

**REVIEW OF FUNDING, GOVERNANCE
AND RISK MANAGEMENT
AT THE INSTITUTE FOR ANIMAL HEALTH**

A REPORT FOR BBSRC COUNCIL

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EXECUTIVE SUMMARY

This report is from an independent review panel established under the chairmanship of Professor Sir John Beringer in December 2007. The panel's remit was to advise BBSRC¹ Council on the future funding, governance and risk management at the Institute for Animal Health (IAH), which occupies sites at Compton (Berkshire) and Pirbright (Surrey). The review was instigated following the Government's response to the foot and mouth disease outbreak in summer 2007.

Animal health research has high economic and social impact in underpinning the UK livestock industry and food supply and in helping to protect both animal and human health. IAH is at the forefront of UK research in animal health and provides key facilities and expertise to deal with outbreaks of serious animal diseases. If IAH did not exist the facilities and expertise would have to be created elsewhere. However, the institute requires major capital investment and important issues of funding, governance and risk management must be addressed.

Redevelopment at Pirbright

The current plan for redevelopment of the IAH Pirbright site, which is to replace outdated buildings and facilitate the transfer of virology staff from Defra's Veterinary Laboratories Agency (VLA) at Weybridge, is of the utmost importance because it will provide a key component of the nation's ability to respond to outbreaks of serious animal diseases. Funding must be found to complete the project, despite escalating costs.

Recommendation 1: We recommend that the Pirbright Site Redevelopment Programme must be carried through to completion without delay.

The planned redevelopment represents an unprecedented opportunity to establish a new national facility and centre of internationally recognised expertise. As a partnership between BBSRC and Defra it should be based on a jointly agreed science and funding strategy to ensure that it will fulfil its various functions. The joint strategy should be in place before the commissioning of the new facility in 2011.

Recommendation 2: We recommend that the redeveloped Pirbright laboratory should be positioned as a new 'National Centre for Animal Viral Disease' and should be founded upon a joint BBSRC-Defra science strategy for animal health and welfare.

Funding

It is critical that the new National Centre is funded on a sustainable basis and that the funding partners, BBSRC and Defra, resolve issues of uncertainty and short-term funding that have caused instability in the past. To allow proper planning, and to ensure that safety and biosecurity are not compromised, core funding must be secure and sufficiently long-term. It is essential that funding includes adequate provision for running and maintaining the facility, and that it should be administered as a single stream.

Recommendation 3: BBSRC and Defra must jointly provide long-term core funding to ensure the sustainability of the new National Centre at Pirbright. We do not believe it appropriate to fund a national facility with statutory responsibilities primarily through the award of research grants and contracts.

Recommendation 4: We recommend that core funding for the new National Centre at Pirbright should be administered as a single stream with a planning horizon of at least five years. Core funding must include adequate provision for core staff, running

¹ Biotechnology and Biological Sciences Research Council – see Annex 4 for further information.

costs, maintenance and renewal of infrastructure, so that safety and biosecurity needs are satisfied.

Governance

The historical ambiguous governance arrangements at IAH (which previous reports have identified as unsatisfactory) must be resolved more quickly than is currently planned, and the institute should move at once to direct control by BBSRC in line with the wishes of the Governing Body as expressed in October 2006.

Recommendation 5: In line with the previous wishes of the IAH Governing Body, BBSRC should take over direct responsibility for governance of IAH. As an interim measure to resolve the current ambiguity of governance, and in recognition of the scale of change facing IAH, we recommend that the IAH Governing Body should invite BBSRC to become a Corporate Trustee for IAH, in order to accelerate the planned move to bring governance under more direct control.

For effective operation of the new National Centre it will be important to ensure a common scientific 'culture' and that management structures are clear, unambiguous and uniform for all staff, including those relocating from VLA.

Recommendation 6: We recommend that a clear single line of management and reporting is established for all staff within the new Centre at Pirbright, for example through seconding relocated VLA staff to BBSRC or *vice versa*. This will require explicit agreement between BBSRC, IAH and VLA management in advance of the staff moves.

The funding partners must agree longer-term governance arrangements, in recognition of the joint nature and multiple functions of the new National Centre. For simplicity, there must be a single owner, and BBSRC and Defra should agree on ownership over the next year. The issue is of such importance that it must be referred to higher authority in Government if it cannot be resolved within that time.

Recommendation 7: In view of the importance of the new Centre at Pirbright as a national facility, and the potential economic and social impact of serious disease outbreaks, BBSRC and Defra must agree long-term arrangements for its ownership and management. If there is no prospect of agreement by April 2009 the matter should be resolved by referral through DIUS and Defra to the Cabinet Office.

Risk management

Appropriate preventative management of risks is vital to ensure safe and biosecure working. As a joint venture the new National Centre provides an opportunity to bring together the best elements of the existing organisations, and this process should begin forthwith.

Recommendation 8: We recommend that appropriate IAH and VLA staff develop jointly agreed risk management procedures. In order that procedures are in place well in advance of the movement of VLA staff to Pirbright, this process should begin immediately.

Future of IAH Compton

The IAH Compton laboratory requires modernisation and Council will need to take major decisions on investment. Those decisions should be informed by full assessment of scientific and strategic need, given that support from Defra for endemic disease work has declined and is expected to continue to do so. If the case is suitably compelling for large scale investment to provide replacement facilities to house work currently at Compton, we can see advantages in co-locating that work alongside the new Centre at Pirbright.

Recommendation 9: We recommend that BBSRC Council's decisions regarding the future of IAH Compton and investment in endemic disease research should be based on a thorough assessment of scientific and strategic need.

Recommendation 10: We recommend that, provided Council is persuaded by the scientific and strategic case, work should be relocated from Compton to join the new Centre at Pirbright.

Future national context

There is a need for improved coordination across the spectrum of funders of research and associated functions in support of animal health and welfare. A national strategy for the underpinning science is needed to set out the research needs and maximise synergies across the various agencies. A new funders' body, with sufficiently high-level representation, would provide the means to develop such a strategy, and we believe that Defra should lead in setting it up.

Recommendation 11: We recommend that Defra, working closely with BBSRC, should lead in drawing together the main funders and stakeholders of animal health and welfare research to develop a joint national strategy for science and funding to underpin the management of risks from animal diseases, both endemic and exotic.

Recommendation 12: We recommend that Defra, working closely with BBSRC, should lead in setting up a funding body for animal health and welfare research, surveillance and associated functions, as a route to developing a joint national strategy and improving coordination across the relevant funders.

As a longer term bold vision to improve coordination further, we advocate a new national agency, which would integrate the functions of several current bodies and operate at arm's length from Government. Nevertheless we emphasise that it is essential that the longer term vision does not distract from the immediate and urgent issues of IAH funding, governance and risk management that need to be addressed. We envisage that the new agency would take over responsibilities for animal health and welfare from Defra, including ownership of VLA, and also take over ownership and management of IAH.

Recommendation 13: We recommend that a new Animal Health and Welfare agency should be established. Animal health and welfare is simply too important to remain as at present; it must be given clear leadership and be made less vulnerable to budgetary fluctuations and 'border disputes' between organisations.

FOREWORD

1. This report is the output of an independent review panel established under the chairmanship of Professor Sir John Beringer in December 2007. The panel's remit was to advise BBSRC² Council on the future funding, governance and risk management at the Institute for Animal Health (IAH).

Origin of this review

2. This is one of several reviews following the outbreak of foot and mouth disease (FMD) in Surrey in summer 2007. Shortly after the outbreak the Government ordered two inquiries, the Health and Safety Executive (HSE) investigation of the Pirbright site³ and the review led by Professor Brian Spratt: *Independent review of the safety of UK facilities handling foot-and-mouth disease virus*⁴.
3. The current review was instigated in response to the Spratt report, where two recommendations were of particular relevance:

Recommendations from the Spratt report:

- **Recommendation 10:** *The plans for future development of the Pirbright site should be reviewed to ensure that all safety critical issues have been addressed. This should be carried out with the help of the full range of relevant experts and regulatory bodies.*
- **Recommendation 12:** *Biosecurity of laboratories that work with FMDV is of paramount importance. Therefore there should be a review of funding, governance and risk management at IAH Pirbright to ensure an appropriate focus on biosafety and biosecurity in the future.*

4. The Government's response⁵ to the Spratt report on both recommendations 10 and 12 stated:

"We agree with both of these recommendations, and at all stages of the design of the new laboratories at Pirbright biosecurity issues have been a priority. The Pirbright Site Redevelopment Programme Board which oversees the project (and which includes members from the IAH, the IAH Governing Body, VLA and the funders), will undertake a review of all aspects of the Pirbright site so as to ensure that all safety critical issues have been addressed [Recommendation 10]. It will report its findings to a review body led by BBSRC, an NDPB of the Department for Innovation, Universities and Science [sic], in conjunction with the IAH Governing Body and supported by Defra, and with a representative of the farming community. This review body will also assess and report on the funding, governance and risk management at Pirbright [Recommendation 12]."

This review was therefore established to consider funding, governance and risk management at IAH Pirbright (Recommendation 12), taking into account the conclusions of a separate review group⁶ addressing Recommendation 10.

² Biotechnology and Biological Sciences Research Council – see Annex 4 for further information.

³ HSE report (August 2007): <http://www.hse.gov.uk/news/archive/07aug/finalreport.pdf>

⁴ Spratt report (August 2007): http://www.defra.gov.uk/animalh/diseases/fmd/investigations/pdf/spratt_final.pdf

⁵ Government response to the Spratt report:

http://www.defra.gov.uk/animalh/diseases/fmd/investigations/pdf/govstatement_fmd2007.pdf

5. BBSRC Council decided that the terms of reference for the review of funding, governance and risk management should be broadened from a narrow focus on Pirbright to include also the IAH Compton site. The two sites are part of the same institute, with close research links, and are covered by the same funding and governance arrangements. They jointly constitute facilities and research capability of national strategic importance in infectious diseases of animals, and provide key components of the UK capacity for emergency response to outbreaks of disease. The review is intended to ensure that the future funding, governance and risk management are appropriate and sustainable for these essential facilities and their associated capability for research, diagnosis and disease surveillance.

Terms of reference

In the context of the report from Professor Brian Spratt on the safety of UK facilities handling FMD virus, and in particular with reference to recommendations 10 and 12, the review group will:

- i. Assess the necessary funding, governance and risk management at the Institute for Animal Health, at Pirbright and Compton, to ensure appropriate biosecurity and to sustain a high quality basic and strategic research capability to underpin UK national interests.
- ii. Report to BBSRC Council in February 2008.

6. The membership of the review panel is provided at **Annex 1**. Further background on the FMD outbreak and the various follow-up reviews is given in **Annex 2**.
7. It is important to note that it was not the purpose of this review to assess the quality of the research undertaken at IAH; this was last done as part of the BBSRC Institute Assessment Exercise⁷ by a Visiting Group of external experts in 2006. Its report confirmed the very high quality and relevance of the research, and stated

"...there is a continued national and international need for the Institute for Animal Health. With its unique expertise and resources, IAH was carrying out internationally competitive research in animal health and welfare as well as fulfilling a vital public safety function in preparedness for disease emergencies."

