids had to identify, as far as possible, any additional expenditure items (including research) foreseen by Departments as being necessary during the PES period. The Treasury also required Departments to indicate whether and how they could make percentage reductions in their overall spending plans for the PES period – for example, of 2 per cent in the next financial year and 5 per cent in each of the other two years. In putting forward their research funding bids, Departments recognised that, assuming success, such additional funds would not be available until the beginning of the following financial year at the earliest (ie, up to 12 months after the bid was submitted).

6.43 If further spending needs arose during the financial year, the Treasury expected Departments to assess whether these could be met by switching resources from their other budgets.[724] Within Departments, the expectation was that a unit that needed more funds would find them from within its other budgets. For example,

[723] Hence the use of the term 'Science Vote' when referring to the budget for expenditure on science and technology, held during this period initially by the DES and then by the OST

[724] For example, in seeking the agreement of the Chief Secretary to the introduction of the slaughter and compensation policy, the Minister for Agriculture, Fisheries and Food (then Mr John MacGregor) indicated that: 'It should be possible to contain the cost this year within the existing provision for Vote IV 3. I shall need to lodge an additional bid for future years, which we can discuss in the PES' (YB88/6.29/4.2). Acknowledging this, the Chief Secretary noted: 'I consider that you should also be able to contain these relatively small costs within your programme' (YB88/7.6/3.2)

departmental directors of research and development would be expected to seek to fund new research from their existing budgets. Only if this was shown to be impossible could the search be widened to other policy or programme budgets. If these avenues were exhausted, the Treasury could be approached for extra resources from the Contingency Reserve, but such a course was regarded as a last resort.[725] This process could lead to delays in allocating funds for new projects.

6.44 Hence, if a Department needed to respond quickly to new research priorities that emerged too late during the year to be included in the PES bid, it would reappraise its existing projects and programmes and reallocate resources accordingly. This was how MAFF identified funds for research into BSE when the disease was initially identified. If the new priorities required funding over a long timescale, the Department would seek additional resources in the next PES round. However, even if its bid was successful, the new funding would not be available until the start of the following financial year at the earliest, up to 12 months after the bid. MAFF's attempts to secure extra funds for research from the Treasury Reserve are described in Part 3 of this Chapter.

Changing priorities for agricultural and food research

6.45 Research and development was just one of many government programmes, and the research arms of Departments (including the DES, which held the Science Vote and distributed it to the Research Councils) had to operate within the PES system. But research into BSE was also affected by two specific policy decisions.

6.46 The first of these was the decision, described earlier in this chapter, that the Government should withdraw from funding 'near-market research'. This had a direct and significant impact upon MAFF, and also upon the AFRC, because:

> Historically, MAFF had been a Department that represented the interests of the agricultural producer, and for that reason it was accustomed to doing a good deal of research that was focused on the interests of the producer.[726]

6.47 The scale of the impact can be gauged from the outcome of a review in 1987/88 of the research and development programmes of the Agriculture Departments.[727] This assessed the extent to which the Government should continue to fund near-market R&D for agriculture, fisheries and food. It recommended that up to £24.7 million of publicly funded near-market R&D, including £21.5 million spent on agriculture alone,[728] should be considered for industry funding. Of the £21.5 million, £17 million was spent by MAFF, with its Agricultural Development and Advisory Service (ADAS) accounting for £11.3 million and the AFRC for £5.6 million. R&D on livestock was £9.7 million, or 45 per cent of spending on

[725] When the Minister for Agriculture, Fisheries and Food (then Mr John Gummer) sought additional provision from the Reserve for the urgent research recommended in the *Tyrrell Report*, the Chief Secretary was advised by his officials to decline the request; they argued that MAFF had had plenty of time to identify offsetting in-house savings and that 'In any event it is still early in the year to concede a claim on the Reserve' (YB89/08.07/15.2)

[726] S311 Gummer p. 14 para. 42. Mr John Gummer was Minister for Agriculture, Fisheries and Food from July 1989 to May 1993

[727] *Report on a review of expenditure by the agricultural departments on research and development* (April 1988) (M11E tab 14). This was carried out by a senior MAFF official, Mr C J A Barnes, and is hereafter cited as the *Barnes Report*). The 'agricultural departments' were MAFF; the Department of Agriculture and Fisheries for Scotland (DAFS); and the Department of Agriculture for Northern Ireland (DANI). The Report was commissioned by the ministerial subcommittee for science and technology, E(ST), a subcommittee of the Ministerial Steering Committee on Economic Strategy

[728] This represented around 22 per cent of total R&D on agriculture; the rest being work in support of statute, to assist policy formulation or implementation, or basic research – see *Barnes Report*, pp. 7–8 para. 17. The remaining £4.5 million was split between DAFS (£2.8 million) and DANI (£1.7 million) – *Barnes Report* (M11E tab 14), p. 42 Annex IV

agriculture;[729] of this, £4.2 million related to all ruminants, including £3.4 million on cattle.

6.48 Dr David Shannon, MAFF Chief Scientist, told the Inquiry that the final figure for near-market research had been determined at around £30 million:

> Responsibility for this work was passed to industry and a counter-balancing cut of £30m was made in the MAFF and the Scottish Office Agriculture, Environment and Fisheries Department (SOAEFD)[730] R&D budgets. The MAFF cut (as adjusted for inflation) was spread over the financial years 1989/90 to 1991/92 (£3.875m rising to £12.1m and £19.2m).[731]

6.49 The second policy consideration was the decision by Ministers to accept a recommendation in 1985 by the Priorities Board for Research and Development in Agriculture and Food[732] that expenditure on research into animal diseases was disproportionate and should be reduced.[733] A number of witnesses commented to the Inquiry on this recommendation. Dr William Watson, until March 1990 Director of the CVL, considered that the Board's view was 'flawed', in part because it assumed greater availability of information than was in fact the case.[734] Mr William Rees, the Chief Veterinary Officer at MAFF until May 1988, commented that:

> I thought there should be more flexibility . . . They had said that the overall spend on animal disease should be reduced by 20 per cent. You cannot really regulate animal disease in that way. We felt there should be more flexibility, that with a new disease we should be able to get new money for it.[735]

6.50 Professors Peter Biggs and John Bourne, the first two Directors of the AFRC's Institute for Animal Health (IAH),[736] told the Inquiry that this reduction in funding had led between 1983 and 1987 to a 40 per cent reduction in the number of science group staff in the four institutions that made up the IAH.[737]

Funders

The Agricultural and Food Research Council (AFRC), 1986–94

6.51 The AFRC comprised a Council of appointed members and a scientific administrative staff headed by a Director-General. Its role was to support research in its field, by means of:

729 Most of the rest was spent on research into crops and horticulture
730 At that time known as the Department of Agriculture and Fisheries for Scotland (DAFS)
731 S101 Shannon p. 4 para. 15
732 See successive Priorities Board reports on M20. This was an independent body set up to advise agriculture Ministers – ie, those of MAFF, the Scottish and Welsh Offices, and the Department of Agriculture for Northern Ireland (DANI). It was chaired by a senior businessman and included as members others from industry and commerce; an academic; farmers or agricultural specialists; representatives from MAFF, the Scottish Office and the AFRC; and (from 1991) a consumer representative. Officials from the Welsh Office, DANI, and (from 1991) MAFF's Economics and Statistics Group acted as Assessors
733 M20 tab 1 p. 30 paras 8.13–8.14
734 T29 pp. 49–50
735 T54 p. 68
736 When set up in 1986, this was known as the Institute for Animal Disease Research (IADR). It was renamed in 1988
737 S106 Biggs p. 4 para. 13; T44 p. 50

i. financial support (eg, to university departments); and

ii. facilities (ie, laboratories and specialist research units),

and to develop and oversee research programmes. To do this, it supported a network of 'roughly 30'[738] research centres and institutes, employing scientists based in them and in universities.

6.52 The Chairman and members[739] of the AFRC were appointed by Ministers: most by the Secretary of State for Education and Science,[740] but four by the Minister for Agriculture, Fisheries and Food (generally, the Grade 2 Deputy Secretary for Land and Resources, the Chief Scientific Adviser, and the Chief Scientists for Agriculture & Horticulture and for Food were members), and two by the Secretary of State for Scotland. In addition, the Chief Veterinary Officer attended meetings as an Assessor.[741] The MRC was represented by an observer at the AFRC Council, an arrangement reciprocated on the MRC Council for the AFRC.

6.53 Professor Sir Thomas Blundell told the Inquiry that:

> . . . all major decisions coming before the AFRC Council were influenced by MAFF. [Its] four representatives . . . were able to scrutinise and influence AFRC research policy and indeed did so quite frequently.[742]

6.54 However, relations between the AFRC and MAFF could sometimes be tense. In 1991 Dr Peter Bunyan, then MAFF's Chief Scientific Adviser, was accused by the ABRC's Chairman of advocating that the Ministry 'wished to make the Councils creatures of MAFF', because he had expressed the view that the AFRC and the Natural Environment Research Council:

> . . . were not using enough of their own funding to commission relevant basic science in order to underpin the specific applied research which. . . the Ministry required, in order to be sure of achieving the best value from its own R&D spend, including that on BSE.[743]

6.55 Dr Bunyan told the Inquiry that this episode:

> . . . did not contribute to good relations between the Ministry and the Research Councils, which were already under strain over the issue of the appointment of a BSE research co-ordinator[744] and the climate of financial constraint and change.[745]

6.56 From the mid-1980s, the AFRC started to refocus its work, reflecting changed views on priorities. Professor Blundell said that:

738 S73 Blundell p. 2 para. 6. Professor Sir Thomas Blundell was Director-General of the AFRC from January 1991 until March 1994, and thereafter Chief Executive of its successor, the BBSRC

739 'Not less than eighteen nor more than twenty-one' – see *Revised Charter of The Agricultural and Food Research Council* dated 19 October 1983, para. 5 (hereafter 'the AFRC Charter')

740 With the agreement of 'those Ministerial colleagues principally concerned' – see *Framework for Government Research and Development* (Cm 5046 July 1972) (M19 tab 3), pp. 11–12 para. 46

741 See, for example, the minutes of the AFRC meeting on 14 June 1988 (YB88/6.14/3.1–3.3)

742 S73 Blundell p. 2 para. 9

743 S125 Bunyan pp. 11–12 para 5.5. Dr Bunyan wrote a paper (YB91/6.21/1.1–1.7) for the annual meeting between the ABRC and departmental Chief Scientists

744 An episode described later in vol. 11: *Scientists after Southwood*

745 S125 Bunyan p. 12 para. 5.5

> . . . there was a general feeling in Mrs Thatcher's Government, and certainly those connected with the AFRC felt strongly that this was [the Government] view, that . . . there had been enough agricultural research . . . we had more food than we needed, and therefore the research needed to be refocused and the funding decreased. So although there is a formal independence of the Research Council, there was clearly a strong pressure from Government to [reorientate] . . . There was a general move from production-related research towards greater concerns for quality of food . . . [and] the environment. Underpinning that an increased emphasis towards basic science should have research which might not be immediately agricultural; in other words, in cell and molecular biology.[746]

6.57 The AFRC also implemented significant changes to its organisation and its network of research units. These developments were prompted by three factors:

i. the 'Rothschild transfer', described above, of funding away from the AFRC itself to MAFF;

ii. the Government's decision, also described above, to withdraw from involvement in near-market research; and

iii. the Financial Management Initiative in Whitehall,[747] with its stress on clear objectives, targets, and lines of accountability.

6.58 Sir Dai Rees, at that time Secretary-elect of the Medical Research Council, told the Inquiry that in his view the AFRC was under pressure in the 1980s to switch its spending away from its research units towards universities, and hence there had been a need to rationalise the former.[748]

6.59 The Inquiry was also told that there was considerable uncertainty at this time about the AFRC's role and focus. Professor Blundell said that:

> The pressures from Government were in many ways reflected by the large presence of MAFF on the Research Council, which always caused some problems as to what our proper relationship should be as a council with an independent charter . . . We set out strategic views . . . We commissioned research . . . In that sense, we were a customer. But the position was confused, because after the Rothschild transfer, a large amount of the research that had originally been within the [AFRC] was transferred to MAFF.
>
> So, in a sense, the Research Council became the representative for the institutes, and carried a contractor role. So there was a great deal of confusion . . . [as to] whether we were effectively an independent Research Council with a charter, and were customers, or whether we were playing the role of contractor and responding to Government pressures, mainly through MAFF policy changes.[749]

[746] T30 p. 18 incorporating revisions proposed in S73A, Blundell
[747] Described in Chapter 6 of vol. 15: *Government and Public Administration*
[748] T22 pp. 131–2
[749] T30 pp. 19–20 incorporating revisions proposed in S73A, Blundell

6.60 In 1985 the AFRC 'published a discussion paper on a long-term view of the Agricultural and Food Research Service'[750] and decided:

> . . . following the principles of the Government's Financial Management Initiative, to introduce a less centralised organisation whereby, within a centrally-determined broad strategy and allocation of resources, Directors of Research will have greater control of the resources they deploy and will delegate more fully responsibilities within their own institutes . . .
>
> . . . to aggregate the existing research stations into a smaller number of institutes, and give each new institute a defined remit that avoids unproductive overlap, in order to give an improved management structure and a more efficient use of resources.[751]

The existing species- and commodity-based units became eight discipline-based institutes.[752] Between 1985 and 1990:

> A staff of approximately 6,500 in the institutes was reduced to 3,500 with considerable re-orientation of scientific programmes and re-prioritisation.[753]

6.61 One change was significant in the context of BSE: the amalgamation of four laboratories, including the Neuropathogenesis Unit (NPU), into a single Institute for Animal Disease Research (renamed the Institute for Animal Health, IAH, in 1988). The development of the NPU is described separately later in this chapter. A factor behind the reorganisation was the high administrative overhead cost of maintaining so many different sites. The need to reduce costs was an ever-present background to the work of the IAH and the NPU throughout the period with which the Inquiry is concerned.

