

THE UNIVERSITIES, SCIENCE AND SKILLS COMMITTEE PUBLISHED ITS SIXTH REPORT OF SESSION 2007-08, BIOSECURITY IN UK RESEARCH LABORATORIES ON 25 JUNE 2008 [HC 360-I], THE GOVERNMENT RESPONSE TO THIS REPORT IS PUBLISHED BELOW

GOVERNMENT RESPONSE TO THE IUSS SELECT COMMITTEE REPORT ON BIOSECURITY IN UK RESEARCH LABORATORIES

1. Introduction

1.1 The Government welcomes the report by the House of Commons Select Committee on Innovation, Universities, Science and Skills into biosecurity in UK research laboratories. The Government agrees that it is essential to maintain the capacity and capability to undertake research on dangerous pathogens as well as to be able to anticipate and respond to outbreaks of infectious diseases of human and animals. The Government also agrees that facilities in which this work is carried out must have proportionate measures in place to avoid accidental or deliberate release of dangerous pathogens.

1.2 The Committee endorses many of the actions that the Government is taking to improve the control of dangerous pathogens, such as moving to a single regulatory framework for human and animal pathogens. However, it also offers thoughtful and constructive comments on areas where further improvements could be made. The Government's response addresses recommendations under the same broad themes as the Committee's report. The response draws upon the views of relevant Government departments and agencies, the Research Councils and the Scottish Executive and Welsh Assembly Government.

2. The regulatory framework and implementation of the Callaghan review

We support the conclusions reached by Sir Bill Callaghan and believe that a single, unified regulatory framework for human and animal pathogens based on risk assessment is the appropriate step forward. We urge the Government to ensure that regulation of work on dangerous pathogens is simplified as far as is practicable with the minimum number of bodies involved, although it may be appropriate for some specialist areas such as counter-terrorist inspection to be administered separately in accordance with the common framework. The Government should co-operate with the devolved administrations to ensure that a similarly high standard of regulation occurs across the UK. (Paragraph 32).

2.1 The Government welcomes the Committee's support for implementing the conclusions of the "Callaghan review" of the regulatory framework for the handling of animal pathogens. That review recommended that there should

be a single regulatory framework, with the containment measures used based on risk assessment, and that the Health and Safety Executive (HSE) should become the single regulatory body for work involving the intentional handling of both animal and human pathogens. It recognised that the Health and Safety Executive already operates a robust permissioning system for work with genetically modified organisms at containment levels 3 and 4.

2.2 The Callaghan review advocated a common set of containment measures, to be developed by the Advisory Committee on Dangerous Pathogens, to accompany the single regulatory framework. It also recommended that the new framework should be of a permissioning nature, requiring notification by the operator and approval by the regulator before work at containment level 3 or 4 can start. The Committee supported the recommendations of the Callaghan review and stressed the need for the measures to be proportionate.

2.3 The Government is continuing to implement the Callaghan recommendations. The HSE is now leading the final phase of work to introduce a single regulatory framework, in liaison with Defra and other relevant Government Departments, the devolved administrations and interested parties.

Unified inspection and enforcement

We recommend that the new unified regulatory framework be a permissioning regime such that approval by the regulator should be required before work can start where an application for work at CL3 or CL4 has been submitted. (Paragraph 33).

2.4 In England, the inspection and enforcement functions for work with animal pathogens are currently being carried out by the HSE on Defra's behalf –

(a) the Specified Animal Pathogens Order 2008 came into force on 28 April 2008. It extends the enforcement powers available to inspectors and aligns them as closely as possible with powers given to HSE inspectors regulating human pathogens under the Health and Safety at Work etc. Act 1974 (HSWA); and

(b) an agency agreement has been made between the Secretary of State for Environment, Food and Rural Affairs and the HSE.

2.5 Currently Wales, Scotland and Northern Ireland have a different approach as responsibility for the legislation on specified animal pathogens is devolved. The HSE is continuing to work with the Scottish Executive and the Welsh Assembly Government to reach similar agency agreements with them. The Northern Ireland Executive will also be introducing a single regulatory framework and will be liaising with the HSE in doing so.

Single regulatory framework

2.6 The first stage of introducing a single regulatory framework has been to identify the legal basis required for the HSE to propose new regulations for animal pathogens. This is a complex process but the HSE has identified the necessary steps to amend the HSWA, through a Legislative Reform Order, to provide that legal basis.