Structure of the report

8. We begin by setting out in Chapter 1 the context of animal health research and its funding in the UK, with reference to other relevant reports and in the broader context of recent and ongoing changes in the governance of the BBSRC-sponsored institutes.
9. We go on to consider in Chapter 2 options for future arrangements for funding, governance and risk management at IAH, resulting in 13 recommendations. Annexes provide further information including background on BBSRC and its research institutes, the 2007 FMD outbreak and subsequent reports, as well as previous reports on IAH and related topics.

⁶ To address Spratt recommendation 10, BBSRC has established a review group, chaired by Professor Martyn Jeggo (Australian Animal Health Laboratory, Geelong, Australia), working in conjunction with existing bodies overseeing the plans for the IAH Pirbright site redevelopment. See also Annex 2.

⁷ Institute Assessment Exercise, 2005-06:

http://www.bbsrc.ac.uk/organisation/policies/reviews/operational/0606_institute_assessment.html

REVIEW OF FUNDING, GOVERNANCE AND RISK MANAGEMENT AT THE INSTITUTE FOR ANIMAL HEALTH

CHAPTER 1: BACKGROUND

INTRODUCTION

1. In this Chapter we set the context for considering the future funding, governance and risk management at the Institute for Animal Health (IAH). Given the substantial economic and social impact of animal disease, we emphasise that the UK needs to manage the risks and respond appropriately to outbreaks of notifiable diseases. IAH, which is sponsored by the Biotechnology and Biological Sciences Research Council (BBSRC), is a major centre for the scientific research and expertise that are essential in our defence against animal disease, but the institute requires major redevelopment. We go on to summarise the current position, and some of the recent developments, in the funding, governance and risk management relating to IAH and other BBSRC institutes. It is important to understand such background before making recommendations for how to move forward.

ECONOMIC AND SOCIAL IMPACT OF ANIMAL HEALTH

2. Animal health research has significant economic and social benefits in underpinning the UK livestock industry, which is valued at £8.3 billion per year⁸, and in helping to protect both animal and human health. The Preston report⁹ (2007) stated:
“Livestock diseases not only adversely impact animal welfare and performance but may also be transmitted directly to humans or via the food chain. In any year it is estimated that at least one additional animal pathogen is transmitted to man and becomes established as a recognised zoonosis¹⁰. The increased international movement of people, livestock and their products, compounded by climate change supporting the extended distribution of arthropod vectors, contribute to an ever greater threat of novel or returning exotic diseases. The potential use of biological agents by terrorists adds significantly to this threat.”
3. The cost of the foot and mouth disease (FMD) outbreak in 2001 was estimated at around £8 billion¹¹ including major impacts on tourism. The 2007 outbreak, despite its limited geographical spread, is estimated to have cost the Government¹² around £47M not including the costs to the wider economy. As well as the direct economic impact, animal diseases can have severe social consequences, notably on human health (from zoonoses) but also wider societal effects such as the disruption to rural livelihoods and communities.
4. Animal health research provides scientific knowledge and expertise that is extremely important for the UK to manage the risks associated with animal diseases, including the threats from current and emerging diseases that can be transmitted to humans, such as avian influenza. Examples of high impact research include work at IAH Pirbright in understanding the transmission of bluetongue virus, so that the UK was

⁸ Eurostat figures, 2002, cited in *Farm Animal Genomics review* (BBSRC, 2005), p12

http://www.bbsrc.ac.uk/organisation/policies/reviews/scientific_areas/0507_farm_animal_genomics.html

⁹ Preston report: *Appraisal of options for the future relationship between the Veterinary Laboratories Agency and the Institute for Animal Health* http://www.bbsrc.ac.uk/media/news/2007/070129_preston_report.html

¹⁰ Zoonosis: any disease and/or infection which is naturally transmissible from vertebrate animals to humans

¹¹ Economic costs of the foot and mouth disease outbreak in the United Kingdom in 2001. D. Thompson *et al* (2002). *Rev. sci. tech. Off. int. Epiz.*, 21 (3), 675-687

¹² Anderson report: *Foot and Mouth Disease 2007: A Review and Lessons Learned* <http://www.cabinetoffice.gov.uk/fmdreview>, p117

better prepared for the recent outbreak of this disease; the leading role that IAH has played in the world-wide programme to eradicate rinderpest, with net economic impact estimated¹³ at around \$1 billion per annum; and the development (based on IAH work) of vaccines for coccidiosis, the most important parasitic infection of poultry world-wide.

5. It is imperative that risks to the livestock industry, and to the UK food supply more widely, are managed effectively. The leading centres for animal health work (including IAH) play essential roles in underpinning the management of those risks, through their important basic research, as well as developing and testing diagnostics, and in surveillance duties to detect new outbreaks of disease.

THE UK FRAMEWORK FOR ANIMAL HEALTH RESEARCH, DIAGNOSTICS AND SURVEILLANCE

6. Research on animal health in the UK, with associated disease diagnostics and surveillance, is undertaken mainly in a small number of specialised publicly funded research institutes, university veterinary schools and some other university departments. Foremost among the UK research centres are Defra's Veterinary Laboratories Agency (VLA) with its main site at Weybridge, and the BBSRC-sponsored Institute for Animal Health (IAH), which occupies sites at Compton (Berkshire) and Pirbright (Surrey). Other centres include the Moredun Research Institute (near Edinburgh) and the Agri-Food & Biosciences Institute (AFBI, in Northern Ireland).

The multiple roles of IAH

7. IAH is one of five research institutes sponsored (i.e., core funded) by BBSRC. It is important to recognise that IAH fulfils multiple functions: not only is it a central component of BBSRC's support for research in animal health, but it provides Defra with essential facilities to enable it to discharge its statutory duties to respond to animal disease threats. The institute has specialist containment facilities, unique facilities in the UK for experimental work on large animals, is an international reference laboratory for various major diseases of livestock, and undertakes internationally recognised basic, strategic and applied research, diagnostics and surveillance for economically important diseases of livestock in their natural hosts. IAH and VLA undertake complementary activities covering different diseases (see **Box 1**).

Box 1: Responsibility for exotic diseases at IAH and VLA

- IAH has international reference laboratory status (at Pirbright) for foot-and-mouth disease, swine vesicular disease, African swine fever, rinderpest, peste des petits ruminants, bluetongue, African horse sickness, vesicular stomatitis, sheep and goat pox and lumpy skin disease.
- Defra's Veterinary Laboratories Agency (VLA) has international reference laboratory status for classical swine fever, Newcastle disease, avian influenza, rabies and a number of endemic viral and bacterial diseases.

8. The Compton site of IAH works mainly with endemic¹⁴ diseases, including bovine tuberculosis, food-borne zoonoses (such as *Salmonella* and *Campylobacter*), coccidiosis (the most important parasitic infection of poultry). It is the reference laboratory for Marek's disease and also provides underpinning work for scientists at Pirbright. IAH Pirbright undertakes research on exotic diseases (mainly viral)

¹³ See <http://www.naweb.iaea.org/nafa/aph/stories/2005-rinderpest-eradication.html>

¹⁴ See also para 79 for discussion of 'endemic' vs 'exotic'

including foot and mouth, bluetongue and African swine fever (Box 1). The Pirbright site is shared with Merial Animal Health Ltd, a commercial animal health company that operates a large-scale manufacturing facility for animal vaccines (notably for foot and mouth and bluetongue) on part of the Pirbright site separated from the IAH laboratories.

9. IAH has been instrumental in the UK's response to acute disease threats including FMD and bluetongue. Its provision of expertise, as well as rapid testing and diagnosis of samples, have been crucial in supporting the management of outbreaks. For example, in the 2007 FMD outbreak, state-of-the-art genome sequencing promptly identified the order in which farms became infected (techniques developed from fundamental genetic research at IAH). In another example of the translation of basic research through to application, rapid diagnosis was provided through the development of a lateral flow device for the detection of FMD virus particles. Results were delivered to Defra within one hour of the samples being received at Pirbright. By comparison the fastest tests available in 2001 took four to five hours¹⁵.
10. IAH also plays a significant role in the provision of training in exotic diseases of animals. As well as training PhD students in basic research, the institute runs practical courses in diagnostics which benefit, among others, field staff from Defra's Animal Health agency (incorporating the former State Veterinary Service).

FUNDING

Funding of public sector research institutes

11. The funding of UK research institutes is complex, partly as a result of historical factors. Various previous reviews have examined the issues.
12. Notable among previous reviews, the 'RIPSS' report¹⁶ (2004) considered the funding and organisation of not only research council institutes but also a wide range of public sector research establishments (PSREs) and concluded that the long-term sustainability of many PSREs was under threat. The report put forward a framework of principles and preferred models, and recommended that research councils and government departments should join up their thinking about what research capacity the country needs in the public sector and how to work together to sustain it. The report argued that PSREs should increase their level of annual investment in asset maintenance, renewal and replacement towards norms accepted for the university sector (approx 4.7% pa of replacement cost).
13. The RIPSS report also recommended that it should be government policy that the fitness for purpose and sustainability of the wider science and engineering base is a matter of joint responsibility of the principal public funding stakeholders (the research councils, government departments and their agencies). It further recommended that research council Chief Executives and Permanent Secretaries of government departments, working through Chief Scientific Advisors, should be jointly accountable for developing joint scientific and investment strategies for their cross-boundary research interests. As a minimum, such an interest exists if the government department procures 15% or more of a research council institute's turnover. This policy has not yet been implemented for IAH by Defra.

¹⁵ Anderson report (see footnote 12), p86

¹⁶ Research Council Institute and PSRE Sustainability Study ('RIPSS') (DTI, 2004): <http://www.berr.gov.uk/dius/science/science-funding/ripss/page22675.html> and <http://www.berr.gov.uk/files/file14578.pdf>

14. Funding for animal health research and related functions in the UK is provided mainly by BBSRC and Defra, with further support from the devolved administrations. BBSRC is the UK's principal funder of research and training across the biosciences, and animal health research represents around 10% of BBSRC's total research funding.

Funding at IAH

15. Despite the central role and importance of IAH Pirbright in the UK's emergency responsiveness to outbreaks of animal disease, the provision of funding (for both Pirbright and Compton laboratories) has been complex – from multiple sources – and prone to uncertainty over many years.
16. Work at both the Compton and Pirbright sites is supported by core funding from BBSRC (£14M in 2007-08), allocated by Council following each institute assessment exercise (but see also para 21 for forthcoming changes). Core funding is supplemented by the institute obtaining further competitive grants from BBSRC; IAH receives by far the largest component of BBSRC's overall animal health research funding. Other funding sources include industry and notably the EU through its Framework programmes.
17. In addition, IAH obtains significant amounts of funding from Defra (£7.7M in 2007-08), both for research projects and (especially at Pirbright) as contracts to provide international reference laboratory services (diagnostics and surveillance). Almost half the funding for the IAH Pirbright laboratory derives from Defra¹⁷.
18. With the move of some VLA staff to the Pirbright site as part of the planned redevelopment (para 29), the funding (and potentially governance) of IAH will become still more complex, with an added component of Defra funding for VLA staff on a predominantly BBSRC site.