6.62 Professor Biggs, Director of the IAH from its establishment until his retirement in 1988, told us:

> There were severe reductions in the funds supporting animal disease research and desperate responses to adjust to this situation.[754]

He added that:

> . . . the funding then began to concentrate on zoonoses and welfare and anything that did not come under that umbrella was not supported as strongly. That was particularly a MAFF approach.[755]

6.63 His successor, Professor Bourne, told us that because the IAH focused on animal disease pathogenesis, it moved into the area of applied research and found itself to some extent in competition with the CVL for MAFF funding. In his view, this stifled collaboration and the interchange of ideas.[756] Dr Bunyan, the Chief Scientific Adviser at MAFF from 1990 to 1995, noted a related tendency in 1991:

[750] *Agricultural and Food Research Council Forward Policy* (October 1985) (YB85/10.00/1.1–1.5)
[751] *Agricultural and Food Research Council Forward Policy* (October 1985) (YB85/10.00/1.1–1.5)
[752] The change was described to the Inquiry in these terms by Dr Shannon (T39 p. 9)
[753] S73 Blundell p. 2 para. 6
[754] S106 Biggs p. 4 para. 13
[755] T44 p. 50
[756] T44 pp. 131–2

> . . . for part of their [the Research Councils'] work to move closer to the market as they seek to widen their search for funds into the more commercial areas.[757]

6.64 The AFRC's involvement in the development of the TSE research programme and with the Consultative Committee on Research (the Tyrrell Committee) and the Spongiform Encephalopathy Advisory Committee (SEAC) is described later in this chapter.

The Biotechnology and Biological Sciences Research Council (BBSRC), 1994–96

6.65 The changing focus of the AFRC's work away from production-oriented research was reflected in 1994, when it was merged with parts of the Science and Engineering Research Council to form a new Biotechnology and Biological Sciences Research Council (BBSRC). This was part of a wider reorganisation of government science announced in a White Paper published during the previous year.[758]

6.66 Like the other Research Councils at that time, the BBSRC was explicitly committed to working towards 'enhancing the United Kingdom's industrial competitiveness and quality of life',[759] and was:

> . . . expected to develop close links with biologically based industries outside the medical and health and environmental fields, which will remain within the remits of the Medical Research Council and the Natural Environment Research Council.[760]

6.67 The BBSRC's maximum membership was reduced to 21 from the AFRC's maximum of 23. All appointments were to be made by the Chancellor of the Duchy of Lancaster.[761] One member each was nominated by MAFF, DTI and the Scottish Office, while the others were intended to provide a balance between scientific disciplines, sectors (eg, farming, pharmaceuticals, food processing – a total of five members from 'industry') and the universities (six members). In his letter appointing the Chief Scientific Adviser of MAFF to the BBSRC, the Chancellor indicated that:

> I would like all Council members, whatever their background or affiliation, to conduct themselves on Council as full members contributing corporately to the Council's overall mission, rather than seeing themselves as representatives of particular disciplines, sectors, institutions or organisations.[762]

[757] YB91/6.21/1.1–1.7, para. 4. Dr Bunyan was commenting on a number of issues relating to the AFRC and the MRC, and also the Natural Environment Research Council and the Economic and Social Research Council (NERC and ESRC respectively)
[758] *Realising our potential: a strategy for science, engineering and technology* (Cm 2250 May 1993) (M19 tab 7)
[759] Cm 2250 May 1993 (M19 tab 7), p. 29
[760] Cm 2250 May 1993 (M19 tab 7), p. 28
[761] BBSRC Charter of Incorporation (16 December 1993) (M19B tab 4), para. 4. In practice, the Chancellor sought the agreement of relevant ministerial colleagues
[762] Mr William Waldegrave to Dr Peter Bunyan, 23 March 1994 (YB94/03.23/4.1)

The Medical Research Council (MRC)

6.68 The MRC was similar to the AFRC in that it comprised a Council of appointed members and a scientific administrative staff headed by a Secretary (from 1993, a Chief Executive). The Council determined its overall corporate strategy, the roles of its subordinate Strategy Committee and Boards, and the allocation of resources. Scientific strategy and policy were determined by the Strategy Committee, while up to five Boards[763] reviewed its scientific portfolio, evaluated long-term research programmes, and assessed proposals for funding.[764]

6.69 During the BSE period, the DHSS (from 1988, DH) and the SHHD were represented on the MRC: DH by the Chief Medical Officer and the Chief Scientist (from 1991, the Director of Research and Development) and SHHD by the Chief Medical Officer for Scotland.[765] The Chief Scientist of SHHD attended as an Assessor.[766] Between 1988 and 1992, the Director of the Public Health Laboratory Service, then Sir Joseph Smith, was also a member. From 1993, appointments were made by the Chancellor of the Duchy of Lancaster.

6.70 The MRC employed its own research staff in a variety of institutes and units. With the AFRC, it funded the Neuropathogenesis Unit (see below). The number of units fell from 56 in 1985 to 48 in 1993. Most of the remainder of the MRC's income was spent on grants to universities (later, Higher Education Institutes) and their medical schools, and on training schemes.[767]

6.71 By far the greater part of the MRC's income was grant-in-aid; its share of the Science Vote allocated annually by Parliament. Other sources of income included DH and SHHD; other Research Councils; charitable income from collaborations with medical research charities and the MRC's own Private Fund portfolio; the European Union, World Health Organisation and other international sources; and collaborative agreements with industry.[768]

6.72 The MRC's primary objective in 1986 was 'to advance knowledge that will improve the health of individuals in the community'.[769] By 1994, this was set out more explicitly:

> To promote and support, by any means, high-quality basic, strategic and applied research and related postgraduate training in the biomedical and other sciences, with the aim of maintaining and improving human health.

In doing this, it was expected to 'meet the needs of users and beneficiaries (including the providers of health-care, and the biotechnology, food, health-care, medical instrumentation, pharmaceutical and other biomedical-related industries)'

763 Of which the most relevant to this Inquiry was the Neurosciences and Mental Health Board
764 S53 Radda p. 5
765 Sir Dai Rees and Professor George Radda told the Inquiry that the Chief Medical Officers played a considerable role in the MRC's deliberations – see T22 p. 82
766 *Concordat between the Health Departments and the Medical Research Council* 1991 (M11F tab 2), p. 2 para. 7
767 This information comes from the MRC's Annual Reviews for the years 1985 to 1996
768 See *Medical Research Council corporate plan, 1996–1999*, p. 43
769 *Medical Research Council Annual Review 1986*

and hence to contribute to 'the economic competitiveness of the United Kingdom, and the quality of life,' and also:

> To provide advice on, and disseminate knowledge and promote public understanding of, research in the biomedical sciences.[770]

6.73 The reversal of the Rothschild transfer described earlier in this chapter was reflected in the formal Concordat, also mentioned earlier, between the MRC and the Health Departments:

> . . . to develop and maintain an effective partnership for the promotion, funding and management of medical research in the UK . . . jointly to address ways of meeting the research needs of the [Health Departments] and the NHS and to use their particular skills and experience to best effect in areas of overlapping responsibility.[771]

The 'overlapping responsibility' was in respect of applied research, including health services and applied clinical research. Basic medical research (biological or clinical) was for the MRC, while operational research and health-related surveillance was generally for the Health Departments.[772]

6.74 Hence, one aim of the Concordat was to ensure that the research activities of the MRC and the Health Departments were complementary, allowing each to focus on their own strengths (eg, DH concentrating on health service needs while the MRC addressed the exploitation of scientific opportunity), and thereby to achieve the best value for public money. Another aim was to ensure that the Health Departments' policies and priorities were informed by scientific advances and opportunities, and that their research needs were understood and addressed by the MRC. Finally, the Concordat sought to ensure that NHS and public health perspectives were understood and taken into account by the MRC in decisions on research funding, and that the needs of MRC research for NHS support were understood and addressed by DH. These objectives were pursued at annual 'stocktaking meetings' between the MRC and the Health Departments.

Summary

6.75 In summary, the main UK government funders of TSE-related research outside MAFF and DH were the AFRC (later the BBSRC) and the MRC.

Providers

The Neuropathogenesis Unit (NPU)

6.76 The NPU had its origins in a recommendation in 1977 by an Advisory Committee on Scrapie chaired by Professor Peter Wildy. The Committee described a provisional scheme for a collaboration between research units at Compton in

770 *Medical Research Council Annual Review 1994*
771 *Concordat between the Health Departments and the Medical Research Council* (1991 edition) (M11F tab 2), p. 1 para. 1 (hereafter '1991 Concordat')
772 1991 Concordat (M11F tab 2), p. 1 para. 4

Berkshire[773] and in Edinburgh to pursue an 'urgent requirement' for an investigation into the relationship between Creutzfeldt-Jakob Disease (CJD) and scrapie agents, and recommended that it should receive additional funding. As both a human disease and an animal disease were involved, support by both the MRC and the Agricultural Research Council (ARC, later the AFRC) would be appropriate and liaison between them was considered important.[774]

6.77 The collaborative work proceeded during the next two to three years in parallel with an Advisory Group on Scrapie Research. This too was chaired by Professor Wildy, and included as members Dr Richard Kimberlin and Dr Alan Dickinson, both experienced researchers into scrapie. In 1980 Dr Dickinson put forward 'a proposal to establish at Edinburgh a joint ARC/MRC Laboratory for the study of the comparative pathology and the pathogenesis of slow virus diseases and CNS degeneration'.[775] He noted that a suitable building at Edinburgh University was about to be vacated by another ARC unit,[776] and proposed that the costs of conversion should be shared by the MRC and the ARC, and that Dr Kimberlin's pathogenesis group should relocate there from the Compton laboratory.

6.78 The Advisory Group supported this proposal,[777] which was endorsed in the autumn of 1980 by the ARC and the MRC.[778] The NPU opened in 1981:

> . . . with the remit of studying scrapie and other unconventional slow infections of the CNS such as Creutzfeldt-Jakob Disease and dementias of the Alzheimer type.[779]

Dr Dickinson was appointed Director and the AFRC was 'fully responsible for the administration of the Unit and the employment of the staff'.[780]

6.79 The Unit brought together a wide range of expertise, especially in the genetics, strain characterisation and transmission of scrapie. In the late 1980s, the NPU was the only significant resource in the UK (and one of only a few worldwide) with knowledge and expertise in TSEs. It was therefore a major source of expertise in the investigation and characterisation of BSE.

6.80 From the start, Dr Dickinson was concerned about the level of funding and how this was split between the two Research Councils. He told the Inquiry that a reduction in the expenditure he had proposed had been imposed at the last moment before the ARC /AFRC would endorse the project; that the initial funding ratio of 70 per cent ARC to 30 per cent MRC was much less equal than he had envisaged;[781] and that the situation had been worsened by the decision in 1985 to reduce public funding for research into animal diseases by 20 per cent.[782]

6.81 Initially, the NPU's progress was slowed by the need to relocate facilities and staff, and because:

i. refurbishment works were delayed;

[773] The Institute for Research on Animal Diseases (IRAD)
[774] *Agricultural Research Council: Report of the Advisory Committee on Scrapie* (YB76/10.12/4.1–4.12), p. 7
[775] Minutes of meeting of Advisory Group on Scrapie Research, 22 May 1980 (YB80/22.5/1.1)
[776] The Poultry Research Centre
[777] Dr Kimberlin, Dr Dickinson, and two others who would be affected by the decision did not take part in the debate or the decision
[778] YB80/10.14/1.1–1.2 and YB80/23.11/1.1–1.2 respectively
[779] *AFRC/MRC Neuropathogenesis Unit: report of an informal visiting group* (YB88/4.6/3.1–3.3), para. 1
[780] YB87/6.00/2.1–2.8, para. 3
[781] This was core funding. New projects were funded from different sources – see S105A IAH p. 5 para. 11
[782] S74 Dickinson A p. 11 paras 68–70

ii. it was necessary to establish pathogen-free colonies of inbred mouse strains; and

iii. financial constraints delayed the appointment of new staff envisaged in the original proposal.[783]

6.82 However, the issues of funding, facilities and location that had arisen during its gestation continued to be significant throughout the period with which the Inquiry is concerned, and had an impact on the way in which the NPU carried out its remit. As the MRC reported to the Chief Medical Officer in June 1990:

> The Unit has had a chequered history; for example on the scientific side it had been the intention (and this was a factor in the MRC's initial involvement) to establish a programme of work on Creutzfeldt-Jakob Disease, but for a variety of reasons (partly but not exclusively financial) this was never possible.[784]

Specialised facilities for work with CJD and other material of human origin were eventually completed in 1994.

6.83 A 1985 Visiting Group was impressed by the quality of the work done so far and planned by the NPU. But it was concerned at the delays and expressed the view that the Director was 'excessively concerned' about the mouse colonies and that he had not given a sufficiently coherent account of the progress made by the Unit and of its future strategies and objectives. They also considered that more interaction was needed with other relevant centres of scientific excellence.[785]

6.84 In October 1985 the AFRC announced the rationalisation of its research institutes described earlier.[786] From June 1986 the NPU became part of a new Institute for Animal Disease Research,[787] with three other laboratories: the Institute for Research on Animal Diseases (IRAD) (at Compton), the Houghton Poultry Research Station (HPRS) (near Huntingdon, Cambridge) and the Animal Virus Research Institute (AVRI) at Pirbright (near Woking, Surrey). It therefore reported to the Director of the new Institute, Professor Biggs.

6.85 Professor Bourne, the second Director (from 1988) of the IAH, was recorded in January 1991 as taking the view that:

> . . . only by bringing the NPU within the IAH had the science at the NPU been protected from MAFF's burgeoning demands for BSE-transmission work. The IAH had diverted most of this 'non-science' pressure from the NPU by re-commissioning a 'mothballed' mouse facility at Compton. It was his [Professor Bourne's] view that the NPU standing on its own could not have withstood MAFF's demands; his aim was and is 'to develop and defend the science of the NPU'. Proportionally, the MRC contribution to core funding had fallen . . . He considered, therefore, that the NPU (and the MRC) was benefiting considerably from AFRC's investment in the unit and he was emphatic that a 'stand-alone' unit was 'not on'.[788]

783 *Report of the Review of the ARC and MRC Neuropathogenesis Unit, 4 March 1985* (YB85/3.4/1.1–1.12), p. 2 para. 3
784 YB90/06.14/14.2
785 YB85/3.4/1.1–1.12, p. 11 paras 10.1–10.5
786 YB85/10.00/1.1–1.5
787 As noted above, this became the Institute for Animal Health in October 1987
788 YB91/1.29/2.1–2.5, p. 2 para. 3

6.86 This change had three significant consequences. Firstly, it led in September 1987 to the early retirement of Dr Dickinson, who found it difficult to accept what he and others saw as a loss of autonomy and of a 'direct line to the [MRC's] Neurosciences Board'.[789] It proved hard to attract a distinguished independent scientist to succeed him, partly because of the difficulty of putting together a sufficiently attractive package of terms and conditions, and partly because of uncertainties over the future funding and status of the NPU.[790] After a succession of internal temporary appointments, Dr Chris Bostock[791] took overall charge of the NPU in April 1990, as head of the IAH TSE programme. Dr Hilary Pickles, the DH Principal Medical Officer whom the Chief Medical Officer had appointed to lead DH's work in relation to BSE, considered that the delay in appointing a new director for the NPU was 'blighting research progress at the most important UK centre for work in this field', and noted that:

> The past history of bad feeling between the research councils over the NPU will make research co-ordination a very difficult, if not impossible, task.[792]

6.87 Secondly, the NPU was directly affected by the ongoing funding problems that afflicted the new IAH. These stemmed from the decision to withdraw from near-market research, which led to a substantial cut in public funding for agricultural research, and from the Priorities Board's recommendation that spending on animal health research should be reduced by 20 per cent. This led to proposals to rationalise and relocate the IAH's facilities, in order to save on administrative overhead costs.