2.7 While that work is on-going, the HSE will simultaneously lead more detailed work to shape the regulatory framework. New secondary legislation will replace three existing pieces of legislation (the Specified Animal Pathogens Order, the Genetic Modification (Contained Use) Regulations) and relevant parts of the Control of Substances Hazardous to Health Regulations. The aim is for the new regulatory framework to be in place by early 2010.

2.8 In developing the new secondary legislation, the HSE will explore a permissioning regime, requiring the operator to notify (prior to approval) all work with human and animal pathogens at containment levels 3 and 4. This may be done in a similar way to that which applies to work with genetically modified organisms.

2.9 The work will also cover other aspects of the regulatory framework. For example, emphasis will be placed on providing a single point of contact for duty holders and the establishment of a clear and consistent approach to risk assessment, containment and control.

2.10 Other Government departments, the Scottish Executive, the Welsh Assembly Government and appropriate bodies in Northern Ireland are being consulted about and are involved with the development of the proposals. The HSE will also be seeking dialogue and involvement with external stakeholders and will consult more widely once their proposals are firmer.

Unified containment framework

Categorisation of pathogens and containment measures

We support a common set of containment measures for animal and human pathogens and urge ACDP, in drawing up these measures, to protect the principles of evidence-based risk assessment. They should consider the implications for the viability of important research if unnecessary containment measures are imposed. We expect ACDP to maintain its regular review of required containment measures and the classifications of pathogens under the new framework. (Paragraph 37).

2.11 The Advisory Committee on Dangerous Pathogens (ACDP) has set up a formal Working Group, chaired by Professor George Griffin, to develop a common set of containment measures for human and animal pathogens based on risk assessment. Members of the Working Group have been identified and invited to contribute to the work. The first meeting of the Working Group took place on 9 September. As well as relevant technical and scientific expertise in assessing the relative hazards of both human and animal pathogens, the ACDP has experience of applying this knowledge and selecting appropriate and proportionate containment and control measures.

Once the containment measures have been developed, the ACDP will continue to keep them under review in the light of developments.

Counter-terrorism inspection

2.12 These actions aim to simplify the regulatory framework as far as is practicable. However, as the Committee recognised, it is appropriate for some specialist areas such as counter-terrorist inspection to continue to be administered separately. Part 7 (Security of Pathogens and Toxins) of the Anti-terrorism Crime and Security Act 2001 will continue to apply to facilities that handle dangerous human and animal pathogens. The National Counter-Terrorism Security Office (NaCTSO) will therefore continue to discharge its statutory responsibility to deliver a bespoke service regarding counter-terrorism security advice to operators of such facilities.

Responsibility for biosecurity

There should be complete clarity over who is responsible for biosecurity, especially on a site of mixed ownership or sponsorship such as at Pirbright. The ‘controlling mind’ must be clearly identified and be expected to manage the risks that it creates. Ultimate responsibility for biosecurity rests with managers of a facility. A strong safety culture is essential for good biosecurity and all those who fund and operate high containment laboratories should ensure that this exists. (Paragraph 43).

2.13 The Government endorses the Committee’s view that there should be complete clarity over who is responsible for biosecurity, especially on sites of mixed ownership or sponsorship. The Government also agrees that a strong safety culture is essential for good biosecurity and that responsibility for this rests with the managers and operators of a facility. The Callaghan review concluded that the primary responsibility for managing risks must lie with top managers of any facility where work on dangerous pathogens is carried out. This has been achieved through clearer and more robust licensing requirements.

2.14 Experience has shown that senior level buy-in is instrumental to developing a robust site safety and biosecurity culture. This is encouraged by the HSE and NaCTSO through advice, guidance and inspections as well as legislation.

2.15 The Management of Health and Safety at Work Regulations 1999 impose duties on employers for co-operation and co-ordination where a workplace is shared, whether permanently or temporarily. Subject to the outcome of consultation, the new legislative framework may include similar provisions to those regulations, or a cross-reference to them, to address the issue of the ‘controlling mind’.

Certification of Biological Safety Officers

We support the role of Biological Safety Officers in enforcing biosecurity and recommend that the Government and the HSE in particular look at ways to support and reward this profession appropriately given the level of responsibility it holds, firstly by establishing a formal accreditation process. (Paragraph 44).