GOVERNANCE AND OTHER CHANGES IN BBSRC INSTITUTES

19. Pertinent recent developments are changes in the governance and associated restructuring of several of the BBSRC-sponsored institutes. During 2006, BBSRC established an independent review, chaired by Sir Brian Follett, of the governance of its seven (at that time) sponsored institutes¹⁸. The Follett review concluded that the current arrangements for institute governance should be modernised. It set out four basic governance models, but did not make specific recommendations for each institute, recognising that different solutions may be appropriate for different institutes.
20. In light of the Follett report, BBSRC Council agreed to consider each institute separately to maximise its opportunities depending on the local circumstances. The governance of IAH (Compton and Pirbright sites) is currently planned to change from 2009. BBSRC owns the IAH sites and employs the staff, but the institute is a company with charitable status, and the Director is responsible to a governing body and the BBSRC Chief Executive. Under the new governance arrangements proposed by Follett, IAH would "move in" (in Follett terminology) to come under the direct control of BBSRC. The institute Director would then report directly and solely to the BBSRC Chief Executive. The move would thus alter the role of the current governing body, but it is expected that a body of external experts would be retained

¹⁷ For further detail of IAH funding see also Anderson report (see footnote 12), p96

¹⁸ Follett report: *Report of an independent review of governance of BBSRC-sponsored Institutes* (BBSRC, 2006): http://www.bbsrc.ac.uk/media/releases/2006/061024_follett_review.html

to provide scientific and strategic advice. The current members of the governing body agreed to serve on the basis that this change in governance arrangements would take place during their term of office.

21. A further significant forthcoming change across the BBSRC institutes will be in the way that BBSRC provides core funding. The core strategic grants (CSG) by which most BBSRC support has been provided in recent years will be replaced in 2008 principally by Institute Strategic Programme Grants (ISPG). These will be large five-year grants, fewer in number than the current CSG projects, and will be assessed by external peer review.
22. In addition to ISPGs, each institute will receive a single Institute Integration Award (IIA), to be held by the institute Director and intended to cover the range of the institute's non-programme, institute-wide activities. One such activity could be to sustain national facilities of key strategic importance: we consider this further in Chapter 2. Institutes will also continue to be able to apply for competitive funding through BBSRC responsive mode committees, as well as seeking funding from other sources including Defra.

RISK MANAGEMENT

23. The assessment and management of risk in government departments and institutes is described within their individual departmental and institutional risk management frameworks. With respect to business risk and its oversight by internal audit, BBSRC has 'risk management assurance statements' agreed with its institutes¹⁹. Defra published its Departmental risk management strategy²⁰ in 2002. We understand that IAH has its own business risk register and below this, individual risk registers pertaining to biosecurity, the project risk (relating to redevelopment plans) and other functional risk registers.
24. The assessment, management and communication of business risk has an important role in any organisation. The Follett report²¹ recognised that the BBSRC Chief Executive has a legitimate interest in the whole of the finances, business systems and managerial capabilities of the institutes, including the management of risk. Clearly, with respect to this review the management of biosecurity in a regulatory context is a key risk to manage with utmost vigilance.
25. Following the FMD outbreak in 2007 the Government ordered a review of the regulatory framework for the containment of animal pathogens in laboratories. The Callaghan report²² (published December 2007) recommended a single regulatory framework to govern work with both human and animal pathogens and that the HSE should become the regulatory, inspection and enforcement body. The Government accepted this and the animal disease licensing arrangements are in the process of revision and transfer from Defra to HSE. The licensing of work at IAH will therefore change in future in line with the revised regulatory framework.
26. IAH has had in place risk management processes to cover its work with animal pathogens. Licences were obtained through Defra as the relevant regulatory

¹⁹ BBSRC Annual Report:

http://www.bbsrc.ac.uk/publications/accounts/bbsrc_annual_04_05.pdf#search=%22risk%22

²⁰ Defra risk management strategy:

http://www.defra.gov.uk/science/documents/papers/2004/SAC%20_04_%2029_Risk_Management.pdf

²¹ Follett report (see footnote 17), p.1 executive summary; p.7, paras. 21-22

²² Callaghan report: *A Review of the Regulatory Framework for Handling Animal Pathogens*
<http://www.defra.gov.uk/news/2007/071213b.htm>

authority, including those under the Specified Animal Pathogens Order (SAPO). In the future this will change under the new framework, as above. However, the arrangements to date have been complicated by the co-location on the Pirbright site of not only the IAH laboratory but also the vaccine manufacturing facility operated by Merial Animal Health Ltd. We set out further details and recommendations in Chapter 2.

IAH REDEVELOPMENT

27. Against this background of the importance of animal health research and the key role that IAH plays, there are nonetheless major issues to be addressed. The Gull review²³ of IAH Pirbright (2002) found the condition of much of the Pirbright site infrastructure was unsatisfactory and identified a clear need for urgent investment in new laboratories and facilities. BBSRC Council and Defra took forward recommendations from the report, as well as those of the Cawthorne report²⁴ (for BBSRC and Defra, 2003), leading to the current major Pirbright Site Redevelopment Programme (PSRP).
28. To date, new high containment animal facilities, access roads and an insectary have been completed. The next phase involves a major new state-of-the-art laboratory complex with high level containment facilities, to replace the current buildings that date from the 1950s and 1960s. It had been agreed that the original estimate of £121M would be jointly funded by BBSRC, the DIUS Large Facilities Capital Fund and Defra. However, costs have recently increased substantially (currently more than £165M) due partly to new regulatory requirements but also to other factors including high inflation for laboratory building work. Nonetheless we concur with the Spratt and Anderson reports that the facility is of such national importance that funds must be found to carry through the redevelopment to completion (see Chapter 2, Recommendation 1).
29. As of part of the redevelopment, the intention is to move the virology work at the Defra Veterinary Laboratories Agency (VLA) from its current location at Weybridge to the Pirbright site, to join IAH virology research in the new laboratory. VLA has facilities and responsibility for research, surveillance and emergency responsiveness on viruses other than those currently covered by IAH Pirbright (see **Box 1**). Bringing the two groups together will provide the UK with a new, expanded and strengthened capability in animal virology. Once the new development is operational (scheduled for 2011/12) it will be one of the foremost facilities of its kind in Europe and probably the world. The plans for this redevelopment are being reviewed in relation to biosecurity requirements, in accordance with Recommendation 10 of the Spratt report (see also **Annex 2**).
30. The IAH Compton site also requires major work to bring it to modern standards; some of the buildings are no longer usable and most of the rest are barely fit for purpose. An estates strategy is being developed to modernise or replace the Compton research facilities and meet regulatory needs. The replacement of facilities (on a site yet to be decided) may require investment of up to £220M over the next 6-7 years. BBSRC is planning to meet 50% of the costs and is seeking the other 50% from DIUS via the Large Facilities Capital Fund. Because of the state of the Compton facilities, some capital expenditure may be needed in the short-medium

²³ Gull report: *Review of the Institute for Animal Health - Pirbright Laboratory*.

http://www.bbsrc.ac.uk/organisation/policies/reviews/operational/0207_iah_pirbright.html

²⁴ Cawthorne report: *Review of the UK's national facilities for infectious animal disease research, surveillance and diagnosis: A report for the Defra and the BBSRC* (September 2003)

term to enable the research programmes at Compton to continue whilst the longer term investment strategy is resolved.

31. Given the extremely high cost of replacing the existing IAH facilities, it is timely for this review to reconsider future options for IAH as a whole and in the wider context of the UK's overall needs for research facilities in animal health.

CHAPTER 2: A FRAMEWORK FOR FUTURE FUNDING, GOVERNANCE AND RISK MANAGEMENT OF IAH

INTRODUCTION

32. Against the background set out in Chapter 1, we now turn to recommendations for the future of IAH. We have formulated our recommendations predicated on the basis that the planned redevelopment of the IAH Pirbright site, including the transfer of some staff from VLA at Weybridge, (see para 27) will go ahead, given the national importance of the facility.
33. We structure this section around three broad considerations:
- The future of IAH Pirbright: the need for a new National Centre
 - The future of IAH Compton
 - The future national context for IAH: coordination of national science strategy, funding and risk management for animal health.

For clarity we attempt to deal with issues of funding, governance and risk management in distinct sections (and initially for Pirbright), but it is important to recognise that many aspects are interdependent, and must therefore be considered as related parts of an integrated package of measures.

34. At the end of this Chapter we propose a way forward that includes an ambitious vision for a new agency that would be responsible for both developing and delivering a coherent national strategy for research and associated functions (surveillance, diagnostics, etc) in animal health and welfare. The new agency would provide a framework within which the work undertaken by IAH and other relevant research establishments would be supported in a more stable and sustainable way than at present. Nevertheless, **we emphasise that it is essential** that the longer-term vision does not distract from the immediate and urgent issues of IAH funding, governance and risk management that need to be addressed.

THE FUTURE OF IAH PIRBRIGHT: THE CASE FOR A NATIONAL CENTRE

35. With the ever-present risk of new diseases emerging or entering the UK and having the potential to cause emergencies, in our view there remains a clear need for a modern, integrated animal health research institute that can sustain coherent programmes of basic, strategic and applied research as well as providing essential diagnostic and surveillance services. If IAH did not exist, the UK would need to set up a national facility (as many other countries have done around the world) to perform its functions in providing the knowledge and expertise, as well as facilities needed for the UK to manage disease risks appropriately.
36. Based on the high strategic relevance of the work at IAH, coupled with high scientific quality, several previous reports (**Box 2**) concluded that there is a clear strategic need for the institute. We fully endorse these findings.
37. There is a strong case for animal health research being based in an institute setting rather than in one or more universities. Mission-driven research institutes such as IAH are able to provide specialised (sometimes unique) facilities and expertise, and to sustain integrated research programmes over longer time scales than are typically seen in the university sector. There is particular merit in co-location of basic work with more applied research, promoting synergistic interactions across research teams. Findings from fundamental work can then be readily applied, for example in

the development of diagnostic tools and vaccines. Equally, basic and strategic research benefits from access to resources arising from more applied work, such as unique collections (within the world reference labs at IAH Pirbright) of viruses from around the world.

Box 2: Previous reports that supported strongly the need for an institute such as IAH

- In 2001-02, Professor Keith Gull chaired a review of IAH Pirbright²⁵
- In 2003, Dr Richard Cawthorne (then Deputy Chief Veterinary Officer) chaired a review for BBSRC and Defra of UK facilities for handling infectious animal disease²⁶
- In 2006, a Visiting Group of external experts chaired by Professor Chris Gilligan reviewed the IAH science programmes as part of the BBSRC Institute Assessment Exercise²⁷
- In 2006-07, Professor John Preston chaired a review of options for the future relationship between IAH and VLA²⁸
- In 2007-08, Dr Iain Anderson led a review of lessons learned from the 2007 FMD outbreak²⁹

Further background information on these reports is provided at **Annex 2**.

38. The remit of IAH covers both endemic and exotic diseases (endemic primarily at Compton, exotic at Pirbright) and there are clear benefits and synergies in undertaking work on both types of disease within a single organisation, since both endemic and exotic viral diseases (for example) may share common biological mechanisms and host animal responses.

The new laboratory at IAH-Pirbright: a National Centre

39. We strongly welcome the agreement between BBSRC and Defra on major joint investment in the redevelopment of the Pirbright laboratory (see 'IAH Redevelopment' in Chapter 1): the Pirbright Site Redevelopment Programme (PSRP) is a commendable long-term commitment of capital funding. We concur with both the Spratt report and Iain Anderson in his recently published report²⁹ that it is essential for the national capability to respond to animal disease threats that the redevelopment is completed as soon as practicable, and we urge both parties to resolve rapidly the problem of resourcing the redevelopment and to see it through to completion with due speed.

Recommendation 1: We recommend that the Pirbright Site Redevelopment Programme must be carried through to completion without delay.