6.88 The AFRC was attracted by the option of co-locating all the IAH's facilities, including the NPU, on a single site at Compton in Berkshire. Transferring the NPU to Compton was 'a recurring theme that seems to have been driven by attempts to save money rather than for any coherent short- to medium-term scientific imperative'.[793] Other possibilities were considered, but the debate returned repeatedly to the Compton option.

6.89 In 1986 the AFRC decided, although not unanimously, to aim to contract the IAH to a single site within five years.[794] However, there was widespread recognition that although a financial and scientific case could be made for relocation, such a move would lead to major disruption and loss of parts of the research programme. Furthermore, at least two reviews recommended against relocating the NPU. The report of a working party chaired by Professor Wildy[795] and published in February 1988 was unequivocal:

> The NPU should on no account be moved as this would seriously disrupt its research programme.[796]

6.90 The NPU Site Group of the AFRC's Animal Health Visiting Group advised in June 1988 that it 'could not identify any scientific benefit from moving the NPU to Compton'.[797] The MRC's Neurosciences Board agreed at the same time that:

[789] YB87/6.30/4.1–4.4, para. 3
[790] S73 Blundell p. 3 para. 11
[791] Head of the IAH's Division of Molecular Biology. In 1997, he succeeded Professor Bourne as Director of the IAH
[792] YB90/11.16/2.2
[793] S308 IAH and the NPU Funding Issues p. 2 para. 5
[794] S106 Biggs pp. 2–3 para. 7
[795] Set up jointly in 1985 by the AFRC and the Agricultural Departments in Great Britain to review public sector funded research and development in farm animal diseases – see M11A tab 4
[796] M11A tab 4 p. 45 para. 5.2.6 (a) (ii)
[797] YB88/4.6/2.1–2.7 para. 32

> . . . a change of location in the next few years could have a devastating effect on the Unit's international competitiveness and on the contribution they could make to the BSE problem.[798]

6.91 The AFRC deferred a decision on moving the NPU to Compton pending discussions with the MRC. By January 1990 it:

> . . . was committed to sustaining the Unit in Edinburgh as an integral part of the AFRC Institute for Animal Health and wished to maintain the joint involvement with MRC.[799]

However, subsequent MRC decisions, described below, led:

i. in 1992 to further consideration of the option of moving all or part of the NPU to Compton;[800] and

ii. in 1995 to recommendations that the protein science work at the NPU should be moved to Compton and that further consideration should be given to relocating the entire NPU programme there.[801]

6.92 This consideration was overtaken by wider developments on BSE, including ministerial concerns about public reaction to perceived reductions in spending on TSE research.[802] Although discussions about the timing of the withdrawal of MRC core funding were continuing, it was decided that 'the NPU will remain in Edinburgh for the foreseeable future although the protein science will be moved to Compton as agreed'.[803]

6.93 The issue of relocation had become interlinked with the third consequence of the setting up of the IAH: the concern of the MRC about its scientific links with the NPU.[804] When the MRC learned, early in 1988, that the AFRC planned to reduce its funding of the NPU in the hope that the reduction would be made up by MAFF or the farming industry, and that this might mean that the NPU did more applied research at the expense of curiosity-driven work, it concluded that:

> Some aspects of the Unit's work were of considerable fundamental importance and had potential implications for man. However, the continuation of the present joint Unit was not necessarily the most appropriate setting in which to pursue work relevant to the MRC.[805]

6.94 The ability of the IAH Director to switch funds between the four laboratories meant, at least in principle, that MRC funds could be used for work that had little or no implications for human health. Dr Dickinson had predicted in 1986 that in such circumstances 'Neuroscience Board members' would be likely to 'rebel'.[806]

6.95 Both Research Councils accepted that:

798 YB88/6.00/1.2
799 YB90/1.15/1.1–1.5, para. 1.1
800 YB92/6.25/3.4–3.6
801 YB95/11.22/5.1–5.2
802 YB96/2.28/1.1; YB96/03.05/3.1–3.2; YB96/3.19/2.1–2.2
803 *Minutes of a meeting of the [IAH] TSE Advisory Group,* 22 January 1996 (YB96/1.11/7.2). The protein science move took place in September 1996
804 Letter of 9 July 1987 from the MRC Secretary to his AFRC counterpart (YB87/7.9/1.1–1.2)
805 YB88/3.1/2.1–2.3, para 3.2. It had already set up a subcommittee 'to give preliminary consideration, in the light of recent developments, to the scientific case for continuing the MRC investment in the Unit, prior to the joint AFRC/MRC review' (YB88/3.1/2.1–2.3, para. 1.2)
806 YB86/9.00/1.1–1.3, para. 8

> . . . there should be a joint MRC/AFRC review of research on slow viral agents in animals and man with particular reference to BSE, as a prelude to joint decisions about the future work of the Unit, its location and management.[807]

This took place in January 1990. Its two key conclusions were that a new Director should be sought and that:

> . . . the person appointed would be expected to redirect its programme to focus on the identification of the [BSE] agent using state of the art cellular and molecular biological techniques.[808]

6.96 However, in July of the same year, the MRC decided to withdraw its annual core funding of £300,000 after three years and replace it with contracts or commissions. Thereafter:

> The level of their financial involvement, which may increase or decrease, will reflect the relevance of the work of the Unit overall to MRC strategy in the field.[809]

6.97 In the event, however, a new funding agreement was reached in 1994 and the MRC maintained its core funding contribution until March 1998.

Arrangements for commissioning and funding research

MAFF

Introduction

6.98 As explained above, the focus of agricultural research changed significantly during the early and mid-1980s. For most of the period with which the Inquiry is concerned, MAFF's own research 'focused very directly on supporting its policies',[810] leaving basic science-led research to the Research Councils and near-market research to industry.[811] However, MAFF also acted as a 'customer' for 'strategic research underpinning the development of new technologies and policies'.[812]

6.99 The main contractors for publicly funded agricultural research were MAFF's Agricultural Development and Advisory Service (ADAS),[813] the Central Science Laboratory (CSL) and the Central Veterinary Laboratory (CVL), and the AFRC/BBSRC institutes, although other contractors were increasingly employed towards the end of the period.[814] Vol. 15: *Government and Public Administration* notes how

807 YB90/06.14/14.2
808 YB90/1.15/1.1–1.5, para. 4.1 and YB90/06.14/14.2
809 YB90/7.18/1.1–1.2, para. 2 and YB90/10.17/6.2
810 *Commissioning and funding research in MAFF 1986–1998* (DM01 tab 5), p. 1 para. 4
811 Government support for near-market research was finally withdrawn by 1991/92 – see M17 tab 1990 p. 19 para. 57
812 *Paper by the Ministry of Agriculture, Fisheries and Food commenting on the Research Council's programmes* (YB91/6.21/1.1–1.7), para. 2(c)
813 'ADAS was essentially an executive arm of the Ministry. Its principal functions were: (a) the performance of certain regulatory duties, eg, the monitoring and control of plant and animal diseases; (b) the provision of scientific, technical and business management advice to the agricultural and horticultural industries; and (c) the formulation and prosecution of research and development in support of functions (a) and (b).' See S124 Bell para. 4
814 DM01 tab 5 p. 4 para. 14

ADAS, the CSL and CVL became Executive Agencies following the 1988 'Next Steps' report,[815] and the section of this chapter on the CVL outlines how commissioning and funding arrangements changed significantly to reflect this.

Oversight

6.100 MAFF's research programme was overseen between 1986 and 1995 by a Grade 2 Chief Scientific Adviser (CSA),[816] who was supported by two Grade 3 Chief Scientists – for Agriculture and Horticulture, and for Food and Fisheries.[817] Until 1992, the CSA was also Director-General of ADAS.[818] In addition, the postholder was (from 1987) Head of MAFF's Regional Offices and (from 1992) Head of MAFF's Information Technology Division.[819] During this period, there were two CSAs: Professor Ronald Bell and Dr Bunyan.[820] The Chief Scientist (Agriculture and Horticulture) was Dr Shannon.[821] He received support on veterinary scientific issues from Dr Kenneth MacOwan.

6.101 Professor Bell told the Inquiry that, as CSA, he:

> . . . delegated . . . all of the detailed commissioning of research both within ADAS and with AFRC and the universities. What I retained, and rarely [sent deputies to], was attendance at Priorities Board, ABRC, the meetings . . . called by the Chief Scientific Adviser at the Cabinet Office and so forth.[822]

6.102 In 1995 the post of Chief Scientific Adviser was abolished and a single Chief Scientist became responsible for agriculture, fisheries and food – and for all the specialist scientists responsible for commissioning research – and reported directly to the Permanent Secretary.[823]

MAFF's commissioning and funding system

6.103 Below the strategic level, MAFF's requirements as a research customer were determined by its science and policy groups, including the State Veterinary Service. A Chief Scientist met senior staff from other funders and providers of agricultural research to review existing programmes and research proposals in the light of departmental customer requirements. Finally, proposals for the development of research programmes were put to Ministers for approval.[824] The scientists in the institutes and laboratories had an important voice in the way the research programme was carried out, and contributed prominently to its direction.[825]

815 *Improving Management in Government: the Next Steps* (Sir Robin Ibbs, 1988) (M18 tab 1)
816 Between 1982 and 1985, MAFF did not have a CSA, following a reduction in the number of senior posts in Whitehall. During that period, the two Chief Scientists had worked in tandem – see T53 p. 13. From 1985, the CSA was a member of the AFRC and its successor, the BBSRC, and of the Advisory Board for the Research Councils (ABRC), and also chaired the Ownership Boards of four of the five MAFF Agencies established from 1990 – see S125 Bunyan pp. 4 and 9–10. The four were the CVL, the Central Science Laboratory (CSL), the Veterinary Medicines Directorate, and the Pesticides Safety Directorate. The aim was to maintain a 'chinese wall' between MAFF as 'owner' of the Agencies and the policy groups which were customers for the Agencies' services
817 The latter reported to the Grade 2 Head of the Fisheries and Food Directorate (from 1989, the Food Safety Directorate), while and also supported supporting the Chief Scientific Adviser. The Chief Scientist (Agriculture and Horticulture) was a member of the AFRC until March 1994, and subsequently became a member of the BBSRC – see S101 Shannon p. 3 para. 12
818 From January 1990, Chief Executive
819 S124 Bell R paras 6, 9 and 10; S125 Bunyan p. 4
820 Respectively, until 31 December 1989 and from January 1990 to June 1995, when the post was abolished
821 Who was Chief Scientist for MAFF, a Grade 3 post, from June 1995
822 T53 p. 25
823 *Commissioning and funding research in MAFF 1986–1998* (M32 tab 7), para. 17. See also T39 (Shannon) p. 13
824 M32 tab 7 pp. 3–4
825 M32 tab 7 p. 3 para. 10

6.104 There was some external peer review of research proposals: for example, the animal health team in the Chief Scientist's Group used outside experts if insufficient internal expertise was deemed to be available.[826] Strategic external overview of the BSE research programme was provided by the Consultative Committee on Research on BSE (the Tyrrell Committee) and by the Spongiform Encephalopathy Advisory Committee (SEAC). Their roles are described in Part 3 of this chapter, but did not include reviewing individual project plans or progress. When in the early 1990s MAFF started to use formal competitions to place some of its research contracts, in order to improve value for money, external referees were involved in assessing the proposals.[827] However, such competitions were used only in a limited number of projects started before 20 March 1996.

6.105 Up to 1991, budgetary responsibility for R&D in MAFF rested with the Chief Scientists. In consultation with their policy colleagues, they established the annual research programme within the budget agreed by Ministers during the annual Whitehall-wide PES round described earlier in this chapter. Expenditure on in-house research (ie, work commissioned from MAFF laboratories, including the CVL) counted as 'running costs', whereas research commissioned externally counted as 'scheme' or 'programme' expenditure. As these were separate Votes, transfers between them required Treasury approval.[828] Dr Shannon told the Inquiry that:

> It was not possible to transfer resources between the external and 'in-house' funding streams without Treasury agreement and this constrained the rate at which funding could be transferred into BSE research. These arrangements changed when 'in-house' laboratories became Agencies in the early 1990s and formal contractual arrangements were established.[829]

6.106 The Government's Chief Scientific Adviser took the view that MAFF did not distinguish clearly enough between the customer and contractor roles. MAFF responded by transferring budgetary responsibility for research from the Chief Scientist's Group (CSG) to its policy-making groups, with effect from April 1991. With the exception noted below, the research funds obtained through the PES round were henceforward spent by the policy-makers, advised by the CSG, which retained its role of ensuring that the research programme was balanced and appropriate. The aim was to ensure that 'each research programme would be decided by the budget officer with responsibility for the expenditure in agreement with the appropriate Chief Scientist':[830] ie, that science and policy interests were both formally given due weight in reaching decisions, an approach known as the 'double lock'.[831]

6.107 Mrs Elizabeth Attridge of MAFF[832] explained that:

> The 'budget' for research work was allocated to Under Secretaries who were advised by their scientific liaison officers from the Chief Scientist's Group.