2.16 The Government acknowledges the important role played by Biological Safety Officers and shares the Committee's view that their role should be embedded within employers' organisational safety arrangements and be more formally recognised and rewarded. It is for the industry to take the responsibility for creating and developing appropriate accreditation schemes. The Government welcomes the work being done by the Institute of Safety in Technology and Research to develop an accreditation system for minimum competence standards for Biological Safety Officers and the HSE is supporting this initiative. This system is due to be launched in October 2008.

3. The HSE in its new role

The Government must ensure that the HSE is sufficiently resourced to enforce the new regulatory framework properly. The shift of responsibility to the HSE for regulating animal pathogens following the Callaghan review should be accompanied by an appropriate increase in the resources the Government provides for this work. The HSE must ensure that it has the necessary veterinary expertise to allow it to regulate the use of animal pathogens and must co-operate with Defra to achieve this. The Government should review the additional resources needed to enable the HSE to deliver the new regulatory framework and publish this, accompanied by the rationale for the resource allocation. (Paragraph 48).

Resources

3.1 The Committee makes an important point about the need to ensure that the HSE is sufficiently resourced to enforce the new regulatory framework properly. The HSE's Board welcomes opportunities to take on additional regulatory responsibilities where they complement the organisation's core role and are properly resourced. Although no formal review has been undertaken, the HSE has already considered the resources it will need. Until the new regulatory framework is introduced, Defra is funding the HSE's inspections of facilities handling animal pathogens in England and has agreed in principle to fund inspections in Wales when the HSE undertakes them. Discussions are taking place with the Scottish Executive about parallel arrangements for Scotland. Defra will also continue to provide veterinary expertise and advice to the HSE.

3.2 The Callaghan review recommended that the new regulatory framework should incorporate a cost recovery scheme to fund the HSE's responsibilities in this area. Proposals for this scheme will be developed and included in the HSE's consultation on the single regulatory framework. In addition, the HSE is working with Defra and the Veterinary Laboratories Agency to identify the level of veterinary expertise required and the most

appropriate way of providing it. As Lord McKenzie confirmed in his evidence to the Select Committee, the Government is satisfied that the HSE will have sufficient resources to deliver the new regulatory framework for human and animal pathogens.

Engagement by the regulator

We urge the HSE to engage as early as possible with those building and operating high containment facilities to avoid resorting to enforcement action. The HSE should review its procedures to consider how best to encourage reporting of incidents and near-misses. (Paragraph 51)

3.3 The Government welcomes the Committee's acknowledgement that a good regulator should engage as early as possible with those building and operating high containment facilities to avoid resorting to enforcement action. It is common practice for the HSE to be involved in early discussions about new build facilities. In the new single regulatory framework the HSE will explore how best to formalise the notification of new premises at an early stage. Enforcement action must always remain an option for a regulator but only in those circumstances where it is merited. Any action taken by the HSE is in line with the HSE's published Enforcement Policy Statement, which is consistent with principles set out in the Macrory and Hampton reports, the Enforcement Concordat and the new statutory Regulators' Compliance Code.

3.4 We acknowledge the Committee's view that the HSE should review its procedures to consider how best to encourage reporting of incidents and near-misses. The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) requires the reporting to the HSE of certain incidents and near misses involving high hazard biological agents that pose a risk to human health. The reporting of defined accidents involving genetically modified organisms is also required under the Genetically Modified Organisms (Contained Use) Regulations 2000, as amended. The Government does not believe that there needs to be a change to RIDDOR but in developing the new single regulatory framework, the HSE intends to retain the requirement in the Genetically Modified Organisms (Contained Use) Regulations and extend it to include incidents and near misses involving animal pathogens. The HSE will continue to take every opportunity (through inspections, guidance and publicity) to raise the profile of reporting incidents and near misses with its stakeholders.

Information held by the regulator

We recommend that the new regulatory framework require the HSE to maintain records of work on dangerous pathogens at a more detailed level than is currently the case and introduce clear guidelines as to whether organisations notify the regulator at a laboratory, site or organisational level. The new framework should be retrospective and should compel all those working with dangerous pathogens to notify the regulator. We urge the HSE to build relationships with those that may require access to such information, such as the animal and public health authorities and security services. (Paragraph 55)

3.5 The Government agrees with the Committee that the new legislative framework should enable the HSE to maintain records of work on dangerous pathogens at a more detailed level than is currently the case and provide clarity as to whether notifications should be made at laboratory, site or organisational level.