40. The new laboratory building that is being established under the redevelopment programme provides an unprecedented opportunity to create a nationally important facility in animal virology, which should be established and positioned as a new world-class national centre of excellence.
41. The VLA staff moving from Weybridge to Pirbright will bring expertise and reference laboratories in viral diseases complementary to those currently worked on at Pirbright (see **Box 1** on page 8). The new grouping (expected to be around 70 staff from VLA added to around 150 from IAH) will create a concentration of international

²⁵ Gull report: see footnote 23

²⁶ Cawthorne report: see footnote 24

²⁷ Institute Assessment Exercise: see footnote 7

²⁸ Preston report: see footnote 9

²⁹ Anderson report: see footnote 12

quality work on exotic diseases of animals. It will include an expanded set of world and EU reference laboratories, underpinned by excellent basic and strategic research coupled with more applied diagnostics and surveillance work. While the main focus will be on viral diseases, the facility would provide scope for work on other types of pathogen that have the potential to cause emergencies. The new integrated facility will be on the front line of response in any UK outbreak of a wide range of exotic animal diseases, with capability to expand effort for diagnostics as required. In addition it will constitute an enlarged and cohesive centre of expertise and advice for Government.

42. The Anderson report³⁰ acknowledged the importance of the redeveloped Pirbright laboratory, commenting that the research conducted at IAH is world class and needs to be positioned at the centre of a national strategy for animal health. Dr Anderson made a personal recommendation (in the foreword of the report) that IAH should be repositioned as a 'National Institute of Infectious Diseases'. We agree with its national positioning but suggest the working title should more explicitly reflect its focus on animal infectious diseases.
43. For effective operation of the new National Centre, it will be essential that BBSRC (Swindon Office and IAH) and Defra (all relevant arms of the Department and VLA) agree a joint science and funding strategy in animal health and welfare as a focus for the Centre's various functions. The joint strategy should be in place before the commissioning of the new facility in 2011. We will return later to the broader issue of coordination across different funders.

Recommendation 2: We recommend that the redeveloped Pirbright laboratory should be positioned as a new 'National Centre for Animal Viral Disease' and should be founded upon a joint BBSRC-Defra science strategy for animal health and welfare.

The status of the redeveloped laboratory as a National Centre would emphasise its importance, its nature as a shared venture between BBSRC and Defra, and the step change it represents in bringing together the internationally recognised expertise in virology from IAH and VLA in new state-of-the-art facilities.

Funding of the new National Centre

44. It is critical that the new Centre is funded on a sustainable basis. One of the main difficulties faced by IAH has been the duality of its principal funding income via BBSRC and Defra. Not only is the institute constantly juggling the different research aims of the two organisations but they also, in large part, work to different funding time scales, where BBSRC typically funds in 3-5 year grants but Defra typically over 1-3 years. This makes financial planning difficult, particularly in relation to maintaining the continuity of the science and facilities.
45. Of particular note is Defra's surveillance contract to IAH-Pirbright, worth around £1.7M per annum. The expertise and facilities at Pirbright are crucial if the department is to fulfil its statutory obligations regarding due vigilance for exotic agents such as foot and mouth disease, yet the surveillance contract is renewed only on an annual basis. It is difficult to see why a longer term planning horizon for this work is not possible.

³⁰ Anderson report: see footnote 12

46. A substantial proportion of funding for an institute (running costs of the facilities and research, as well as capital investment) must be sufficiently long-term to allow proper financial planning and provide stability. This would include allowing for timely renewal of infrastructure and necessary provision for biosecurity, which must be a paramount consideration. As numerous previous reports have highlighted, IAH has historically not been properly funded for long-term sustainability of the infrastructure, leading to increasingly dilapidated facilities at both Pirbright and Compton. We note that inadequate provision for maintenance and renewal has been widespread also in the university sector, but nonetheless both BBSRC and Defra, as principal funders, must carry some of the responsibility for past neglect of IAH. We do acknowledge that BBSRC has increased funding in recent years but further investment is needed. Future funding (however it is to be organised – see below) must include adequate provision for running costs, and for maintenance and renewal of infrastructure, as well as research, so that safety and biosecurity needs are satisfied.
47. It cannot be acceptable for more than £165M of public money to be allocated to the redevelopment of IAH Pirbright without a binding agreement by BBSRC and Defra to provide core funding to ensure its sustainability.

Recommendation 3: BBSRC and Defra must jointly provide long-term core funding to ensure the sustainability of the new National Centre at Pirbright. We do not believe it appropriate to fund a national facility with statutory responsibilities primarily through the award of research grants and contracts.

One stream of core funding

48. For clarity of operation there should ideally be one single stream of core funding, rather than the mixed model of principally BBSRC and Defra sources that has been problematic to date.

Recommendation 4: We recommend that core funding for the new National Centre at Pirbright should be administered as a single stream with a planning horizon of at least five years. Core funding must include adequate provision for core staff, running costs, maintenance and renewal of infrastructure, so that safety and biosecurity needs are satisfied.

Longer term funding commitments

49. If a single stream of funding proved to be not realistically achievable, then stability of funding and sustainability must be achieved via an alternative route. We can envisage a model where there would continue to be two main streams of funding but with both on similar 5-year terms and administered seamlessly as far as possible:
- In the case of BBSRC, the funding for research and recurrent costs would be provided at full economic cost through 5-year Institute Strategic Programme Grants and an Institute Integration Award (see para 21-22).
 - In the case of Defra, the fixed costs of fully serviced accommodation, including cost of capital would derive principally from agreement around a 20-year accommodation lease with respect to the new Pirbright laboratories.
50. Regarding the BBSRC funding, it will be important that the running of the national facility is not put at risk by one or more ISPG not being renewed. Animal disease work in containment facilities is intrinsically expensive. Therefore core funding through the Institute Integration Award (IIA – see para 22) must be on a sufficiently large scale to ensure sustainability. In recognition of the role of Pirbright as a

national facility, Council should not be constrained by preconceptions about the proportion of total funding for IAH that should be allocated through the IIA, and should give consideration to ring fencing if necessary.

51. We heard from Defra about the Department's budgetary position which makes it difficult to commit funds for periods longer than the current 3-year spending review cycle. Whilst we appreciate this position, we note that the research councils and other government departments also have to operate within the spending review framework and yet they manage to commit research funding over longer periods.

Governance

52. We are aware that, following the Follett review³¹ in 2006, the governance of BBSRC-sponsored institutes is being modernised (see para 19). There is little value in rehearsing again here the features of good governance set out in the 2006 report; Council is well aware of these. We do, however, make some further recommendations relating to the overarching governance of IAH and specifically the future management of the new National Centre at Pirbright.

Resolve IAH governance now

53. Governance of the IAH has long been recognised as being unsatisfactory and specific comments to this effect were made to BBSRC, Defra and the Governing Body in the Gull report³² (2002).
54. In October 2006 the Governing Body responded to the Follett report with unanimous agreement that BBSRC direct control was the preferred option for governance of the institute. The then Chair of the Governing Body made clear the willingness of the Governing Body to surrender its autonomy to BBSRC direct control. Further, the Governing Body suggested that BBSRC should establish an External Advisory Committee with skills including financial, estates, livestock and veterinary expertise as well as scientific research expertise. In early 2007 new member expertise was added and existing members agreed to extend their tenure to facilitate the transfer process.
55. BBSRC Council discussed governance of IAH with the IAH Director and Governing Body Chair at the February 2007 meeting. Council agreed that IAH should come under direct BBSRC control but, due to phasing of the governance changes across its sponsored institutes, the IAH changes would not be effective until April 2009. The Governing Body Chair pressed for priority and speed in development of a route for this transfer.
56. In our view April 2009 is too long a time scale and the remaining ambiguity surrounding IAH governance must be resolved immediately by bringing the institute under direct BBSRC control. This is not a reflection on the current Governing Body, which has performed well under extremely difficult circumstances. Rather it is in accord with their previously expressed opinion and reflects the requirement to make governance, reporting and lines of responsibility at this institute as simple as possible, as quickly as possible.
57. We have been advised that a mechanism to bring IAH under direct BBSRC control quickly is that of Corporate Trusteeship. It is incumbent on the Governing Body to

³¹ Follett report: see footnote 18

³² Gull report: see footnote 23

invite BBSRC to become a Corporate Trustee, having satisfied itself that its charitable aims will be protected. It could be a temporary measure to resolve and simplify governance, giving Council much greater control, until the new Centre is commissioned and longer-term governance/management arrangements can be put in place.

Recommendation 5: In line with the previous wishes of the IAH Governing Body, BBSRC should take over direct responsibility for governance of IAH. As an interim measure to resolve the current ambiguity of governance, and in recognition of the scale of change facing IAH, we recommend that the IAH Governing Body should invite BBSRC to become a Corporate Trustee for IAH, in order to accelerate the planned move to bring governance under more direct control.

A single line of management for the new National Centre

58. Whilst the transfer of around 70 VLA staff to the new national centre at Pirbright is a great opportunity for the science it will inevitably cause local governance challenges. It is essential for effective operation and risk management that all staff in the institute report through a single line of management to the Director. It is not acceptable for a large cohort of ex-VLA staff to report through a different line, perhaps even off-site. All staff should understand and share the same institute mission, strategy etc in a single scientific 'culture'. In the next section we turn to the question of overall ownership of the new Centre, but under the current arrangement with BBSRC owning the site and employing the staff, a simple solution to address the need for a single line of management would be to second the relocated VLA staff to BBSRC.

Recommendation 6: We recommend that a clear single line of management and reporting is established for all staff within the new Centre at Pirbright, for example through seconding relocated VLA staff to BBSRC or vice versa. This will require explicit agreement between BBSRC, IAH and VLA management in advance of the staff moves.

A matter of ownership

59. If the new Pirbright facility is to be positioned as a national centre of excellence it is essential first and foremost that the main funders regard the venture as a true partnership with clear joint responsibility for its sustainability, in accordance with the RIPSS principles (para 12-13). There remains, however, the issue of overall ownership, which includes the question of who employs the Director. Should the facility remain essentially as a BBSRC institute into which Defra places funding for the research and services it requires, or should it transfer to become a mainly Defra-owned institute into which BBSRC is a principal funding partner supporting the basic science?

60. Iain Anderson in the foreword to his report³³ stated (in the context of funding and governance):

"...the old arrangements at Pirbright must now be discarded. My hope is that a new consensus can be formed to move forward swiftly on a firm, sustainable basis, and I believe that Defra is best placed to take the lead in making this happen."

Although Anderson did not stipulate that Pirbright should move to be under Defra management he expressed the personal opinion that Defra should at least lead in

³³Anderson report: see footnote 12

driving forward and championing the new arrangements. As the government department with overall policy responsibility for animal health, we agree that Defra should reflect its responsibilities by taking more of a leading role.