826 MAFF Memorandum, *Chief Scientist's Strategic Fund and the Animal Health Research Programme* (May 2000) (M6 tab 9), p. 2
827 M6 tab 9 p. 2
828 In line with the convention that transfers between Votes required parliamentary approval, and also because of specific controls imposed at that time by the Treasury on running costs
829 S101 Shannon p. 8 para. 30
830 Submission to the Minister of Agriculture, Fisheries and Food, *Research and development: role of the priorities board and arrangements for commissioning* (9 June 1989) (YB89/6.9/4.1–4.15), p. 9 para. 17(d)
831 M32 tab 7 p. 4 para. 13
832 The Grade 3 (Under Secretary) Head of MAFF's Emergencies, Food Quality and Pest Control Group from August 1985 to December 1989, and thereafter Head of the Animal Health Group (which merged with MAFF's headquarters veterinary staff to form the Animal Health and Veterinary Group in 1990) until August 1991

> Dr MacOwan was the AHVG[833] Scientific Liaison Officer. Any money becoming 'free' at the end of a 3 year contract was theoretically available for reallocation to finance new work and under a system of 'double locks' the commissioning of new work needed agreement by both the Chief Scientist and the Policy Under Secretary and merits were assessed by the MAFF Research and Development Committee which had also . . . to take into account the views of priority committees set up to consider the work needed by or jointly financed by the industry. Also involved were the AFRC which through the Office of Science and Technology had an input into the balance of research between establishments.[834]

She added that when the CVL became an Agency (as noted below), it was:

> . . . considered a self-standing organisation with whom formal research contracts had to be drawn up. Contracts, many of them of an informal nature, with both the Central Veterinary Laboratory and the various research institutes under the AFRC were required to be put on a formal basis, costed and given specific dated goal posts to achieve.[835]

6.108 The overall budget was allocated to policy groups in the autumn. But they had to identify 5 per cent of their allocation to be 'donated to a central resource to provide flexibility in the overall programme'.[836] Their allocations were only finalised two or three months later, and a group's '5 per cent donation' could then be redirected to another policy area or programme, to reflect MAFF's developing priorities.

6.109 The Chief Scientist (Agriculture and Horticulture) retained a relatively small share of MAFF's overall research budget (known as his 'special' or 'strategic' fund) of around £4 million, to use at his discretion.[837] It had two purposes: (a) to fund novel approaches, and exploratory and strategic work to address possible future problems (including areas of research which cut across several policy interests); and (b) to address immediate research issues when other budgets were fully engaged – eg, when issues emerged during a financial year after resources had been allocated. This budget could be used to commission both internal and external research.[838] It had the subsidiary purpose of broadening the contractor basis by introducing open competitions for selected small projects.

6.110 The current MAFF Chief Scientist told the Inquiry that, while research was to be funded by the operating divisions,[839] his role was to ensure that they 'took a long enough term view and also exercised their responsibilities properly'– ie, to have an overview of MAFF research and development to ensure that it was effective and that there were no gaps.[840]

6.111 The ROAME programme management approach was also introduced in the early 1990s, to tighten up management and control. Under ROAME, a Rationale

[833] The Animal Health and Veterinary Group
[834] S78 Attridge pp. 5-6 para. 14
[835] S78 Attridge p. 6 para. 15
[836] S101 Shannon p. 13 para. 46
[837] Prior to 1991, a similar 'fund' had existed, intended to widen the range of contractors employed. It was taken from the external research Vote, so could not be used to fund work in MAFF's own laboratories (such as the CVL)
[838] MAFF Memorandum: *Chief Scientist's Strategic Fund and the Animal Health Research Programme* (April 2000) M6 tab 9 p. 1
[839] That is, the policy groups who then had budgetary responsibility
[840] T39 (Shannon) p. 28

and Objectives were identified, and projects were subject to Appraisal, Monitoring and Evaluation.

Prioritising research projects

6.112 As noted earlier in this chapter, 'agricultural R&D had been seen as a prime target for cuts by the Treasury . . . since about 1985'.[841] Downward pressure on budgets meant that research proposals had to be ranked and prioritised. Strategic advice on priorities and on the allocation of funds was provided by the Priorities Board.[842] When this was established, Ministers indicated that they would expect to accept its advice. It was supported by sectoral Research Consultative Committees,[843] which comprised research scientists and technical experts from industry.

6.113 Professor Bell who, as CSA, was a member of the Priorities Board, told the Inquiry that it:

> . . . never saw its role as campaigning for more money. It saw its role as determining priorities within a total budget set by the various funding agencies . . . We were trying to . . . determine a pattern of spend across monies coming from various places: the Agricultural and Food Research Council derived money from the DES, MAFF had its source of funds from the Government, Scottish funds, Irish funds and so on . . . we were trying to set a pattern across all Government Departments within this area of agriculture and food. [844]

6.114 Despite the Board's recommendation in 1985, noted earlier, that expenditure on animal health should be reduced by 20 per cent, total R&D expenditure by MAFF on animal health and welfare rose from £15 million in 1988 (of which research into TSEs accounted for less than £1 million) to £24 million in 1996 (with around £7 million on TSE research). This increase was funded entirely from within MAFF's overall research budget, thus diverting funds from other, non-TSE, aspects of animal health.[845]

6.115 The Priorities Board continued until 1993, and then recommended longer-term priorities and that it should itself be wound up. Ministers decided that a successor independent advisory body was not needed. Instead, a small group of senior staff from the main funding bodies was set up in 1995, to ensure that the overall programme of publicly funded research in the fields of agriculture, fisheries, the agri- and marine environment and food was coherent. This Agriculture, Food and Fisheries Research Funders Group was to keep under review the requirements for publicly funded research in these fields; to ensure that there was effective coordination between Departments and Research Councils so as to prevent duplication or significant gaps in the research they commissioned; and to make sure that research programmes and proposals took account of the needs of industry and

841 S101 Shannon pp. 3–4 para. 14
842 As noted earlier in this Chapter, the Board was chaired by a businessman and comprised members from industry and commerce, academia, farming and agriculture, the relevant Government Departments, the AFRC and (from 1991) a consumer representative's membership as set out in footnote 750 above
843 From 1990, Advisory Sectoral Groups including one on the environment – see M32 tab 7 pp. 3–4
844 T53 pp. 19–20
845 M32 tab 7 p. 10

other end-users.[846] It was supplemented by a series of Concordats between MAFF and the BBSRC and the MRC,[847] to promote effective interaction between them. MAFF's own research programme was kept under review and prioritised by a Research and Development Committee, chaired by the Chief Scientific Adviser.[848]

The Central Veterinary Laboratory (CVL)

6.116 Before the CVL became an Agency in 1990,[849] its budget was part of MAFF's Vote allocation.[850] It was responsible for all R&D work required by the State Veterinary Service (SVS), and also contributed to work on disease surveillance. The Director reported to the Chief Veterinary Officer (CVO) who, as head of the SVS, had a major influence on the CVL's work. As Dr Little, the CVL's first Chief Executive, told the Inquiry:

> Before 1990 . . . the CVL was part of MAFF. Any 'customer' relationship therefore existed within that one-Ministry context. Funding was provided to fill posts, and the post holders were there to do whatever job was required. The CVL was not expected to be independent or proactive, but rather it was part of the State Veterinary Service, with the CVO as its senior officer. It ran very much on a system of management by 'command and control'.[851]

6.117 The CVL's budget covered research and disease surveillance, and it could therefore carry out work at the interface between these two areas.[852] In this way, funds could be provided for initial research into emerging diseases such as BSE.[853] If the CVL needed to secure further research funding outside the PES bidding process, the Director would approach the CVO and MAFF's Chief Scientist (Agriculture and Horticulture). If funding was not available, the research would not be undertaken, or funding would be diverted from lower priority projects at the CVL.

6.118 When the CVL became an Agency, the CVO no longer had management responsibility and it no longer had access to MAFF's Vote. Instead, it 'was required to recover the full cost of all its work by charging its customers for services provided'. Dr Little explained that:

> . . . MAFF was responsible for commissioning and paying for the services that it received, as was any other customer. This meant that individual customers were responsible for deciding what work to commission from the CVL. The CVL was not in a position to initiate work of its own volition, as it had neither the funding nor the authority to do so.[854]

[846] *Agriculture, Food and Fisheries Research Funders Group: First Report June 1997* (M11E tab 15). The membership consisted of the Chief Executives of the BBSRC and the Natural Environment Research Council (NERC), senior scientists from MAFF, the Scottish Office and the Department of Agriculture for Northern Ireland (DANI), and representatives from the Welsh Office Agriculture Department and the Forestry Commission
[847] And also the Natural Environment Research Council (NERC)
[848] From mid-1995, when the CSA post was abolished, by the Permanent Secretary
[849] As Chapter 6 of vol. 15: *Government and Public Administration* explains, Agencies were established to carry out executive functions of government, leaving Departments to focus on policy development and administration. They were conceived as being run along business lines by a Chief Executive who reported directly to the appropriate Minister
[850] M56 tab 14 p. 35. In the early days of Agency status, the CVL continued to have its expenditure financed from MAFF's Vote allocation
[851] S331B Little para. 4
[852] M32 tab 7 p. 3
[853] M32 tab 7 p. 3
[854] S331A Little p. 4 para. 19

6.119 However, following the delegation of research funding in 1991, the CVL had access to the 'special fund' held by the Chief Scientist (Agriculture and Horticulture).[855]

The Department of Health (DH)

Introduction

6.120 Research commissioned directly by DH was policy-driven, while the MRC focused on basic and science-led research. Before 1991, DH had a part-time Chief Scientist, whose role was to advise on the scientific aspect of the Department's work and its R&D policy and programme. The Chief Scientist was supported by a Deputy Chief Scientist and Director of Research Management (a single post), and by a Research Management Division comprising administrative branches and several professional branches dealing with medical, social, nursing and other aspects of the research programme. From 1 January 1991, a full-time Director of Research and Development was appointed, with the initial task of developing and taking forward a comprehensive multi-disciplinary R&D strategy for the .[856]

Funding sources

6.121 DH had direct and indirect access to a number of government-financed budgets to fund the research it needed to address areas of concern and provide the evidence base for policy formulation and evaluation. The main budgets available for health research were as follows:

i. the Medical Research Council (described above);

ii. the Department's own Policy Research Programme;

iii. the NHS R&D programme; and

iv. non-departmental public bodies (NDPBs) that carried out research to support their own functions – eg, the National Institute for Biological Standards and Control.

The Policy Research Programme

6.122 The Department's Policy Research Programme addressed particular policy problems and needs relating to the NHS, public health and social services. Spending under the Programme rose from £15 million in 1988 to £27 million in 1996.[857]

6.123 Needs for research funding were identified directly by Ministers or senior officials and arose from policy considerations. Prioritisation was achieved through a strategic user group, the Departmental Research Committee, made up of senior policy officials and chaired by the Director of Research and Development. Once issues had been prioritised, research requirements were formulated into a

[855] S101 Shannon para. 47
[856] DH Press Release, 24 April 1991: *A Research Strategy for Health Care: launch of the Department of Health's new R&D Programme* (YB91/04.24/13.1–13.3)
[857] *Research on BSE funded by the Department of Health: BSE memorandum DH4/98* (DH01 tab 5), p. 2

specification and researchers were invited to submit proposals. These were peer-reviewed by academics selected by the Department before contracts were let.

Basic research was the responsibility of the MRC

6.124 DH did not undertake or commission basic biomedical research itself. This was funded by the MRC, whose remit and organisation are described above, together with the Concordat between it and the Health Departments. Apart from being represented on the MRC Council, DH was involved in the appointment of the Chairmen and Deputy Chairmen of MRC Boards and in the process of filling membership vacancies, and (with the other Health Departments) could nominate at least three independent scientific members to take a particular interest in its priorities.[858]

6.125 DH actively identified NHS and wider Health Department R&D needs and priorities (with MRC assistance where appropriate) and commissioned and funded work in priority areas. It also asked the MRC to develop proposals in areas in which the latter had a particular expertise; these might be funded by the Health Departments or by the MRC. In addition, DH participated in MRC strategic planning. The MRC considered proposals within its remit in the light of DH's views of NHS needs and priorities, and responded to those needs by developing its own initiatives.

6.126 The coordination of strategic planning was facilitated by DH attendance at meetings of the MRC Strategy Development and Awards Advisory Groups, while the MRC attended meetings of the Departmental Research Committee. Programmes were coordinated by regular contacts.

6.127 Coordination was also required between science and policy. DH was the primary customer for much MRC research and therefore had to be aware of the wider implications of scientific developments in the MRC's remit. The Concordat required the MRC to alert DH to relevant developments in basic science. For its part, DH identified areas within the MRC's remit where development of new and existing research could help the achievement of departmental objectives.

The Wellcome Trust

6.128 During the period covered by the Inquiry, one of the objectives of the Wellcome Trust, a registered charity, was to support research in the biomedical sciences, by funding all types of research from the basic sciences related to medicine, to the clinical aspects of medicine and veterinary medicine.[859] The Trust provided grants for individual projects and programmes of research as well as for larger research groups and centres, equipment and infrastructure. Its policy was set by the Governors of the Trust within the remit set by its founder, Sir Henry Wellcome. Research budgets were allocated by the Governors and were distributed depending on the scientific importance of, and opportunity in, each area, as well as on the funds available from other sources. Grant applications were managed within

[858] *Concordat between the Health Departments and the Medical Research Council* (1991) (M11F tab 2), p. 3 para. 9
[859] But it does not normally consider support for cancer research, as funds are available from other sources – see *Grants and Support for Biomedical Research* (Wellcome Trust) (M11 tab 12), p. 17

topic areas and were assessed by independent peer review before being submitted to an advisory panel in the appropriate area. Final decisions on the funding of projects were reached by the Governors.[860]

PART 3: RESEARCH INTO TSEs – A NARRATIVE ACCOUNT

MAFF's TSE research

6.129 This Part of Chapter 6 reviews the way in which MAFF initially developed a research programme and sought funding for it. We focus on the earlier stages of the process, which laid the foundations for the way the research programme developed.

6.130 From 1988, the CVL/NPU research programme was subject to scrutiny by the committees of experts appointed by the Government to advise it on BSE and measures necessary to address the disease. The first of these was the Southwood Working Party, whose work is considered in detail in vol. 4: *The Southwood Working Party, 1988–89*. The second was the Tyrrell Committee (the Consultative Committee on Research into Spongiform Encephalopathies), set up in 1989 and chaired by Dr David Tyrrell. The third was the Spongiform Encephalopathy Advisory Committee (SEAC), set up in 1990 and also chaired by Dr Tyrrell. A full account of these two committees is given in vol. 11: *Scientists after Southwood*.

1987

6.131 Having been responsible for identifying the new disease via the network of Veterinary Investigation Centres, the CVL initiated the earliest research into BSE. Initial investigations were aimed at characterising the new disease and studying its epidemiology. So far as the former was concerned, early indications suggested that the disease was a transmissible spongiform encephalopathy (TSE), and by the beginning of June 1987 investigations had already been set in train to confirm this. These aimed to establish whether the disease was transmissible to experimental animals (hamsters were used initially), and whether SAFs, known to be associated with TSE diseases, could be detected in treated samples from brains of affected animals.

6.132 Study of the epidemiology of the disease was instigated on 3 June 1987, when Mr Wilesmith, head of the CVL Epidemiology Department, was asked to investigate the new disease. Within a week, he had designed a pro-forma questionnaire and had begun to visit farms on which cases of the disease had been reported.[861] The subsequent epidemiological work is described in Chapter 3 of vol. 3: *The Early Years, 1986–88*.

6.133 At this stage Dr Watson, Director of the CVL, asked his colleague Mr Bradley to coordinate the research work on BSE.[862] A 'BSE group' was formed whose members were to carry out the initial investigation and experimentation

860 M11 tab 12 p. 63
861 S91 Wilesmith paras 12–19
862 YB87/6.3/1.1

relating to BSE.[863] Mr Bradley immediately began discussions with the members of the group about the required experimental work.[864]

6.134 Dr Watson recognised that a great deal of expertise in TSE diseases existed at the NPU in Edinburgh. Indeed, the NPU was the only centre in the UK involved in TSE research and was experienced in the transmission of scrapie to experimental animals. Dr Watson therefore instigated discussions between the two institutes at the end of May 1987. The question of whether the initial contact might have been made earlier is considered in Chapter 2 of vol. 3: *The Early Years, 1986–88*.

6.135 At Dr Watson's request, Dr Richard Kimberlin of the NPU visited the CVL on 9 and 10 June 1987, to discuss the coordination of CVL–NPU collaboration and the future course of a research programme.[865] He met the Experiment Leaders, as well as Dr Watson and one of his Deputy Directors, Dr Shreeve.[866]

6.136 On the basis of proposals from the Experiment Leaders and the discussions with the NPU, specific objectives for a BSE research programme began to be formulated. During the coming months, through a process of consultation with the Experiment Leaders, Mr Bradley, Drs Watson and Shreeve, the NPU and others, the ideas for experiments evolved and were refined into firm project proposals.

6.137 Consideration was given at an early stage to the need to obtain funding for the necessary programme of research. Mr Bradley noted in a minute to BSE group members on 10 June 1987 that, while some of the work was considered to fall within the CVL's existing services, some was clearly R&D, and would require funding. He asked for indications at the earliest opportunity of the outline for the programme and some estimated costs, including work that might be done elsewhere as part of the planned programme, in order to develop a case for funding from the Chief Scientist's Group (CSG).[867] Dr Watson, too, noted the importance of obtaining funding. He told us:

> I was very aware that the budget for research and development for BSE needed to be sufficient, and that the research that would need to take place was occurring against a backdrop of cuts of both staff and budget at CVL, that had been continuing for some years. Research officer and scientific officer posts, along with support staff, were being cut in many departments and the budgets reduced. Wherever possible, commercial funding had to be obtained to support research projects. During the late 1980's, three groups of scientists from the poultry, biochemistry and bacteriology departments, and some in parasitology, were mainly committed to commercially funded work. Nevertheless, the BSE programme had to be put into place. The resources necessary for the programme was an issue that was under constant review and is mentioned throughout this statement. The budget for the SVS, including the CVL, was apportioned through the Director General of ADAS. In order to secure further funding for any area of research, I would approach the CVO and the Chief Scientists Group ('CSG'). The CSG was ultimately responsible for approving expenditure on research and development commissioned by MAFF, which included the research on BSE. If the

863 S71 Bradley para. 31
864 YB87/6.3/1.1; YB87/6.10/2.1
865 S70 Watson para 32
866 YB87/6.17/2.1–2.5
867 YB87/6.10/2.1

> funding was not available, then I would have to either not run the experiments, or reallocate funding from other projects.[868]

6.138 By 23 September 1987, Dr Watson was in a position to brief Dr Shannon, the Chief Scientist (Agriculture and Horticulure), on BSE, and to outline the proposed experimental work. Dr Shannon agreed that further detailed investigations and an experimental programme were necessary, and they decided that detailed project proposals with costings would be prepared and submitted to him 'as a marker for the expenditure required.'[869] Dr Watson asked Mr Bradley to prepare the proposals.[870]

6.139 Mr Bradley told Dr Shreeve in a minute dated 29 September 1987 that he was working on the project draft. At the same time he put forward proposals for registering a BSE research project. He said that it was envisaged that there would be four experiments (composed of sub-experiments). These represented the four areas into which the proposed work fell: epidemiology, transmission, clinico-pathology and molecular biology (including SAF) studies. The four experiments would be formally submitted to the Directorate for approval, and then registered.[871] Dr Shreeve agreed with this approach.[872] The four experiments were eventually approved by Dr Shreeve (the Programme Manager) and Dr Watson in late November 1987.[873]

6.140 Meanwhile, by 22 October, Mr Bradley had completed a project draft for submission to the CSG.[874] He noted that it would at this stage comprise four experiments, with potential for a fifth genetic breeding experiment later. Dr Watson forwarded the draft to Dr Shannon on 5 November 1987. Dr Watson pointed out that the fourth experiment, molecular biology, was a proposed package of collaborative work involving the NPU and the CVL. The NPU would therefore be looking for commissioned funding. He also pointed out that, in the CVL R&D programme as a whole, several projects had been curtailed or stopped to allow resources to be switched to work of higher priority, and that a further shift of resources to the BSE project would exacerbate these problems.[875] Dr Watson therefore asked Dr Shannon to look at the commissioned R&D in other ADAS services and elsewhere with a view to identifying work of lower priority that could release funding to support the required work on BSE.

6.141 Dr Shannon replied on 22 December 1987. He expressed the view that new funding would be difficult to find. He was prepared to consider supporting the work at the NPU from the 'special fund'. However, as to the work necessary at the CVL, he said that the only possible way forward would be to reappraise current programmes, and he identified certain work that he regarded as being of lower priority than BSE work.[876] We note that the special fund could not be used for in-house work: funding would therefore have to be identified by reordering of priorities.[877]

[868] S70 Watson para. 31
[869] YB87/9.23/2.1
[870] YB87/9.23/1.1
[871] YB87/9.29/1.1
[872] YB87/10.5/1.1
[873] YB87/11.20/1.1; YB87/11.20/3.1; YB87/11.26/1.1
[874] YB87/10.22/1.1–1.5
[875] YB87/11.05/3.1–3.7
[876] YB87/12.22/2.1–2.2
[877] T39 p. 62 (Shannon)

6.142 By 20 December 1987, Mr Bradley had prepared a paper on the 'logical approach' to BSE research. In his covering minute to Dr Watson, he identified a number of questions to which answers were needed:

> A Is BSE transmissible to primates? (& by inference to man).
>
> B What tissues contain the agent? – and in what concentration. Likewise for milk. What is the minimal infective dose for (a) a primate (b) a calf?
>
> C How can the agent be destroyed?

He went on to suggest experimental action from which answers might be obtained and concluded:

> There are clearly a large number of experiments we could do & should do. The first thing to decide is where to put the effort and decide the priorities. Can we please discuss in the light of the documents presented & decide a practical short list of experiments we can conduct concurrently given the resources to do so. I can then plan & cost the outline. [878]

6.143 Mr Bradley's logical approach to research was as follows:

> 1. Demonstrate transmissibility.
>
> | | | |
> |---|---|---|
> | Inoculum | – | richest likely source of agent |
> | Recipients | – | a) same species |
> | | | b) likely laboratory species |
> | | | a) and b) concurrent |
> | Routes | – | most likely to transmit i/c + i/p |
>
> 2. Demonstrate agent titres in organs, tissues, body fluids.
>
> | | | | |
> |---|---|---|---|
> | Brain* | Muscle* | Bone | Skin |
> | Spleen* | Red offals | Blood | *More important |
> | Placenta* | Other offals | Milk* | |
>
> 3. Demonstrate agent titres as in 2 at different intervals after infection.
>
> 4. Demonstrate agent resistance to
>
> | | | |
> |---|---|---|
> | heat | | |
> | pasteurisation (milk) | | |
> | radiation | | |
> | chemicals | – | chloral |
> | | – | NaOH |
> | | – | other. |

[878] YB87/12.20/1.1–1.6

5. If 1 successful attempt transmission to other species.

Primates	Horses)	i/c brain
Sheep	Pigs)?	primates also: milk oral
Mink	Poultry)	meat "

6. Demonstrate transmissibility of sheep scrapie to cattle.

7. Demonstrate minimal infective doses for cattle, primates and laboratory model – BSE and scrapie.

8. Investigate means of eliminating BSE infection from herds – (a) embryo transfer (b) calf snatching.

9. Develop tests to identify resistant and susceptible animals & cheaper tests for detection of infection preferably ante mortem.

6.144 By this stage, some work was already in hand. In a minute to Dr Watson on 31 December, intended for inclusion in a submission to Ministers, Mr Bradley noted that work in progress included: epidemiology, clinico-pathology, molecular biology (identification of SAFs), transmission to hamsters (CVL), cattle (CVL) and mice (NPU) and investigation of pedigrees of affected and control animals.[879] He also identified proposed extensions to these studies, namely transmission to marmosets (being initiated in association with medical colleagues); inoculation of placenta and milk into cattle and hamsters (CVL); and inoculation of heat-treated brain into hamsters to determine the heat sensitivity of the agent.

6.145 In a separate minute to Dr Watson, Mr Bradley listed the non-BSE work that had by this stage been stopped, reduced or delayed in order to divert resources to BSE work:

i. in the Pathology Department, projects on emerging diseases other than BSE, and research on bovine foetal development and sarcocystis, were scaled down. Work on border disease and renal dysgenesis was stopped, while planned work on chlamydia and bluetongue was postponed; and

ii. in the Epidemiology Department, work that was stopped included research on TB in badgers and on sheep pulmonary adenomatosis.[880]

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6.146 Attempts to progress the comprehensive research programme continued throughout 1988. Mr Bradley revised his draft material for inclusion in a submission to Ministers in January 1988, and prepared a complete draft submission in March,[881] although it does not appear that either was subsequently presented to Ministers.[882] Mr Bradley also prepared a further paper for Dr Watson discussing and prioritising

879 YB87/12.31/1.1–1.2
880 YB87/12.31/2.1
881 YB88/3.13/3.1
882 YB88/3.7/4.1

the experiments that were required.[883] He suggested that experiments should be sequential, rather than concurrent. While primary studies were carried out, time should be spent designing the secondary experiments well and ensuring that the resources were obtained to undertake them.[884]

6.147 Among proposed primary studies, Mr Bradley included developing a laboratory model for transmission, and establishing a genetic marker test for use in live animals to identify the genotype controlling disease expression.[885] Mr Bradley's secondary experiments included: 'Determine the transmissibility of scrapie from sheep to cattle with a view to validating the current epidemiological hypothesis of the origin of the agent from sheep entering the feed chain.'

6.148 In April 1988 Dr Hope of the NPU expressed concern that no definite funding for even the top priority experiments had been forthcoming. Mr Bradley asked Dr Watson whether more could be done via the Minister or the Permanent Secretary.[886] Dr Hope visited the CVL in early May. Mr Bradley reported to Dr Watson that Dr Hope agreed that the genetic marker studies needed to be completed before cattle could be used for experimentation. This therefore had a very high priority. Moreover, Dr Hope agreed that they could only proceed with BSE studies sensibly when an experimental animal model, or cattle, were identified as hosts. Scrapie experiments on the other hand, could proceed, and it was suggested that they try and confirm experimentally how infection started in cattle.[887]

6.149 Existing studies and proposals for further research into BSE were evaluated and discussed by Dr Shreeve and CVL scientists in May 1988.[888] At this stage, the fifth experiment under the BSE project had been initiated, namely molecular genetic studies.[889]

6.150 This discussion in May formed the basis of a submission to Mr Donald Thompson, the MAFF Parliamentary Secretary, in June 1988.[890] The CVO indicated in his covering minute that, subject to Mr Thompson's agreement, discussion would begin with the CSG on the possibility of obtaining funds for commissioned R&D (other than near-market elements of the programme). The submission noted that the projects/experiments which made up such a programme were dependent on the questions to which answers were required. Nine questions were listed and, for some, experiments that might provide answers were discussed. Among these was the question whether vertical transmission could occur from dam to offspring: a study of selected offspring of affected cows was proposed to address this. Another of the questions was whether the natural or modified scrapie agent was the cause of BSE in cattle, and a transmission experiment to answer this question was proposed.

6.151 Mr Bradley continued to try and progress the BSE R&D effort. On 16 June he wrote to Dr Watson:

> There has recently been much discussion on future R&D with a whole series of proposals put forward. It is time to take stock of these proposals and select

883 YB88/3.13/2.1
884 YB88/3.13/2.1
885 YB88/3.13/1.4–1.5
886 YB88/4.5/2.1
887 YB88/5.4/2.1–2.3
888 YB88/5.9/3.1–3.12
889 YB88/5.5/1.1–1.2
890 YB88/6.29/8.8

> a short list for serious investigation. Without this approach we are in danger of doing nothing or being blown by the wind.
>
> We need some guidance and direction here so that we can harness our skilled resources to the task in hand. It seems to me the pressures from the rendering industry . . . are aiming us in one direction whereas the availability of resources for semen and ET work are going in another. We must also heed the scientific validity and sequencing of various options.
>
> Can we please discuss, sort the corn from the chaff and develop some specific objectives and determine the experiments to meet them?[891]

Interim recommendations from the Southwood Working Party

6.152 The work of the Southwood Working Party is discussed in detail in vol. 4: *The Southwood Working Party, 1988–89*. They first met on 20 June 1988, and Sir Richard Southwood wrote the next day to Mr Andrews, the MAFF Permanent Secretary, making four interim recommendations.[892] Three of these were of direct relevance to the research planning that was taking place. The first was a recommendation that an expert working party on research should be established by the MRC (and possibly the AFRC) to advise on the research that was in hand, and on what was required. An urgent question for the body would, he suggested, be a review of the current laboratory work on the transmissibility of the agent. vol. 11: *Scientists after Southwood* discusses the steps taken over the following months to implement that recommendation.