61. The Anderson report was also critical of the way BBSRC has managed IAH Pirbright, and implied that this necessitated a change of management in the future. We agree that IAH has not been managed in a way that has ensured sustainability. This is in part the result of failures by BBSRC, previous IAH management and previous Governing Bodies, but in practice has been a result of difficulties arising from the arm's length relationship BBSRC has had with its institutes, the stresses from reductions in Defra funding, the inability of BBSRC and Defra to agree the implementation of RIPSS, and the invidious position of the Governing Body, which neither employs the staff nor owns the institute.
62. We are aware that BBSRC's approach to its institutes has changed, particularly with the modernisation of governance, formal business planning and the establishment of an Estates and Equipment Board. However, our confidence that BBSRC was the obvious partner to manage the new Centre would have been enhanced if the governance and sustainability issues had been addressed and resolved long ago.
63. It is also important when considering the future management to take into account the distinct missions of both funding partners and their support for different aspects of animal health. BBSRC's mission is to support research; it has no remit to ensure that the public and animals are protected from harm arising from animal diseases. This is the responsibility of Defra and the VLA, who do this through their own laboratories and jointly with BBSRC through IAH. Over the last couple of decades BBSRC has maintained an increasing level of funding for research in IAH, while budget cuts (and the lack of extra resource to Defra to enable it to finance Full Economic Costing) have resulted in a steady decline in Defra funding. The present outlook is for continued BBSRC funding, at about the same level as the last few years, but further cuts from Defra at both the VLA and IAH.
64. We conclude that there is no clear and obvious answer as to whether BBSRC or Defra should manage IAH Pirbright in the future. In large part it depends on the balance of its dual function; is it primarily a centre for basic research or primarily a centre for the management of animal diseases, including diagnostics and surveillance roles? It may be that the simple solution is to continue with BBSRC ownership and management, given that the Council owns the land and will employ around two thirds of the staff. If research currently at IAH Compton were to be relocated to Pirbright (see below – para 78), that proportion would be higher and the argument for continued BBSRC management could be stronger. If Defra were to take over management, a further issue to be resolved would be how to ensure continued eligibility for BBSRC funding of the more basic research³⁴. But whatever the outcome, BBSRC and Defra must decide between themselves, and decide quickly. We concur with Anderson that if the issue cannot be resolved at departmental level it should be referred further within Government.

Recommendation 7: In view of the importance of the new Centre at Pirbright as a national facility, and the potential economic and social impact of serious disease outbreaks, BBSRC and Defra must agree long-term arrangements for its ownership and management. If there is no prospect of agreement by April

³⁴ Government laboratories (including VLA) are in general not eligible for funding from the Research Councils – see <http://www.rcuk.ac.uk/research/eligibility.htm>

2009 the matter should be resolved by referral through DIUS and Defra to the Cabinet Office.

Risk management

65. IAH already has in place a risk management system, and detailed procedures are being reviewed by other groups in line with recommendations of the Spratt review (see also **Annex 2**). Proper funding and governance arrangements that ensure sustainability and renewal of infrastructure, including the considerations set out above, will lead naturally to better risk management. Nevertheless, we consider the following points to be the most salient.

Culture and accountability

66. Considering the nature of the work at IAH there must be a strongly embedded culture of risk management, safety and biosecurity throughout the institute. This must start with an explicit leadership commitment from senior management. The risk management culture should reflect a unity of purpose and of action throughout the organisation. In addition the organisation will likely need specific culture change to work with the expected new HSE-based regulations.

67. The Spratt report commented³⁵:

“There was evidence of a lack of urgency and ownership of risk at all levels, resulting in the failure to take appropriate decisions on the funding for essential improvements in safety critical infrastructure.”

We believe a step improvement in the institutional management of risk is warranted, both in the interim and in the future new Centre. We would expect the new Centre to develop quickly a refreshed, compelling vision, and to enact a substantive shift towards the proactive and preventative management of (residual) risk. We are encouraged by recent reappraisals of IAH’s corporate risk register and by its inclusion as a standing item at IAH Executive meetings.

68. We endorse IAH’s intent to appoint a dedicated risk manager, this signalling one step towards an improved commitment to embedding risk management more firmly within the organisation. The bringing together of VLA and BBSRC staff on one site provides an excellent opportunity to establish a risk management culture encapsulating the best elements of the existing cultures of both groups of scientists.

Recommendation 8: We recommend that appropriate IAH and VLA staff develop jointly agreed risk management procedures. In order that procedures are in place well in advance of the movement of VLA staff to Pirbright, this process should begin immediately.

69. Risk management at the institute should be implemented in line with current codes of good practice in risk management^{36, 37} and the code of good corporate governance (revised Turnbull code³⁸). The institute should maintain, actively manage and review

³⁵ Spratt report (see footnote 4), p57

³⁶ HM Treasury (2004). *The orange book. Management of risk – principles and concepts*, HM Treasury London, 50pp

³⁷ Office of Government Commerce (2007) *Management of risk: guidance for practitioners*, TSO, 170pp

³⁸ Financial Reporting Council (2005) *Internal control: revised guidance for Directors on the Combined code*, 15pp

at least quarterly a regularly updated business risk register³⁹, with clear accountabilities for risk management. There must be Director-level accountability for risk management and consideration given to publishing the key business risks in the Institute's annual report.

70. Specifically, there must be unambiguous responsibility and accountability for safety and biosecurity, the appropriate training of staff and contractors, record keeping, risk assessment and agreed procedures, including those for visitors. An organisational culture of vigilance will ensure that staff see preventative risk management, safety and biosecurity as integral to their everyday work and to the success of the Institute. Safety and biosecurity should be addressed in individuals' annual objectives and appraisal processes.

One 'controlling mind'

71. IAH has a dedicated biosafety officer who reports to the institute Director. The BSO must be part of the institute's executive and act as the lead individual on all aspects of biosafety and biosecurity. We also advocate a clear route to refer above the Director if necessary.
72. The presence of the Merial vaccine production facility on the Pirbright site creates some special risk management considerations, as have been highlighted in other reports following the 2007 foot and mouth outbreak. We fully endorse the findings of the Callaghan review regarding reform of the regulatory framework for animal pathogens (para 25), but also, in particular, the need for a clearly identified 'controlling mind' for safety and biosecurity. Ideally we would advocate a single overarching Biological Safety Officer (BSO) with responsibility and an appropriate degree of authority for biological safety and biosecurity across the whole Pirbright site, including Merial (and any other organisations operating on the site). But we accept that this may not be realistically achievable, given that the organisations are of very different types (research laboratories vs. vaccine manufacturing plant).
73. We are aware of, and strongly welcome, the plans for Merial to develop its own service and waste disposal infrastructure, thus becoming more independent of IAH. We would advocate that it should become entirely independent. We also welcome the agreement to improve sharing of information between Merial and IAH. Nevertheless, for the purposes of biosecurity the company and the institute must be considered as a single entity unless and until Merial becomes entirely self-contained. Until that time, in accordance with the recommendations of the Callaghan report, a single BSO should have appropriate jurisdiction over the whole site.

Regulation and licensing

74. Clearly, biosecurity procedures at the institute must conform to regulatory requirements and current best practice. Biosecurity procedures should be proportionate to the risks they seek to manage, and not unduly complicated. Buildings, services and infrastructure developments must, by design, support the risk management requirements of the institute. Buildings, services and infrastructure needs must be reviewed and actively accounted for within investment plans for the institute. We are pleased that the Jeggo report (see footnote 6) will inform BBSRC, IAH and Defra on biosafety and biosecurity aspects of the design requirements for

³⁹ General guidance on managing risk in Government is available on the Government's risk portal at www.hm-treasury.gov.uk/documents/public_spending_reporting/governance_risk/psr_governance_risk_riskguidance.cfm

the redevelopment of the Pirbright site. We are aware of the emerging recommendations of the Jeggo review and we endorse, in particular, the view that:

- Best practice in biosafety and biosecurity should be a primary consideration in the design of the site redevelopment. Any changes to the design intended to control increases in capital costs should be focused where the impact on biosafety and biosecurity would be minimal.
- The process for tendering and issuing contracts for the construction work should not be allowed to compromise the biosafety and biosecurity aspects of the design: proper control of the design must be retained.
- Management of biosafety and biosecurity must not be over-complicated, and should be as simple as possible while consistent with best practice. An external advisory group for biosafety and biosecurity could be valuable to support the ongoing management of risk.

It is clear that the redevelopment plans are still evolving and some aspects will need to be reconsidered once the new regulatory framework has been put in place. We urge Council to continue the process of evaluating risk management at every step.

75. We share the concerns (raised in other reports following the 2007 FMD outbreak) that separate SAPO licences were issued to Merial and IAH, and that even though they shared the same site there was no joint risk management. IAH was not made aware of the details of the Merial licence (because of commercial confidentiality) despite it allowing the release of potentially large quantities of live virus into drains on the site. Another concern is that it appears that the granting of a SAPO licence to IAH (renewed in 2007 for a further 5 years) was deemed to be endorsement that the facilities were appropriate for the level of risk. We assume that this is one reason why redevelopment has not progressed further, six years after it was first recognised that much of the Pirbright site was unsuitable for the work being done (Gull review, 2002).
76. We fully endorse the progress to achieve better communication and more open sharing of information between IAH and Merial. Under the future revised regulatory framework to be implemented following the Callaghan report, we would hope that greater transparency can be maintained, perhaps to the extent of a joint site licence to cover all animal pathogen work.
77. Council may wish to consider the risks, costs and benefits accruing from the current arrangement with Merial leasing part of the Pirbright site (with a lease until 2015).

THE FUTURE OF IAH COMPTON

78. IAH Compton requires modernisation (see para 30) and Council will shortly need to decide whether and how to do that. In our view, decisions on the best way forward for Compton must be made on the basis of future need for research in endemic diseases. That question of science need is outside the scope of the current review, but we make the following observations and recommendations to Council.
79. We referred earlier (para 38) to the benefits of working on both endemic and exotic diseases within a single institute. It is important to note that the definition of what constitutes 'endemic' or 'exotic' is liable to change over time, as new diseases emerge, spread or are introduced (e.g., bluetongue). We will use the term 'endemic' here as a convenient shorthand, but acknowledge its shortcomings. It is also

important to understand that there is at present no simple divide of IAH staff. Much exotic disease research includes Compton-based staff: for instance, the FMD and bluetongue immunology groups are located at Compton.

80. Both types of disease may share common biological mechanisms, and research on one type will often inform work on the other. It will often be easier to work on endemic diseases (e.g., with fewer requirements for high containment) and then apply that knowledge to exotic diseases.
81. Defra funding has declined particularly for endemic disease research and this trend is expected to continue, possibly to the extent of Defra withdrawing support entirely, other than for food-borne zoonoses and bovine tuberculosis. The question then arises as to what extent research on other endemic diseases should continue and how it should be funded.
82. In its recent consultation on Responsibility and Cost Sharing⁴⁰, Defra sets out proposals that more responsibility for funding of animal health and welfare should transfer to the 'user' sector, i.e. the farming and associated industries. While we entirely support the concept of engaging with users (for example, in helping to set research priorities), BBSRC Council needs to consider the possible impact of the changed mode of funding for longer-term basic research.
83. If the industry does not step in to pick up funding for endemic disease research as Defra withdraws its support, then it could be argued that its priority for BBSRC should also reduce. BBSRC could be seen as having a duty as a main public funder of research on endemic diseases to maintain a core national capability but we would question whether BBSRC could or should substitute for the entirety of Defra's historical funding in this area.
84. Given the necessity to balance competing priorities for finite funds, a crucial immediate question for Council is to what level and in what areas should BBSRC continue to fund research on endemic diseases of livestock, beyond that supported through responsive mode?
85. The outcome of that decision is crucial to the next steps for Compton. If BBSRC Council judges that research on endemic disease will be less of a priority then it follows that the redevelopment of the facilities currently at IAH-Compton could be more modest.
86. We are aware that IAH management has expressed preference to co-locate the Compton research on the Pirbright site, entailing further new building in addition to that already planned. Providing the 'need' and 'scale' criteria (para 81) are met, then we can see advantages in such a move, in bringing together the full range of IAH expertise on a single site, with benefits of improved synergies across complementary lines of research, as well as efficiencies in the provision of shared facilities.
87. Nonetheless, Council should consider the full range of available options, which could range from large-scale redevelopment at Pirbright or on another site, to relocation of parts of the Compton portfolio to other sites (which might include other institutes, vet schools or leading university departments), to retention of a reduced scale of activities within IAH on a site to be agreed. The over-riding consideration should be to deliver the science that is required in the most appropriate and cost-effective manner.