6.153 The second interim recommendation was that MBM should be given to cattle and laboratory animals to test the hypothesis that scrapie was the origin of the disease, and also that experiments should be conducted with scrapie (as a proxy for BSE) to determine the likelihood of its transmission via milk or muscle.

6.154 The third interim recommendation was that priority should be given to the epidemiological work on transmission of the disease in cattle herds. Sir Richard said that, in practice, this meant that arrangements must be made to ensure that the offspring of about 150 cows with BSE were identified and monitored (even if this involved some financial compensation for the farmers).

6.155 The CVO, Mr Cruickshank of MAFF's Animal Health Group, and Dr Watson met Mr Thompson on 7 July. Mr Thompson felt that all necessary research on BSE should be carried out 'whatever the cost', and he agreed that the CSG should be approached.[893] Following the meeting, Dr Watson directed that certain experiments be initiated and that others be progressed.[894] Mr Bradley told the BSE group that financial resources required to carry out the programme were being sought immediately. He asked the relevant Experiment Leaders to identify necessary staff resources, expertise and capital expenditure.

6.156 Mr Bradley visited the NPU during July 1988. He reported to Dr Watson on his visit and on the NPU R&D programme.

891 YB88/6.16/2.1
892 YB88/6.21/1.1
893 YB88/7.14/2.1–2.3
894 YB88/7.18/2.1

6.157 In early August Dr Shreeve reported that the Prime Minister had apparently directed that BSE R&D should be afforded high priority, and that it was becoming clear that the Government would fund most if not all of the research.[895] He identified as possible sources of funding money obtained from near-market savings at the CVL and elsewhere, Vote 3, Dr Shannon's Open Contracting Fund,[896] and a supplementary bid. Accordingly, a five-year R&D programme for the CVL was required, to be submitted to the Minister early in September, ie, within three weeks. It was envisaged that the programme could then be put to the advisory group on research proposed by the Southwood Working Party. Following production of the programme, 'initiatives should be put in hand to obtain appropriate funding'.

6.158 A programme was subsequently prepared by Mr Wilesmith in August 1988 and a revised version was forwarded by Dr Watson to the CVO, Mr Meldrum, on 9 September.[897] Mr Meldrum in turn forwarded it to Professor Bell, MAFF's Chief Scientific Adviser, and, because he understood it was needed for the Minister's PES meeting with the Treasury, to Finance Division.[898] Mr Meldrum said that, in addition to future needs, extra funds for R&D for the current financial year were needed to allow R&D that had been stopped in other areas to be resumed. He suggested that some of this might be available from the CSG. Mr Meldrum also reported his efforts to obtain industry funding. He anticipated that future research would be considered by the BSE R&D coordinating group recommended by the Southwood Working Party, once it was established.[899]

6.159 During September, the annual bilateral PES meetings between the Chief Secretary to the Treasury and the Minister of Agriculture took place. Mr MacGregor, the MAFF Minister, made a late bid for additional funds to support R&D in a number of areas, including BSE, but was unsuccessful.[900]

6.160 One piece of research that was already in hand produced results during September 1988. Researchers at the NPU achieved transmissions of BSE to a particular strain of mice.[901] This was an important step towards identifying a suitable model for infectivity experiments, which was one of the factors that had been identified as delaying such research.

6.161 Dr Shannon, to whom Mr Meldrum had copied the R&D programme, contacted Professor Bell on 12 October. He said:

> As I see it the aim within MAFF should be to have in place (or planned) the programme of work which we feel is necessary to meet our responsibilities in relation to BSE. If we have done our job properly this will then be endorsed by the Research Committee in due course. The work proposed by Mr Meldrum is principally at CVL. If the programme is to gain acceptance it will need to involve a wider range of laboratories (AFRC and Universities) where there is appropriate expertise. We will need to carry interested research partners with us.

895 YB88/8.3/1.1
896 That is, the 'special fund'. See T39 p. 61
897 YB88/9.9/2.1–2.16
898 YB88/9.26/5.1
899 YB88/9.26/5.1
900 YB88/9.8/6.1–6.6; YB88/9.22/4.1–4.2; YB88/10.13/4.2
901 YB88/9.27/2.1

> It has not been made clear where the funding (and any additional funding) will come from but on the assumptions that it will involve funds for which I have responsibility I would wish Dr MacOwan to be involved fully in the discussions.[902]

6.162 Representatives of MAFF (including the CVL) and the IAH (including the NPU) met at the CVO's office on 17 November 1988 to discuss BSE R&D.[903] Dr Watson explained that CVL had not received any extra funding, and that BSE R&D had been funded by closing other projects. Dr Hope explained that the NPU's work had been funded by diverting resources from its scrapie programme (then funded by DES). The work in hand was reviewed in detail, and there was discussion of the future R&D programme. One project that was now said to have a lower priority was the scrapie-to-cattle experiment, since this work had been done in the US but not published.[904] Professor Bourne said that it was not anticipated that the NPU would conduct experiments in cattle; it was agreed these would be done by the CVL.[905]

Further input from Sir Richard Southwood

6.163 Vol. 4: *The Southwood Working Party, 1988–89* discusses Sir Richard's meeting with Ministers on 24 November, following the second meeting of his Working Party. During the course of the meeting, he again emphasised the importance of keeping the cohort of offspring of affected animals intact.[906]

6.164 On 14 December 1988 Mr Bradley updated the R&D programme paper that had first been prepared in August.[907] The following day, the second of the regular (approximately twice-yearly) BSE R&D meetings between the CVL and NPU took place.[908] In a minute to Dr Watson prepared following the meeting, Mr Bradley outlined the actual and proposed programme of R&D by the CVL and NPU. He recorded his view:

> It is essential that appropriate funding and resource allocation is provided immediately without the prelude of time-consuming administrative procedures. An exception must be made for this work. Documentation can be dealt with concurrently or following fund allocation and provision. Progress (initiation for some experiments) is currently stagnating due to absence of funds and other resources.[909]

6.165 Mr Bradley's updated R&D programme paper outlined the aims of the CVL programme, the work that was already taking place, and the proposed work. The position on the five experiments at the end of 1988 was:

i. **Epidemiology**: by December 1988 Mr Wilesmith's epidemiological studies had identified MBM as the medium through which, on current evidence, BSE had spread (see Chapter 3). The future objectives were directed at two key aims of the programme: investigating further the hypothesis that MBM was the source of BSE, and determining whether

902 YB88/10.12/3.1
903 YB88/11.17/3.1–3.5
904 Mr Bradley had reported on this work, begun in 1978, to Dr Watson: YB88/10.00/1.1
905 YB88/11.17/3.1–3.5
906 YB88/11.24/3.1
907 YB88/12.14/3.1–3.11
908 YB88/12.15/5.2–5.7
909 YB88/12.15/4.1–4.6

BSE transmitted naturally in cattle, either vertically from dam to offspring (maternal transmission), or horizontally between animals (or both). However, no maternal transmission experiment was in place at this stage.

ii. **Clinico-pathological studies** to describe the histopathology of BSE were in progress.

iii. **Transmission**: by December 1988 a number of transmission studies were in progress. Hamsters and calves had been inoculated at the CVL; marmosets had been inoculated at the MRC/CRC[910] laboratory (Northwick Park – funded by the MRC); mice had been (by now successfully) inoculated at the NPU (funded by AFRC/MRC); goats had been inoculated at the NPU; and plans to inoculate mink at the CVL were at a fairly advanced stage. Sheep had also been inoculated at the NPU, although this was not included in Mr Bradley's paper.[911]

Transmission experiments to determine the infectivity of specific tissues were also being planned. Tissues specifically identified were the placenta (experiment at design stage), semen (still at design stage, although semen from one BSE-infected bull had been collected) and embryos (at design stage). Testing of other tissues and a pathogenesis study were also envisaged, but all of these experiments awaited the establishment of a suitable animal model.

The stated aims of these experiments were to determine whether BSE was transmissible; to determine whether the BSE agent could be transmitted by semen or embryos from infected and affected cattle; to determine whether the BSE agent was identical to the natural scrapie agent or a modified scrapie agent, and whether there were multiple BSE strains; and to determine the conditions required for sterilisation and to make rendered material safe.

iv. **Molecular biology**: SAFs had been identified in February 1987, and confirmed by western blotting in October 1987. Work in progress, which was aimed at determining whether the BSE agent was identical to the natural scrapie agent or a modified scrapie agent, and whether there were multiple BSE strains, included assembling a lesion/SAF/PrP profile for brains, which might correlate with the agent strain. This would be extended to other tissues once the techniques were optimised.

v. **Molecular genetics**: studies to determine any genetic factors involved in disease expression in cattle, and to determine whether an equivalent to the *sinc* or *sip* genes existed in cattle, were in the planning stage. Some suitable animals/herds had been identified and blood samples were being collected and stored.

[910] Clinical Research Centre, Harrow
[911] YB89/11.21/1.8

1989

The Southwood Working Party's approach to research

6.166 As noted above, the Working Party made interim recommendations in June 1988, one of which was that offspring of BSE-affected cattle should be obtained and monitored (this was referred to as 'the offspring' or the 'maternal transmission' study). On 24 January 1989, comments were requested within MAFF on a draft submission to the Parliamentary Secretary recommending the purchase and retention of 300 such offspring and 300 controls.[912] The draft submission indicated that the study was being carried out on a voluntary basis, which meant that there would be nothing to stop the owners slaughtering the animals at any stage, without even informing MAFF. If a number of farmers chose to do so during the period of observation, the study would be invalidated.

6.167 The Southwood Working Party presented their report to Ministers on 3 February 1989. In it, they noted that MAFF had identified 300 offspring of affected cows, and they urged that all necessary resources be made available to ensure that these animals were monitored and were not destroyed before they were old enough to display the disease, should they be infected. Otherwise acquisition of knowledge about vertical transmission could be delayed for some years.[913]

6.168 The *Southwood Report* noted that the Working Party's interim recommendation that a committee be set up to advise, coordinate and oversee the research work in this area had been accepted. It also identified areas of research that the Working Party believed should be considered in the fields of epidemiology, transmission, genetic studies, molecular biology and surveillance. As the Working Party noted, many of the recommended studies were already under way or were planned.

6.169 After some discussion, a revised version of the draft submission on the 'offspring' or 'maternal transmission' study was sent to the Parliamentary Secretary on 28 February 1989 by Dr Watson.[914] He emphasised the importance placed on the study by the Southwood Working Party, and recorded that the TSE consultant, Dr Kimberlin, and Dr Rosalind Ridley of the MRC had that morning agreed that it was essential that all the offspring in the cohort were under the complete control of MAFF. The submission estimated the costs of the study at £1.5 million over the full period of 6–7 years.

6.170 The study was one matter considered when the MAFF Permanent Secretary, the CSA, the CVO, Dr Watson and others met on 1 March 1989 to discuss the funding of the proposed new R&D programme.[915] They agreed that the study should be commissioned and that MAFF should purchase the whole study group of cattle. Dr Watson agreed to coordinate the preparation of a properly costed research proposition to be put to the new Consultative Committee on Research chaired by Dr Tyrrell, and also of a paper to be put to the Treasury at the same time, indicating the extent to which the study could be funded with existing resources, and the extent to which additional resources would be necessary.

912 YB89/1.24/6.1–6.7
913 IBD1 para. 8.1
914 YB89/2.28/5.1–5.4
915 YB89/3.2/2.1–2.3

The Tyrrell Committee

6.171 The work of the Tyrrell Committee is discussed in detail in vol. 11: *Scientists after Southwood*.

6.172 The maternal transmission study was discussed by the Committee at its first meeting, on 13 March 1989.[916] It noted that, while a more efficient [and cheaper] design using fewer animals could be put forward, this would be at the price of two years' delay. Dr Tyrrell agreed to circulate urgently a draft letter to the Permanent Secretary on the proposal.

6.173 The Committee also noted at this meeting that it would not consider research applications (although there might be exceptions for work originally it had suggested).[917] Individual members of the Committee would be recommended to the funding bodies as referees for relevant grant applications, and a list of these applications would be supplied for information and, if appropriate, comment. Hence, the Committee would not act as peer reviewers.

6.174 Among other general matters discussed were the centres that might be able to assist in fundamental and animal work.[918] The Committee noted: 'Factors limiting progress in understanding BSE included not only inadequate financial resources but also shortage of skilled manpower. The bulk of the work would have to remain with CVL and NPU, since no-one else matched the extent of their expertise.' However, certain other centres were identified for specific areas of work. The Committee also noted that since animal epidemiologists were few in number, modellers with more experience in human work might be able to help.

6.175 On 17 March Dr Shannon sent a minute to the Permanent Secretary, Mr Andrews, about the proposed R&D programme for BSE and salmonella.[919] His view was that they were not yet ready to make the detailed case for additional funding to the Treasury. There were details to be sorted out with the CVO and ADAS (relating to the reordering of priorities and the funding of the AFRC work at the NPU), and he proposed to hold a meeting to achieve this, and report back. Mr Andrews accepted that they were not yet ready to go to the Treasury, but asked for further advice as soon as possible.[920]

6.176 Dr Tyrrell wrote to Mr Andrews on 21 March to summarise his Committee's discussion of the proposed maternal transmission experiment.[921] He noted that transmission from dam to offspring might be detected by carefully recording the development of cases in herds. Alternatively calves might be removed as proposed. The most clear-cut experimental design, he said, would be to separate them shortly after birth and maintain them under close supervision on MAFF premises. However, ensuring that they had not received any suspect feed supplement would restrict the study to calves born after the ruminant feed ban became operative. This would mean about two years' delay in the answer being available, since some of the oldest offspring of affected cattle were now over two years of age. The opportunity to use ADAS experimental husbandry farms to hold the animals might also be lost if not taken up at once. Therefore the trial had been designed to show whether calves

916 YB89/3.13/3.1–3.4
917 YB89/3.13/3.1–3.4
918 YB89/3.13/3.1–3.4
919 YB89/3.17/5.3–5.5
920 YB89/3.17/5.2
921 YB89/3.21/9.1–9.2

available now from affected cows would have a significantly greater incidence of disease than contemporary controls. Consideration had been given to the number of animals (a total of 660) needed to ensure that if there was a low but significant rate of transmission, this would be detected by the study. Dr Tyrrell expressed the hope that his observations would assist Mr Andrews in deciding the form the study would take and how urgently it should be taken forward.