⁴⁰ Defra consultation: <http://www.defra.gov.uk/corporate/consult/ahw-nextsteps/index.htm>

Recommendation 9: We recommend that BBSRC Council's decisions regarding the future of IAH Compton and investment in endemic disease research should be based on a thorough assessment of scientific and strategic need.

Recommendation 10: We recommend that, provided Council is persuaded by the scientific and strategic case, work should be relocated from Compton to join the new Centre at Pirbright.

Implications of IAH on a single site at Pirbright

88. If all or part of the research currently at Compton were to be relocated to the Pirbright site then we would envisage this being most likely accommodated in an additional new laboratory adjacent to the current new build. Given the broader scientific remit under those circumstances, it would be appropriate to reconsider the name of the expanded Centre and to broaden the working title we proposed above to (for example) 'National Centre for Animal Health'.
89. While the considerations for funding, governance and risk management set out above would still apply, additional challenges or requirements would come into play for IAH consolidated onto one site.

Funding of IAH on a single site

90. With regard to funding, the challenge is to ensure that the institute as a whole is sustainable. We discussed above the funding of the new National Centre already under development at Pirbright and many of the same considerations would apply to an expanded Pirbright that included work relocated from Compton. However, with declining funding from Defra for endemic disease research currently at Compton, we would anticipate that research transferred from Compton would be funded largely by BBSRC through ISPGs and an IIA, supplemented by further grant funding won competitively from BBSRC and other sources.

Governance of IAH on a single site

91. It would be important that all work within the institute was under a single cohesive management structure, and that the full range of activities should be integrated as far as possible, to avoid the risk of some aspects becoming isolated and in particular avoiding any artificial polarisation into 'exotic' and 'endemic' silos. We anticipate that at least some of the BBSRC core funding through ISPGs should operate across different research areas, with the aim of promoting multidisciplinary approaches and maximising the opportunities for cross-fertilisation. Similarly, supplementary funding through responsive mode grants should be cross-IAH wherever appropriate. IAH already operates in this fashion in numerous respects, and we would wish this to continue.
92. One model for management on a single site could be to appoint Deputy Directors, for example with one for research and a second covering surveillance and associated functions (including reference laboratory services). The Deputies would free the Director from some of the burden of day-to-day management, allowing more time for strategic issues. This is a model used at some other BBSRC institutes, although we recognise there would be financial implications. It would also be important to avoid imposing artificial barriers and to ensure effective integration of research with surveillance and other activities.

Risk management at IAH on a single site

93. There may be risk management issues associated with working with exotic diseases alongside endemics on a single site, including practical complications with different levels of containment required for different types of work. In addition, valuable resources such as specially developed lines of livestock could in principle be put at risk in the event of accidental release of exotic pathogens if held on the same site. Such considerations have sometimes been raised in the past as a reason not to consolidate the two types of research. But we note that other countries successfully operate research institutes in this way and in our view the scientific benefits of consolidation would outweigh the risks – provided those risks are properly assessed and managed.

THE FUTURE NATIONAL CONTEXT FOR IAH

Coordination of national strategy, funding and risk management for animal health

94. We could not conclude our report on the future governance, funding and risk management at IAH without considering briefly the wider UK context in which the institute or new National Centre should sit and operate.

The need for a national research strategy

95. The UK currently lacks a coherent overarching national strategy for animal health research. Considering the social and economic importance of animal disease (see Chapter 1), we find it surprising that there is no common agreement between policy makers and funders on the key facilities, science and skills that are needed in this crucial area.
96. In 2004, the Government produced the '*Animal Health and Welfare Strategy for Great Britain*'⁴¹ which sets a broad policy framework for England, Wales and Scotland. But it barely mentions the importance of research in informing policy and decision making, and provides no views on underpinning science requirements and priorities.
97. There are a number of funders of animal health research in the UK including Defra, DfID, the devolved administrations, research councils (principally BBSRC) and certain larger charities, e.g. Animal Health Trust, Wellcome Trust. It seems self-evident that there would be overall benefit for these funders to be party to a national strategy for research that at the very least sets out common science needs, maximises synergy and minimises duplication. Such a strategy would also benefit the research community which, whilst maintaining its flexibility to respond to emerging issues, would have a clear steer on the funders' key priorities, something that is currently lacking. We envisage that the new National Centre at Pirbright should be central in helping to deliver the overarching strategy.
98. Ideally Council should be making its decisions regarding the future funding and governance of IAH (especially the future of IAH-Compton) against the background of an agreed national strategy for research. Unfortunately Council will need to take key decisions in its absence. Nonetheless, if future disease risks are to be managed properly, with policy-making underpinned by high quality scientific evidence, it remains an important goal to achieve such a national strategy as a central plank on which to build more joined-up UK responsiveness to animal disease threats.

⁴¹ *Animal Health and Welfare Strategy for Great Britain*: <http://www.defra.gov.uk/animalh/ahws/strategy/ahws.pdf>

Recommendation 11: We recommend that Defra, working closely with BBSRC, should lead in drawing together the main funders and stakeholders of animal health and welfare research to develop a joint national strategy for science and funding to underpin the management of risks from animal diseases, both endemic and exotic.

Overarching coordination: a new funding body for animal health and welfare

99. In order to improve coordination across the full spectrum of relevant funders of research and associated activities in animal health and welfare (AHW), we propose that a new funders' body should be established. This could be set up relatively quickly, requiring only that the relevant funders agree to participate actively and that a secretariat is made available.
100. We do not envisage that the new body would, in itself, hold a central research budget, but by bringing together the relevant funders and stakeholders, particularly Defra, BBSRC and the devolved administrations it will:
- Provide national strategic oversight of the AHW research area, ensuring that the funding activities of its members are coordinated to maximise synergy, value for money and impact
 - Develop, and then ensure delivery of, the national AHW strategy (above)
 - Horizon scan for emerging threats and needs or gaps in terms of research, facilities and skills.
101. For the funders' body to be effective, its members must be very senior in their organisations and be able to take the necessary funding and strategic decisions. Consequently it should be chaired by the Defra Chief Veterinary Officer (CVO) or Deputy CVO and include the BBSRC Chief Executive, with equivalent status individuals from the other organisations.

Recommendation 12: We recommend that Defra, working closely with BBSRC, should lead in setting up a funding body for animal health and welfare research, surveillance and associated functions, as a route to developing a joint national strategy and improving coordination across the relevant funders.

102. Iain Anderson proposed⁴² establishing a new 'Independent Advisory Committee on Animal and Emerging Infectious Diseases' to provide independent high-level expert advice to government. We can see merit in such a committee, and its advice could helpfully inform the new funders' body, in particular for the formulation of the national AHW strategy, scientific priorities and identifying research needs.

A new agency for Animal Health and Welfare

103. The measures described above to develop a more joined-up and coordinated approach to science underpinning AHW across the UK would undoubtedly be an improvement on the current situation where major funders are working broadly in similar directions but largely in isolation. The funders' body would, however, by its nature as a non-statutory body, be limited in its capacity for implementing and taking forward a joint strategy, since responsibility for funding would remain with the individual funding bodies, each with their own remit, changeable budgets, strategic goals and specific scientific priorities. This is precisely the lack of overall clarity and divided 'ownership' that has bedevilled the field of AHW.

⁴² Anderson report (see footnote 12): personal recommendation in the Foreword

104. An admittedly radical and longer-term solution would be to create a new 'national agency' for AHW. We are under no illusion that such a bold move would face considerable policy and legislative hurdles, and it is certainly not a 'quick fix'. Nevertheless there are clear precedents – for example the Food Standards Agency – where important areas of policy been removed from one or more government departments and made the responsibility of a new independent body. And along with the shift in policy responsibility goes the necessary statutory enforcement lead.
105. Without getting mired here in the constitutional details and whether or not the FSA is wholly the right model, we see the underlying principles for a new animal health and welfare agency as follows:
- We envisage a transfer from Defra of responsibility for AHW including research and also emergency response, diagnostics, surveillance and reference laboratories. The agency would take responsibility for VLA as well as the Animal Health agency (incorporating the former State Veterinary Service). It would become the British competent authority in Europe, and coordinate with sister agencies across Europe through ERA-NET⁴³ and other mechanisms as appropriate.
 - The Agency would manage the laboratories at Pirbright, ensuring adequate facilities for research – basic, strategic and applied. BBSRC would fund research in that environment on the basis of its excellence and strategic relevance.
 - The agency would operate on the principles of openness and transparency, and regarding as paramount the protection of human and animal health and the environment from infectious diseases of animals.
 - While Defra's current responsibilities cover England and Wales, the new agency should operate with counterparts across Great Britain. Animal disease does not recognise borders. The new agency would set a science strategy for AHW, taking into account the advice and priorities of BBSRC, industry and the devolved administrations.
 - It would be important for the new agency to have its own central budget set in government spending reviews either as a ring-fenced element of a departmental budget or wholly independent. Part of its funding could derive from the 'cost sharing' principles being consulted upon by Defra (para 82).
106. We believe there would be clear advantages in bringing responsibility for AHW under one independent and properly constituted body that would embrace functions currently undertaken by several disparate bodies. Not only would a new agency provide better integration and coordination at a national level, but it would also provide a ring-fenced budget arguably less sensitive to the ebb and flow of departmental priorities and financial constraints.
107. A new independent agency would, importantly, place the management, response and preparedness for serious animal disease outbreaks at arm's length from government ministers, reducing the potential for accusations of political interference. Similar arguments supported the case for an independent Food Standards Agency in the late 1990s.

⁴³ ERA-NET (EU scheme for coordination of national research programmes): see <http://cordis.europa.eu/coordination/era-net.htm>

Recommendation 13: We recommend that a new Animal Health and Welfare agency should be established. Animal health and welfare is simply too important to remain as at present; it must be given clear leadership and be made less vulnerable to budgetary fluctuations and 'border disputes' between organisations.

PANEL MEMBERSHIP

Name	Affiliation	Position / notes
Professor Sir John Beringer CBE (chair)	independent	Formerly University of Bristol; member of Council for Science and Technology ; Chair, John Innes Centre Governing Council
Professor Keith Gull CBE FRS FMedSci	University of Oxford	Wellcome Trust Principal Research Fellow; Professor of Molecular Microbiology; Chair, IAH Governing Body
Professor Tony Minson	University of Cambridge	Professor of Virology and Pro Vice chancellor for Planning and Resources
Dr Alistair Penman	independent	Formerly Unilever; Former member of BBSRC Council
Professor Simon Pollard	Cranfield University	Head of Department, Sustainable Systems; Professor of Waste and Environmental Risk Management
Mr Meurig Raymond MBE	National Farmers' Union	farmer; deputy president, NFU
Mr Alick Simmons	Defra	Deputy Chief Veterinary Officer

Secretariat: Strategic Planning Unit, BBSRC Swindon Office

Dr Paul Burrows
Dr Huw Tyson
Dr Adrian Pugh

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FURTHER BACKGROUND: THE 2007 FOOT AND MOUTH OUTBREAK AND FOLLOW-UP REVIEWS

The 2007 foot and mouth disease outbreak

1. On 3 August 2007 Defra announced there was a suspected foot and mouth disease (FMD) outbreak at a farm in Normandy, Surrey, located less than 5 miles from the IAH Pirbright site. Genome sequencing showed that this and the subsequent cases identified following the original outbreak were all related.
2. The virus strain causing FMD in the first infected herd of cattle was a laboratory strain not naturally found in the environment and was one upon which work was being carried out by all three occupants of the Pirbright site ahead of the first outbreak - IAH and two private companies, Merial Animal Health Ltd and Stabilitech Ltd. During the most likely period of infection, 14 and 25 July 2007, Merial were engaged in large-scale FMD vaccine production (10 000 litres). The quantities involved were much larger than those for IAH and Stabilitech (less than 10 millilitres in each of the latter cases), but at a level permitted by Defra.

Two main inquiries following the FMD outbreak

3. Following the outbreak of FMD in Surrey in August 2007, the Government ordered two inquiries, the Health and Safety Executive (HSE) investigation of the Pirbright site⁴⁴ and the review led by Professor Brian Spratt: *Independent review of the safety of UK facilities handling foot-and-mouth disease virus*⁴⁵.

The HSE report

4. The final HSE report, published on 7 September 2007, indicated that the cause of the outbreak was almost certainly the escape of live virus from Pirbright, most probably in the period immediately following 20 July. However, due to very small differences in the strains used at all three organisations at Pirbright, it had not been possible to pinpoint the exact origin of the virus.
5. It was likely that waste water containing the live virus, having entered the drainage pipe work, then leaked out and contaminated the surrounding soil. Excessive rainfall in July may have increased the potential for virus release from the drains. HSE found that during the period of the investigation both human and vehicle movements at Pirbright were not adequately controlled. HSE established that some of the vehicles, probably contaminated, drove from the site along a road that passes the first infected farm. The HSE concluded that this combination of events was the likely link between the release of the live virus from Pirbright and the first outbreak of FMD.

The Spratt report

6. The review group led by Professor Spratt was asked to look at biosafety at the Pirbright site and whether a breakdown in biosafety led to the FMD outbreak. It was also unable to determine with confidence which of the two facilities, IAH or Merial, was the source of the outbreak virus. However, it did find several areas where biosafety and biosecurity at the site must be improved.

⁴⁴ HSE report (August 2007): <http://www.hse.gov.uk/news/archive/07aug/finalreport.pdf>

⁴⁵ Spratt report (August 2007): http://www.defra.gov.uk/animalh/diseases/fmd/investigations/pdf/spratt_final.pdf

7. The recommendations covered four main areas:
- Immediate action on containment (*Recommendations 2, 5, 8, 9*)
 - Further action on biosecurity and biosafety (*Recommendations 4,6,7,13*)
 - Funding, design and governance (*Recommendations 10, 11, 12, 13*)
 - Regulatory and inspection framework (*Recommendations 14*)

Follow-up reviews

8. Following the two main FMD inquiries, five reviews were set up to take forward various recommendations from the Spratt and HSE reports. BBSRC was responsible for convening three of these review groups to respond to recommendations 5, 10, and 12 (this review) in the Spratt report:

- **Recommendation 5:** *IAH should have a thorough review of the safety of all laboratory activities to ensure that procedures which could release infectious FMDV into the containment laboratories are eliminated.*
- **Recommendation 10:** *The plans for future development of the Pirbright site should be reviewed to ensure that all safety critical issues have been addressed. This should be carried out with the help of the full of relevant experts and regulatory bodies.*
- **Recommendation 12:** *Biosecurity of laboratories that work with FMDV is of paramount importance. Therefore there should be a review of funding, governance and risk management at IAH Pirbright to ensure an appropriate focus on biosafety and biosecurity in the future.*

9. The Government's response⁴⁶ to the Spratt report on Recommendation 5 stated:

"We agree, and believe that IAH should carry out a more far-reaching review of the safety of management procedures for all pathogens. IAH will appoint an independent person to lead the review. The Biotechnology and Biological Sciences Research Council will work with IAH to assist in undertaking the review and applying any findings from it."

10. Accordingly, BBSRC has established an external group to make an independent assessment of the process and outcome of an internal review by IAH of arrangements for the risk assessment and safe management of its pathogen-handling procedures. The group, chaired by Professor Willie Donachie of the Moredun Research Institute, will report to the Institute's Governing Body and to BBSRC. The review, which is being undertaken in two phases, will cover activities involving all pathogens at both the Pirbright and Compton laboratories of IAH.

11. The Government's response on both Recommendations 10 and 12 of the Spratt report stated:

"We agree with both of these recommendations, and at all stages of the design of the new laboratories at Pirbright biosecurity issues have been a priority. The Pirbright Site Redevelopment Programme Board which oversees the project (and which includes members from the IAH, the IAH Governing Body, VLA and the funders), will undertake a review of all aspects of the Pirbright site so as to ensure

⁴⁶ Government response to Spratt report:
http://www.defra.gov.uk/animalh/diseases/fmd/investigations/pdf/govstatement_fmd2007.pdf

that all safety critical issues have been addressed [Recommendation 10]. It will report its findings to a review body led by BBSRC, an NDPB of the Department for Innovation, Universities and Science [sic], in conjunction with the IAH Governing Body and supported by Defra, and with a representative of the farming community. This review body will also assess and report on the funding, governance and risk management at Pirbright [Recommendation 12].”

12. The review group chaired by Professor Sir John Beringer was therefore set up to consider funding, governance and risk management at IAH Pirbright (Recommendation 12). A separate review group, chaired by Professor Martyn Jeggo (Australian Animal Health Laboratory, Geelong, Australia) and working in conjunction with existing bodies overseeing the plans for the Pirbright site redevelopment, will address primarily Recommendation 10.

Other Government reviews

13. The fourth and fifth of the reviews were instigated by the Government and have been recently completed:
 - Sir Bill Callaghan was asked by the Government to chair a review of the regulatory framework for animal pathogens, as recommended by the HSE in its report on the Pirbright outbreak 2007. The report from the Callaghan review was published⁴⁷ in December 2007. Among its recommendations were that there should be a single regulatory framework to govern work with both human and animal pathogens and that the HSE should become the regulatory, inspection and enforcement body. The Government accepted all the recommendations and is taking them forward.
 - Dr Iain Anderson was asked to chair a review of the Government's reaction to the 2007 foot and mouth disease outbreak. Dr Anderson previously conducted an inquiry into the 2001 outbreak, and was asked to review his lessons drawn from the 2001 outbreak and identify any others arising from the 2007 outbreak. The report from the 2007 outbreak was published⁴⁸ in March 2008. Among its recommendations were a personal proposal (in the Foreword) to reposition Pirbright as a new 'National Institute for Infectious Diseases'.

⁴⁷ Callaghan review: *A Review of the Regulatory Framework for Handling Animal Pathogens*
<http://www.defra.gov.uk/news/2007/071213b.htm>

⁴⁸ Anderson review: *Foot and Mouth Disease 2007: A Review and Lessons Learned*
<http://www.cabinetoffice.gov.uk/fmdreview>

PREVIOUS REPORTS ON IAH AND THE FUNDING AND GOVERNANCE OF INSTITUTES

Previous reports on IAH

1. There have been several previous reports into various aspects of IAH in recent years.

Gull report

2. Professor Keith Gull (a member of the Beringer review panel) chaired a review of IAH Pirbright⁴⁹, published in 2002. It concluded that there was a continuing danger to the UK of known and novel exotic diseases of large farm animals, and that Pirbright's role would continue to be highly relevant. The group recognised that investment was required in the laboratories and considered whether to rebuild or relocate, but could only support the relocation of Pirbright's research activities elsewhere if that plan were part of a single, major new infectious disease facility, as the costs involved would be substantial.
3. BBSRC Council took forward recommendations from the review, leading to the current major redevelopment plans for the Pirbright site (original estimate £121M, to be jointly funded by BBSRC and Defra). The plans include the relocation of the virology work at the Veterinary Laboratories Agency (VLA) from its current location at Weybridge to the Pirbright site (Pirbright and Weybridge are about 15 miles apart).

Cawthorne report

4. In 2003, Dr Richard Cawthorne (then Deputy Chief Veterinary Officer at Defra) chaired a working group to consider the UK's national facilities for infectious animal disease research, surveillance and diagnosis. Its remit was to advise Defra and BBSRC on present and future needs for laboratory and animal containment facilities to undertake work on exotic diseases, particularly those with a zoonotic potential. The report⁵⁰ reaffirmed the continuing need for work on exotic animal disease and included recommendations that the facilities at IAH Pirbright (including the high containment facilities) should be updated urgently, and that relocation of the VLA virology work to Pirbright should be pursued.

Institute Assessment Exercise

5. In 2006, a Visiting Group of external experts chaired by Professor Chris Gilligan reviewed the IAH science programmes as part of the BBSRC Institute Assessment Exercise⁵¹. Its report confirmed that:

"...there is a continued national and international need for the Institute for Animal Health. With its unique expertise and resources, IAH was carrying out internationally competitive research in animal health and welfare as well as fulfilling a vital public safety function in preparedness for disease emergencies."

⁴⁹ Gull report: http://www.bbsrc.ac.uk/organisation/policies/reviews/operational/0207_iah_pirbright.html

⁵⁰ Cawthorne report: *Review of the UK's national facilities for infectious animal disease research, surveillance and diagnosis: A report for the Defra and the BBSRC (2003)*

⁵¹ Institute Assessment Exercise, 2005-06:
http://www.bbsrc.ac.uk/organisation/policies/reviews/operational/0606_institute_assessment.html

Preston report

6. This study⁵² was commissioned by BBSRC and Defra in 2006 to evaluate the future relationship between IAH and VLA. The options considered ranged from closer collaboration and the retention of two institutes to total integration into a new organisation which would embrace the totality of VLA and IAH. The review criteria were captured under the headings of:
 - Sustain the delivery of world class science to support evidence-based policy development and decision making that can adapt to changing requirements
 - Support the UK to respond effectively to a national emergency
 - Protect the UK taxpayer - ensure financial sustainability over the medium term
7. The report recommended Option D from the following four options presented:

Option A: Both organisations remaining autonomous but working with increasing collaboration.

Option B: Merger of the VLA and selected activities from Pirbright

Option C: Merger of the VLA , Pirbright and some additional activities

Option D: Both VLA and IAH in a single structure.
8. In December 2006, BBSRC Council discussed the Preston report and decided to support Option A - closer working between independent organisations, rather than the merger favoured in the report. The Council also considered at that time that it would be inappropriate to consider the relationship any further for at least the next two years.

IAH and other Public Sector Research Establishments (PRSEs)

9. In addition to reports specifically relating to IAH, other recent reports on public sector research establishments and institute governance arrangements are pertinent.