6.177 On 3 May 1989 the Chief Scientist's Group informed Mr Thompson of the programme of BSE (and salmonella) research recommended by its R&D subcommittee.[922] Planning of the maternal transmission experiment continued.[923] Mr Bradley had been appointed as project leader,[924] and on 4 May he noted that once funds were provided – 'and it is important to pay farmers for animals promptly and have funds for feed/veterinary services available at the outset' – it was thought that one month would be needed before the first animals were moved in.

6.178 On learning that the R&D programme would be considered by Ministers before it was submitted to the Treasury, Mr Bradley voiced concern about delays to Mr Meldrum:

> CSG advise that even if the submission to Treasury is approved and prompt, funds are unlikely to be available until the Autumn. . . . This further round of bureaucracy will result in more delay especially with the initiation of the offspring experiment which is becoming impossible to defend. May I suggest that you write to Professor Bell indicating both our frustration at repeated preparation of documentation which bears no fruit and the inability to progress important experiments recommended by Professor Southwood (and I anticipate supported by the Tyrrell Committee). If we are to succeed in this disease and provide information for Ministers to make decisions or defend actions, we must short cut the 'red tape' and obtain what we can from the Treasury so the new R&D can begin.
>
> Professor Bell said the offspring experiment cannot begin until funds are available (meeting minutes K C Taylor 7.3.89) but I understand the Management Board said it should go ahead without. This is not only difficult to reconcile but impossible to deliver as farmers and hauliers have to be paid promptly at the start of the experiment. Each delay increases the number of animals becoming pregnant and thus reduces the source number and delays the experimental result. Dr Watson and I commenced preparing information for submission to the Minister on BSE R&D as early as January 1988. It is regrettable that we are still doing the same nearly 18 months later and are unable to progress the offspring experiment, the infectivity studies (via NPU) and new work due to lack of funds and staff.[925]

6.179 On 18 May 1989 Mr Wilesmith sent Mr Bradley a separate proposal for the maternal transmission study,[926] for formal approval.[927]

922 YB89/5.3/2.1
923 YB89/5.4/3.1–3.2
924 YB89/4.12/5.1
925 YB89/5.22/4.1
926 Or offspring study
927 YB89/05.22/13.1

6.180 On 26 May Mr Andrews minuted Mr Meldrum about the maternal transmission study.[928] He said that although he understood the funding problem, they must find the resources to initiate and carry forward the work. Mr Meldrum minuted Professor Bell on the subject expressing his 'extreme concern about the delays'.[929] He said that progress was 'impossible in the absence of any assurance that funds are available' and that one year had been lost already. The losses were exacerbated by the fact that the study had to be carried out only on non-pregnant and non-lactating animals; and 'the oldest of the offspring and controls will already have been served – and more will be served every month'. Mr Andrews, to whom Mr Meldrum's minute was copied, said that he wanted the work on the study to begin straightaway. He asked for a note from Mr Geoffrey Hollis, Head of MAFF's Financial Planning Division, on how the work would be funded pending the outcome of discussions with the Treasury on financing.[930]

6.181 Mr Andrews held a meeting on 5 June 1989, and asked for two submissions on research funding to be prepared for the Minister.[931] He confirmed this in a note to Professor Bell the next day. The first submission was to go forward the same week, on the immediate problems associated with setting up the maternal transmission experiment, in particular how it was to be financed in the short term before extra funds from the Treasury were obtained. The second, to go forward the following week, was to be a submission enabling the Minister to go to the Chief Secretary of the Treasury seeking supplementary funding in the current financial year and in the next PES for the necessary research into BSE (and salmonella). This was to be based on the earlier submission, circulated by Dr MacOwan, and was to set out why the research was needed, why it was to be carried out in-house, and the implications for other non-BSE work if extra funding was not forthcoming.

6.182 Accordingly, Professor Bell prepared a submission for the Minister on 9 June inviting him to agree to both the initiation of the maternal transmission experiment and the making of a bid to the Treasury for the full funding of the experiment.[932] He explained that some of the first year's costs would be deferred to the following year, and that, as an interim measure, the remainder of these costs would be underwritten from within the SVS budget. The Minister agreed on 12 June and Mr Bradley took steps to set the study in hand.[933] Following this approval, things moved quickly: the first animals arrived at the Experimental Husbandry Farm on 19 July 1989 and Mr Bradley reported that the experiment was under way.[934]

Interim Report of the Tyrrell Committee

6.183 Volume 11: *Scientists after Southwood* describes the recommendations of the Tyrrell Committee in its Interim Report, which was completed in June 1989, and the response of Ministers and officials to them. This process naturally interacted with the work that was already in progress on developing a BSE R&D programme, and obtaining funds for it. Mr Meldrum, for example, noted that the Report did not assist them in coming to a view on which projects should be funded, and suggested

928 YB89/5.26/6.1
929 YB89/5.31/5.1–5.2
930 YB89/5.31/6.1
931 YB89/6.6/5.1
932 YB89/6.9/10.1
933 YB89/6.12/6.1–6.2; YB89/6.12/6.3
934 YB89/7.24/9.1

that no paper should go to the Treasury seeking additional funding for BSE R&D until the Report had been carefully scrutinised.[935] He suggested a meeting between himself, Dr Shannon, Dr MacOwan, Dr Watson and Professor Bourne. Mr Andrews agreed in principle, although he preferred that the work should be done in-house, that is, without at that stage involving Professor Bourne. He asked that they review which of the Tyrrell recommended projects were in hand, and which were not, and that they advise him urgently.

6.184 The second of the two submissions requested by Mr Andrews on 5 June – a revised submission to the Minister in support of the supplementary bid for funding for the current financial year and the PES bid for 1990/1 and subsequent years – was forwarded by Dr Shannon to Mr Andrews on 20 June.[936] Mr Richard McIvor, Head of MAFF's Finance Guidance Division, to whom the draft submission was copied, made a number of comments on what was needed in the submission to persuade the Treasury to provide the funding.[937] He said that they needed to relate individual R&D projects closely to policy initiatives and to illustrate their preparedness to reassess the worthwhileness of every research project they were currently undertaking.

6.185 The two strands, Dr Shannon's R&D submission of 20 June and the response to the Tyrrell Committee's Interim Report, were brought together by Dr MacOwan in a draft of the urgent advice requested by Mr Andrews, which he circulated for comments on 26 June.[938] This identified work that was in hand, and provided a table aligning the research proposals in the Interim Report with those in Dr Shannon's submission. Following discussions, a revised version was sent to Mr Andrews by Dr Shannon on 30 June 1989. Mr Andrews chaired a meeting to discuss the draft submission on 13 July. It was agreed that a letter should be drafted for the Minister to write to the Secretaries of State for Health and for Education and Science inviting them to agree that they had no choice but to fund as an immediate priority all work given two or three stars by the Tyrrell Committee.[939] Two tables were produced following the meeting – one dealing with MAFF work, and one dealing with work considered the responsibility of other Departments.

6.186 Volume 7: *Medicines and Cosmetics* describes how these tables dealt with Tyrrell recommendation A1d (investigation into the fate of bovine tissues) and C2a and C2b (transmission studies relevant to pharmaceuticals). Much of the other work recommended by Tyrrell was, according to Dr Shannon, in hand or planned.[940]

Bid for supplementary funds from the Treasury

6.187 As described in vol. 11: *Scientists after Southwood*, Mr Andrews sent the revised submission and draft letter to the new Minister of Agriculture, Fisheries and Food on 28 July, and Mr John Gummer, who had been appointed to that post a few days earlier, duly wrote to the Secretaries of State for Health and for Education and Science. His letter included a draft press announcement about the implementation of research recommended by Tyrrell, but noted that this was contingent upon extra money being available from the Reserve for that year. The letter was copied to the

935 YB89/6.19/5.1
936 YB89/6.20/6.1
937 YB89/6.22/10.2
938 YB89/6.26/4.1–4.5
939 YB89/7.14/1.1–1.2
940 YB89/07.14/5.1–5.6; see Table 1 in this minute

Chief Secretary for the Treasury Reserve, Mr Norman Lamont, and therefore constituted a bid for extra funding.

6.188 Experiment Leaders and others met at the CVL on 28 July, when Dr Watson reported that Mr Andrews had instructed that all projects given two and three stars by the Tyrrell Committee should be initiated immediately. The position at the NPU on project C1a (tissue infectivity studies) was said to be uncertain, and there was a consensus that somebody senior should 'tell the AFRC to progress 2 star and 3 star work'.[941]

6.189 Following the meeting, Mr Bradley prepared documents identifying restraints on progress on the recommended research.[942] In relation to transmission studies C1a and C1b, he said that it was imperative that this work was initiated forthwith. An approach via senior management to the Permanent Secretary to instruct immediate funding of this work identified as NPU research would, he said, largely solve the problem. If this was not possible, there would be a serious danger of public criticism. Mr Bradley noted that the work could not be undertaken in-house on the scale necessary and in the timescale demanded. Setting up a mouse colony at the CVL was a more expensive alternative. The restraints Mr Bradley identified for these experiments were 'animal accommodation, specialist staffing (animals and pathology), capital equipment for storage of tissues and accommodation for such storage'.

6.190 Mr Meldrum met Dr Watson and Mr Bradley on 7 August 1989 to discuss BSE R&D. He said that no further cuts in non-BSE R&D at the CVL should be made to accommodate BSE work. The new R&D should be initiated and he would take up any shortfall of funding with the Permanent Secretary. There was also discussion of the problems with the tissue infectivity studies, and Dr Watson suggested in a minute to Mr Meldrum the following day that he might wish to consider what advice should be given on how stimulus might be applied to get this moving.[943]

The Treasury rejects the bid

6.191 The Chief Secretary to the Treasury replied to Mr Gummer on 11 August. While agreeing that it was necessary to carry out research into the causes of BSE, he had difficulty with the proposed funding arrangements. In the current year, he felt that the necessary funds could be found within MAFF's overall research budget. He added that the possibility of funding from industry should have been considered, given that it was very unlikely that BSE was transmissible to humans.[944] Officials had also advised Mr Lamont that it was 'still early in the year to concede a claim on the Reserve'.[945] He wrote a similar letter to Mr MacGregor, since 24 July the new Secretary of State for Education and Science, who had written to Mr Gummer agreeing to his proposed announcement about the *Tyrrell Report*, subject to funds being made available from the Reserve.[946]

941 YB89/8.3/10.1–10.3
942 YB89/8.3/6.1–6.11
943 YB89/8.8/4.1–4.7
944 YB89/8.11/1.1–1.2
945 YB89/08.07/15.1–15.4
946 YB89/9.19/1.1; YB89/10.2/9.1

6.192 The Treasury did not provide additional funds for the research recommended by the Tyrrell Committee, although they did agree to a modest increase in provision for the external programme.[947] Mr Brian Dickinson, Principal Finance Officer in MAFF, told the Inquiry:

> Well, what happened was [the Minister] withdrew the bid for strategic research and development. He withdrew the bid for extra BSE and salmonella research in terms of getting more money for it. But he retained the bid for an uprating of the externally commissioned research generally to take account of cost increases, which I think in particular were the pay increases in Research Councils. So that overall there was an increase in funding, but then out of that resultant amount it was necessary for the Ministry to find whatever we needed to pay for what was clearly the priority, namely BSE and salmonella. That meant crowding out other spending.[948]

The Treasury did, however, provide £6.3 million over three years for what became the AFRC's Biology of the Spongiform Encephalopathies Programme (BSEP), which is described briefly later in this chapter.

6.193 On 14 December 1989 Mr Bradley minuted the CVO regarding tissue infectivity studies.[949] He stated that since his last document (9 November 1988) refinements to the list of tissues for potential study were required, resulting from the introduction of the ban on Specified Bovine Offal; extrapolation of data from Hadlow's studies into scrapie in sheep; the requirements of the research programme; additional uses of bovine tissues by the pharmaceutical industry; and additional uses of bovine tissues on farm land, in schools, etc. He noted that mouse transmission studies at the NPU were limited in years one and two to 30 in each, and in year three to 20. Already 13 of the available transmissions for year one were in progress, including semen, placenta, spleen, buffy coat and others. Four more were proposed and approved (liver, udder, pancreas and milk), which left only 13 available for year one. Mr Bradley noted that the tissues of highest priority for transmission studies should be identified and sent to the NPU for inoculation. He attached a draft list for proposed tissues to complete the quota for year one. These were: embryos, uterine flushings, semen, testis, ovary, abomasum, reticulum, rumen, omasum, oesophagus, distal ileum, prefemoral lymph nodes and foetal calf serum. Following consultation, Mr Bradley put forward a revised list of tissues to be inoculated in year one.[950] As vol. 11: *Scientists after Southwood* notes, all the projects identified by the Tyrrell Committee as being of two- or three-star importance were put in hand.