Research Council Institute and Public Sector Research Establishment Sustainability (RIPSS) report

10. The 'RIPSS' report⁵³ (2004) considered the funding and organisation of not only research council institutes but also a wide range of public sector research establishments (PSREs) and concluded that the long-term sustainability of many PSREs was under threat. The report put forward a framework of principles and preferred models, stating that the Government should take a holistic view of the need for strategic PSRE capacity and the contribution it makes to the science and engineering base, and that research councils and government departments should join up their thinking about what capacity it is that the country needs in the public sector and how to work together to sustain it. It recommended that PSREs should increase their level of annual investment in asset maintenance, renewal and replacement towards norms accepted for the university sector.
11. The report also recommended that it should be government policy that the fitness for purpose and sustainability of the wider science and engineering base is a matter of joint responsibility of the principal public funding stakeholders (the research councils,

⁵² Preston report: http://www.bbsrc.ac.uk/media/news/2007/070129_preston_report.html

⁵³ *Research Council Institute and PSRE Sustainability Study* ('RIPSS') (DTI, 2004)
<http://www.berr.gov.uk/dius/science-funding/ripss/page22675.html> and
<http://www.berr.gov.uk/files/file14578.pdf>

government departments and their agencies). Also, that research council Chief Executives and Permanent Secretaries of government departments, working through Chief Scientific Advisors, should be jointly accountable for developing joint scientific and investment strategies for their cross-boundary research interests. As a minimum, such an interest exists if the government department procures 15% or more of a research council institute's turnover.

Institute governance – Costigan and Follett reports

12. In 2005, the Costigan report⁵⁴ examined the governance of research council institutes, centres, etc and recommended improvements in the arrangements for the BBSRC-sponsored institutes in order to make them compatible with best practice.
13. The report concluded that BBSRC Council needed to consider the relationship between itself, the institutes, and their governing boards, and achieve clarity on the different roles. It suggested a number of options for changing the governance model, and also noted that the then current lack of clarity about Defra's future needs and budgets presented real challenges to BBSRC.
14. In response to the Costigan report, BBSRC Council asked Sir Brian Follett to advise on governance of the BBSRC-sponsored institutes. The Follett report⁵⁵ (2006) summarised the situation as follows:

At the heart of the governance issue is the tension between the levels of responsibility and risk held by the BBSRC, and the independent status of the institutes as companies limited by guarantee and registered charities. The BBSRC's requirement to exert influence and control the institutes, stemming from the Chief Executive's Parliamentary accountability, is incompatible with their constitutional autonomy. This weakness is systemic. It becomes acute when institutes are under strain, particularly when they experience financial difficulties.

Without contesting the importance of effective governance, a wider perspective was needed for the review. Governance cannot be isolated from fundamental questions about the purpose and role of the institutes in the 21st Century and the distinctive contribution they should make to the BBSRC's mission and to the government's Science and Innovation Framework. Clarity about the purpose of the institutes must precede, then shape, options for good governance. Scientific excellence and effective knowledge transfer are the primary requirements of any research council institute.

Sustainability is a recurring problem for the institutes, exacerbated in some by continuing reductions in Defra funding. The task of leading a BBSRC institute with its emphasis upon operational management and raising research income makes senior posts unattractive to many leading scientists and the institutes are not always attracting outstanding young scientists.

15. The Follett report concluded that governance arrangements should be modernised, and this has led to significant changes among several of the institutes, with further changes planned or under discussion.

⁵⁴ Costigan report: *Research Council Institutes, Centres, Surveys and Units: a Review of Governance Issues* <http://www.berr.gov.uk/files/file27331.pdf>

⁵⁵ Follett review: *Report of an independent review of governance of BBSRC-sponsored Institutes* http://www.bbsrc.ac.uk/media/releases/2006/061024_follett_review.html

16. Among these have been changes to the composition of IAH, which now comprises just two sites, at Compton and Pirbright. The Neuropathogenesis Unit (NPU, in Edinburgh), which formerly carried out most of the IAH research in transmissible spongiform encephalopathies (e.g., BSE and scrapie), transferred in 2007 from IAH to join the BBSRC-sponsored Roslin Institute. The merged institute (now named The Roslin Institute) is to transfer to the University of Edinburgh to form part of a new centre for animal sciences being established from 2008, in a consortium that also includes the University of Edinburgh's veterinary school and the animal science researchers of the Scottish Agricultural College and the Moredun Research Institute.

BACKGROUND INFORMATION ON BBSRC, INSTITUTES, IAH AND VLA

BBSRC

1. The Biotechnology and Biological Sciences Research Council (BBSRC⁵⁶) is a non-departmental public body (NDPB) constituted by Royal Charter. BBSRC is one of seven UK research councils funded through the Government's Office for Science within the Department for Innovation, Universities and Skills, and forms part of Research Councils UK (RCUK⁵⁷).
2. BBSRC's mission, defined by Government and embodied in the Council's charter, is:
 - to promote and support high-quality basic, strategic and applied research, and related postgraduate training, relating to the understanding and exploitation of biological systems;
 - to advance knowledge and technology, and provide trained scientists and engineers, which meet the needs of users and beneficiaries, thereby contributing to the economic competitiveness of the United Kingdom and the quality of life;
 - to provide advice, disseminate knowledge and promote public understanding in the fields of biotechnology and the biological sciences.
3. Users and beneficiaries of the Council's research and training include the agricultural, bioprocessing, chemical, food, healthcare, pharmaceutical and other biotechnological related industries, together with universities, government departments and other public-sector organisations.
4. BBSRC's overall goal is to support science of international quality, relevant to its mission. The Council has a responsibility to sustain a broad base of interdisciplinary research and training in the non-medical life sciences which will help to create prosperity, improve the quality of life, inform policy-making or contribute in other ways to the public good. It seeks to develop research capabilities relevant to the needs of industrial and other users and beneficiaries to enhance the management and utilisation of biological resources.

BBSRC-sponsored institutes

5. BBSRC supports science in over 100 universities and other research institutions, mainly through the award of fixed-term grants for specific projects. The Council also funds work on a rolling, longer-term basis in a number of research institutes and other centres. In particular, five institutes are currently "sponsored" by the Council and receive, on average, between one third and a half of their income from BBSRC.
6. As of April 2008, the BBSRC-sponsored institutes⁵⁸ are:

Babraham Institute (BI)	Cambridge
Institute for Animal Health (IAH)	Compton, Berkshire; Pirbright, Surrey

⁵⁶ BBSRC: <http://www.bbsrc.ac.uk/>

⁵⁷ RCUK: <http://www.rcuk.ac.uk/>

⁵⁸ BBSRC institutes: http://www.bbsrc.ac.uk/organisation/institutes/sponsored_institutes.html

Rothamsted Research (RRes)	Harpenden; Broom's Barn, Suffolk; North Wyke, Devon
Institute of Food Research (IFR)	Norwich
John Innes Centre (JIC)	Norwich

7. These institutes receive core funding from the Council in the form of a Core Strategic Grant (CSG) awarded over a period of 4-5 years after each round of the Institute Assessment Exercise. From 2008, CSG funding will be replaced by Institute Strategic Programme Grants (ISPG) and an Institute Integration Award – see para 21 in the main report. The balance of institute funding comes from a number of other sources, including competitive research grants from BBSRC and other UK government sources, industry and the EU.

Institute for Animal Health (<http://www.iah.bbsrc.ac.uk/>)

8. The Institute for Animal Health (IAH) was formed in 1987 through the merger of previously distinct bodies and operates at sites in Compton (Berkshire) and Pirbright (Surrey). It is a major centre for research on infectious diseases of livestock, including many that transmit to man. The institute is a registered charity and sponsored by the BBSRC.
9. The IAH has an annual income of over £29M and employs around 400 staff. The institute receives core and competitive funding from BBSRC, for fundamental and strategic research. Substantial funding is also secured from Defra, mainly in support of applied research and capacity to respond to an outbreak of a notifiable disease, such as foot and mouth disease. The IAH has International Reference Laboratory status for many diseases on the OIE list.
10. The focus of work at Pirbright is on exotic viral diseases of livestock, whilst the research at Compton centres primarily on endemic diseases and underpinning approaches to studies on infectious disease. However, this separation is not exclusive, with a programme, in collaboration with VLA, on avian influenza based at Compton.
11. The principal diseases studied at IAH include food-borne zoonoses, avian influenza, bovine tuberculosis, coccidiosis and Marek's disease at Compton, with foot and mouth disease, African swine fever, rinderpest, bluetongue and other orbiviruses at Pirbright.
12. The institute published its science strategy in 2005, outlining its 10 year strategic objectives. The focus is on cattle and poultry with fundamental programmes on the immunology and genomics of both species.
13. The IAH Governing Body provides support on scientific and fiscal issues to the management team; members of the body are trustees and directors. The BBSRC Council determines BBSRC policies and strategies and receives reports, recommendations and advice from several boards and committees which cover a range of BBSRC's activities, including those relating to the IAH.

Veterinary Laboratories Agency (www.defra.gov.uk/corporate/vla/)

(Reproduced from Preston report (January 2007), Chapter 3)

14. The Veterinary Laboratories Agency (VLA) is an Executive Agency of Defra established in 1995, and comprises a main site at Weybridge supported by a nationwide network of 15 regional laboratories. The mission of the VLA is “*to safeguard public and animal health through world class veterinary research and surveillance*”.
15. The VLA currently employs just over 1400 staff with an income of £107M, 90% of which is provided by Defra. The science, surveillance and commercial programmes deliver a range of services to its customer base. A comprehensive surveillance network, multi-disciplinary research programme and the provision of an effective national emergency response enable the VLA to meet these requirements.
16. To provide this service, there are six main customer-focused programmes which are supported by discipline-based groups including pathology, epidemiology, risk analysis, applied immunology, microbiology and chemistry.
17. The six programmes are:
 - Statutory and exotic viruses
 - Statutory and exotic bacteria
 - International trade
 - Emerging diseases and welfare
 - Food and Environmental Safety
 - TSEs
18. A seventh programme is focused on commercial work, the aim of which is to generate surpluses for reinvestment in the business.
19. In terms of governance, the VLA Ownership Board, chaired by a non-executive, provides advice on strategic direction to Defra while the VLA Strategy Management Group, chaired by the CEO, retains oversight and management of operational delivery, and provides strategic direction to the CEO.

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Animal Health and Welfare Strategy for Great Britain

<http://www.defra.gov.uk/animalh/ahws/strategy/ahws.pdf>

ABBREVIATIONS

AFBI	Agri-Food & Biosciences Institute
AHW	animal health and welfare
BBSRC	Biotechnology and Biological Sciences Research Council
CSG	Core Strategic Grant (BBSRC core funding to a sponsored institute)
CSR	Comprehensive Spending Review
CVO	Chief Veterinary Officer
DARD	Department of Agriculture and Rural Development (Northern Ireland)
Defra	Department for Environment, Food and Rural Affairs
DIUS	Department for Innovation, Universities and Skills
FEC	full economic cost
FMD	foot and mouth disease
FSA	Food Standards Agency
HSE	Health and Safety Executive
IAA	Institute Integration Award (component of BBSRC institute funding from 2008)
IAH	Institute for Animal Health
ISPG	Institute Strategic Programme Grants (replacing CSG from 2008)
NDPB	non-departmental public body
PSRP	Pirbright Site Redevelopment Programme
RIPSS	Research Council Institute and PSRE Sustainability Study
SAPO	Specified Animal Pathogens Order 1998
VLA	Veterinary Laboratories Agency