6.194 The Tyrrell recommendations had included the following epidemiological study:

> **Survey of brains of cattle routinely sent for slaughter to monitor incidence of unrecognised infection.** Although there is no firm evidence for evasion of compulsory notification and slaughter of BSE-suspect cattle, formal study of cattle presented as acceptable for human consumption would

947 YB89/10.31/2.1–2.5 para. 5
948 T38 p. 106
949 YB89/11.14/3.1–3.3
950 YB90/2.12/3.1–3.4. Already in progress were semen, spleen, nyala brain, kudu brain, buffy coat, M diaphragma, M semitendinosus, cow brain (2), fixed cow brain (2), placenta (2) and milk (toxicity trial); to be collected were embryos, uterine flushings and a more suitable semen sample; selected to be inoculated were midrum, liver, udder, mesenteric lymph node, CSF, kidney, milk (full study), pancreas, distal ileum, prefemoral lymph node, rumen and foetal calf blood

> provide reassurance and might even reveal spongiform change in animals with atypical or subclinical infection that has not been recognised.[951]

6.195 However, a number of those closely involved with BSE considered that this project was not worthwhile, because it required substantial resource input while not promising particularly useful results. Mr Meldrum told the Inquiry that the aim of such a study would be 'to monitor the incidence of unrecognised infection and also to provide reassurance that there was no evasion of compulsory notification and slaughter of BSE suspect cattle', but that in his view:

> . . . this project would place a very large burden on our over-stretched BSE diagnostic laboratories and I questioned whether it was likely to provide any valuable information that would have any bearing on any possible human health implications of the disease. I placed greater emphasis on veterinary ante-mortem inspection of cattle and the SBO controls to meet the legitimate public health concerns raised in this section of the Tyrrell Committee report. I was also aware that research proposals were in hand to examine a sample of positive and negative bovine brains to ensure that there was no change in the histopathological appearance of the disease.[952]

6.196 The matter was raised by the House of Commons Select Committee on Agriculture during hearings in May and June 1990, one member stating that he could not see 'how epidemiological work of any merit can go ahead without routine sampling of cattle brains which may or may not have scrapie-like disease'. But Dr Pickles of DH, Dr Tyrrell himself and Dr Kimberlin, who each gave evidence to the Committee, were all cautious. Dr Pickles told the Committee:

> I think I should explain to do this survey, on the evidence we had available that very, very small numbers of clinically affected animals reach slaughterhouses, the survey would involve not just histology of brains which is fairly quick but would actually involve inoculating brains from animals that looked normal, even brains that looked normal under the microscope, into a large number of mice and then taking it from those mice into more mice. You are doing it on thousands of brains for a very, very small chance of any information that would be of value scientifically. That is an enormous use of resources over a long period of time for very small return which is why, in fact, the rating has now dropped even lower, as the Minister has said. It is not a worthwhile project and does not really provide information on epidemiology.[953]

Later she added:

> I think it is important to point out we are talking about human resources. There are a limited number of people who have sufficient skills to do this sort of work and it is very important they spend their time on the important topics.[954]

6.197 Dr Tyrrell acknowledged that the project presented problems:

951 IBD1 tab 4 p. 10. The proposal for a system of random monitoring of the brains of cull cattle for BSE was raised in the House of Commons in May 1989 by Mr Ron Davies MP: YB89/5.17/1.3. Dr Tyrrell told the Inquiry that the single star signified that 'it would be worth doing if resources were available' (S11 Tyrrell p. 5 para. 17)
952 S184A Meldrum section I para. 31
953 IBD1 tab 7 p. 7
954 IBD1 tab 7 p. 7

> . . . if you kill animals as they go through the abattoir and take the brain out, you could look for the changes of spongiform encephalopathy in the brain. This is very laborious. It is not particularly sensitive; it is, in fact, very doubtful whether you would see any until the animal was sick or just about to be sick, and therefore you would consume certainly a very large amount of the very precious resources we have in expert neuropathological skills and what you would probably find would be a large number of negatives.[955]

6.198 Dr Kimberlin said:

> If I may summarise it very simply, in my opinion, the enormous amount of labour that would be involved in manning an operation of this kind is not worth the additional information it would produce.[956]

6.199 The Committee's report stated that:

> Those calling for the random testing of cattle which have been slaughtered without having first shown clinical symptoms argue that such tests would accelerate our understanding of the likely extent of the disease. This form of research was not accorded high priority by the Tyrrell Committee (because of its heavy demand on technical resources), although the Committee did recommend it as having some value. **We believe the Minister is correct to adopt the research priorities recommended by the Tyrrell Committee, but trust that he will give due consideration to this proposal when improved diagnostic tests become available.**[957]

6.200 Although there was general scepticism about this project within MAFF at this time,[958] the Permanent Secretary, Mr Andrews, was:

> . . . uneasy about possible criticism for not pursuing some of the individual lines of research recommended in the Tyrrell Report even though we have good reasons for not doing so. I should be grateful if you would consider whether we should put a short note to Tyrrell reporting on how his Committee's research recommendations are being followed up. This would give us an opportunity of explaining why we are not pursuing a small number of items and getting his endorsement.[959]

6.201 Mr Meldrum told the Inquiry that the intention at the time had been that charts summarising the position on the Tyrrell Committee's recommendations were to be put to SEAC at their next meeting.[960] However, neither this nor any other summary of MAFF's response to the Tyrrell Committee's Interim Report appears to have been tabled at subsequent SEAC meetings.

955 IBD1 tab 7 p. 76
956 IBD1 tab 7 p. 76
957 IBD1 tab 7 p. xx
958 Dr MacOwan advised that 'the techniques available cannot be expected to yield results which would reflect the level of infectivity in slaughtered cattle' (YB90/6.11/15.3), while Mr Charles Capstick, a MAFF Deputy Secretary, noted that 'to arrive at any reasonably robust statistic of incidence it would be necessary to sample thousands of brains', that this would not be cost-effective, and that another study provided a more focused approach to studying the development of the disease (YB90/6.11/15.1)
959 YB90/6.21/4.1
960 S184A Meldrum p. 155 para. 33

SEAC

6.202 The Tyrrell Report also recommended that a 'standing mechanism' might be required to oversee the cooperation and coordination of research.[961] In the event, this was part of the wider remit given to the Spongiform Encephalopathy Advisory Committee (SEAC), which started work in April 1990. An account of its work and mode of operation is given in vol. 11: *Scientists after Southwood.*

6.203 The present volume does not set out how the MAFF R&D programme developed from this period onwards. Volume 11 describes the discussions that took place about the coordination of BSE R&D, including the question whether a research supremo should be appointed. Eventually SEAC was asked to oversee and coordinate all publicly funded research on BSE and other spongiform encephalopathies. It produced two interim reports on research, in April 1992 and September 1994 respectively.

Project funding and TSE research by others

6.204 In addition to the work on BSE carried out at the CVL and NPU, research into TSEs was funded by the Department of Health, the Medical Research Council (MRC), the Biotechnology and Biological Sciences Research Council (BBSRC) and The Wellcome Trust.

DH-funded TSE research

6.205 The need for research into an emergent disease of cattle was considered by DH to be a matter for MAFF, although the potential implications for public health were recognised.[962] The two Departments agreed that most of the recommendations for research in the *Tyrrell Report* related to animal issues and hence were for MAFF to take forward. However, two studies fell within DH's remit: surveillance of CJD cases, and monitoring of occupational groups with high exposure to bovine tissues. A third area of research identified by the Tyrrell Committee involved the potential transmissibility of disease into mice from pharmaceuticals containing products of bovine origin, in particular bovine serum albumin. This was considered to fall jointly to DH and MAFF.

6.206 Volume 8: *Variant CJD* describes how the CJD Surveillance Unit (CJDSU) was set up in May 1990, to build on epidemiological work by Professor Bryan Matthews that had originally been funded by the MRC. The CJDSU was funded by DH and the Scottish Office. Its remit was to monitor the incidence and epidemiology of CJD with a view to detecting any changes in the pattern of the disease, and to provide neuropathological validation of any clinical diagnosis, both retrospectively and prospectively. The Unit was also asked to carry out a case control study to help identify epidemiologically any particular risk groups and factors associated with CJD. Prospective monitoring of specific occupational groups, a separate study recommended by the Tyrrell Committee, was not

[961] IBD1 tab 4
[962] DH01 tab 5 para. 17

undertaken since it was not judged to be cost-effective. It was expected that changes in the occupational incidence of CJD would be detected in the general study.

6.207 Between 1992 and 1995, the CJDSU was nevertheless involved in investigating occupational risks from CJD, prompted by the deaths of four dairy farmers. Meanwhile studies at the NPU had been set up to examine the strain characteristics of CJD in farmers with BSE on their farms, of contemporary cases of CJD where no occupational link existed, and of cases of CJD occurring before the emergence of BSE. These studies were funded by the MRC. However, following the identification of vCJD, DH provided additional funds to the NPU, for work aimed at characterising the nature of the new disease.

6.208 What became of the recommendation for transmission studies specifically relevant to pharmaceutical manufacture is described in vol. 7: *Medicines and Cosmetics*.

6.209 DH also funded Professor John Collinge, at St Mary's Hospital, Paddington, to carry out molecular genetic studies of the human prion protein. In 1996 DH provided funding for expanded animal housing facilities both at the NPU and for the prion research group at St Mary's.

TSE research by the Research Councils

6.210 Most of the TSE work funded by the Research Councils took place at the NPU. The research initiated in response to the emergence of BSE was carried out within existing projects in collaboration with the CVL. It resulted in many key discoveries, but attracted no extra funding and other work was therefore delayed.[963] However, when more funds became available in 1989, the AFRC set up the Biology of the Spongiform Encephalopathies Programme (BSEP) mentioned earlier.

6.211 BSEP was designed to build on the strengths developed at the NPU and to 'complement and underpin' MAFF's work on BSE and research on CJD funded by the MRC and the Health Departments.[964] It was funded partly from the AFRC's core budget and partly from additional funding for TSE research of £6.3 million (spread over three years, to 1991/92) secured in the PES round in 1989[965] (subsequently extended to £9 million over four years[966]).

6.212 The first research programme, BSEP-I, ran from 1991 to 1994. Research proposals were reviewed by external referees. The initial tranche of applications was assessed, and funding allocated, by a board chaired by Professor Bill Jarrett.[967] Thereafter, this task was performed by the BSEP Working Group.

6.213 When the initial funding was exhausted, there was a delay of one year. This was because of funding and policy uncertainties arising from the demise of the AFRC and the establishment of the BBSRC, and from the ongoing round of 'prior options reviews' of public sector research laboratories.[968] Professor Jeffrey Almond, who coordinated BSEP for the AFRC, told the Inquiry that the funding

963 Details of the kind of work affected are given in S308 IAH and the NPU: Funding Issues p. 9 para. 37
964 YB95/1.27/1.1–1.4, para. 3
965 S73 Blundell pp. 4–5 para. 14 and YB91/5.10/7.1–7.4, para. 8
966 YB93/3.30/2.1–2.7, para. 2.3
967 YB91/5.10/7.1–7.4, para. 9 and T30 p. 71
968 S73 Blundell p. 4 para. 17. 'Prior options reviews' are described briefly in Chapter 6 of vol. 15: *Government and Public Administration*

hiatus was disruptive: 'my lab essentially emptied at the end of BSEP I' because of the scientists' uncertainty about their future.[969] Recognising that further funds would have to be sought and justified in competition with other priorities, the Working Group considered how the AFRC should support research relating to spongiform encephalopathies in future. A number of points were agreed, including:

i. a new programme should support longer-term strategic studies related to BSEP and new areas of work;

ii. the level of funding should be scientifically justified rather than limited by the current funding level;

iii. the fundamental problems of the biology of spongiform encephalopathies and their wider ramifications should be emphasised; and

iv. a five-year programme should be sought.

6.214 The MRC decided at that time to move from priority support to responsive mode support.[970]

6.215 In March 1994 the newly established BBSRC affirmed its commitment to the programme[971] but, until the new funds were available, the salaries and research costs of staff employed under BSEP-I were funded largely by the IAH to avoid any hiatus in advancing the research.[972] Applications for BSEP-II funding were invited in September 1994, and projects costing in total some £5.2 million were supported over the next four years.[973]

MRC: the Murray Committee and the Allen Committee

6.216 The Coordinating Committee on Research on the Spongiform Encephalopathies in Man (the Murray Committee) first met in October 1990. Its remit was to:

> (i) identify and as appropriate coordinate medical research in the UK relevant to the spongiform encephalopathies (SEs) in humans, and place it in the international context;
>
> (ii) identify new opportunities for research and the individuals and teams that might be encouraged to undertake it; and specifically identify work the MRC might commission within the NPU; and
>
> (iii) report not less than annually to the MRC through the Neurosciences Board.

6.217 Apart from its Chair, Professor Sir Kenneth Murray, the members included Professor Ingrid Allen, at that time Chair of the MRC's Neurosciences Board and also a member of SEAC; Professor Jeffrey Almond, who subsequently coordinated

969 T12 p. 42
970 YB93/6.28/1.3 para. 4.2
971 YB94/3.24/1.1–1.5, para. 5.1
972 S308 IAH and the NPU: Funding Issues p. 9 para. 36
973 S73 Blundell para. 17

BSEP for the AFRC; and independent scientists. There were observers from DH,[974] the Scottish Home and Health Department (SHHD), and the AFRC.[975]

6.218 The Murray Committee established a Clinical Subcommittee, chaired by Professor Allen, to coordinate:

i. current and future studies relating to SEs in man;

ii. the follow-up of patients with, or at risk of, iatrogenic SE infection; and

iii. the application of new methodologies and techniques to refine the definition of SEs in man and improve diagnosis.[976]

6.219 Professor Allen told the Inquiry that:

> We were particularly concerned with epidemiological monitoring and neuropathological definitions and debated whether atypical dementias should be included in the epidemiological studies. The importance of this debate was the possibility that if BSE affected humans the clinical presentation might be atypical for CJD. The subcommittee was also concerned with the difficulties of diagnosing dementia in the elderly and with the possibility that CJD might be missed in this age group.[977]

6.220 Apart from identifying certain scientific issues, the Murray Committee concluded that:

> (i) because methodological and logistical constraints were considerable, strengths in other relevant fields needed to be harnessed – ie, collaboration with groups and centres not then committed to TSE research; and
>
> (ii) the Clinical Subcommittee should help coordinate epidemiological and clinical studies of sporadic CJD, familial CJD/GSS, iatrogenic CJD and atypical dementias.

6.221 It recommended that support for such work should be given priority within the MRC's normal competitive peer review system and that the Committee itself could have a useful continuing role in reviewing progress and priorities.[978]

The Wellcome Trust

6.222 Although the Wellcome Trust did not have a TSE programme *per se*, funding was awarded to TSE-related projects through the Trust's declared interests in genetics, veterinary medicine and infectious disease research.[979]

6.223 Since 1986 the Trust has provided funds for projects, studentships and fellowships mainly in prion research. In particular, one of the main thrusts of the Trust's TSE research has been through the funding of Professor Collinge's work,

974 Dr Hilary Pickles
975 IBD2 tab 2 pp. 16–17
976 IBD2 tab 2 p. 17
977 S50 Allen para. 13
978 YB91/12.03/3.2
979 M11 tab 7 p. 4

which began in June 1990. The other major effort of the Trust's programme has been through the funding of the Infectious Disease Epidemiology Group in Oxford.[980] Although the Group was not initially funded for TSE research, resources were diverted to this field, given the high priority of the work and the Group's extensive involvement in the analysis of the BSE epidemic.

[980] Headed until recently by Professor Roy Anderson