3.6 Following the foot and mouth disease outbreak at Pirbright, the HSE immediately set up a project to scrutinise, update and improve the robustness of information already held relating to work with biological agents, to check alignment with the current regulatory framework. All dutyholders were contacted and the HSE's records were subsequently updated to ensure accurate details of all facilities working with biological agents were recorded.

3.7 The new single regulatory framework will build on this database by including an integrated notification system that covers all work undertaken on human and animal pathogens and genetically modified organisms. A proposed transitional period of three to six months will allow dutyholders to notify retrospectively all existing activities. This will help to ensure that regulators have a full picture of the sites and laboratories where work is taking place and with which pathogens.

3.8 The HSE maintains close links with other Government departments and agencies that have an interest in the work being carried out with pathogens, such as the Health Protection Agency and the Security Services, and will continue to build on these as the new regulatory system is developed. The HSE has begun to build new relationships with organisations and agencies working in the field of animal pathogens, such as the Veterinary Laboratories Agency. For example, HSE inspectors will be giving presentations and attending the VLA's annual conference.

4. Facilities and capacity

Coordination of overview of capacity

The Government should know the location, capacity and capability of all high containment laboratories in the UK. We accept that individual agencies are obliged to ensure they possess sufficient facilities for their own needs. However, given the costs of building and maintaining high containment laboratories, efficient use of facilities is essential. (Paragraph 74)

4.1 The Government does know the location, capacity and capability (equipment, suitably trained staff) of all high containment laboratories in the UK and agrees that the efficient use of publicly funded facilities is essential. The Government welcomes the Committee's acknowledgement that individual agencies must be responsible for ensuring that they possess sufficient facilities for their own needs. For example, in considering the research required to support the development and implementation of its policies, Defra has considered, and will continue to consider, the specific requirement for containment level 4 facilities for animal pathogens, including those capable of

handling large animals. However, the Government agrees that there would be benefits from greater collaboration and coordination of high containment research capacity and associated issues.

Inter-agency group

While we commend the MRC for instigating the review of CL4 facilities currently underway under the chairmanship of Professor Griffin, we are disappointed that having started the process of identifying gaps in the UK's provision of high containment facilities, Defra did not act to address these. We believe it to be more appropriate that the Government lead a review of CL4 facilities than the MRC, given that the scope of those represented on the steering committee is somewhat wider than the MRC. (Paragraph 75)

We recommend that the Government form a standing inter-agency body responsible for the strategic planning and co-ordination of containment level 4 facilities. Its members would include representatives of the Research Councils and Government departments that sponsor high containment facilities. (Paragraph 76)

We recommend that within a year this inter-agency body undertake a detailed audit of the CL4 facilities currently available in the UK to determine capacity and capability, drawing on Professor Griffin's review. Capacity at CL3 should be assessed subsequently. (Paragraph 77)

We recommend that the inter-agency body regularly review the capacity available for research at high containment and that it be consulted during redevelopment or building projects to look strategically at the need for new facilities, the potential for their shared use and whether particular capabilities should be included to provide what the UK requires. Early considerations should include the provision of post mortem facilities and facilities to handle large animals at ACDP4. It should also consider plans for the best use of high containment facilities during disease outbreaks. (Paragraph 78)

We recommend that where possible, co-operation take place at a European and international level to promote burden-sharing and to investigate whether some facilities could be provided and shared at a European level where this is practicable. (Paragraph 79)

CL4 facilities are expensive to run and larger facilities benefit from economy of scale. We recommend that the body designated to co-ordinate CL4 capacity in the UK look at mechanisms by which spare capacity at existing facilities can be made reliably available to university researchers wishing to work at CL4, rather than allowing an unnecessary proliferation of facilities. Nevertheless, so long as sufficient resources are available to build, run and maintain a CL4 laboratory in the long-term to the required high standards, we have no objection in principle to universities operating these facilities. (Paragraph 88)

4.2 The Government shares the Committee's view that it would be useful to have a regular forum for those Government stakeholders and Research Councils that sponsor high containment facilities. Regular dialogue would improve mutual understanding and support a strategic approach to the UK's science capacity and capability, while enabling individual departments and agencies to retain responsibility for their own requirements. As the Committee recognises, there are a number of issues that the group could usefully consider. For example, they might consider whether there is scope for better use of existing facilities (including making spare capacity available to others such as university researchers), the need for a large animal facility, the recruitment and retention of staff, a common approach to security vetting, the scope for international cooperation, and future demands. Although funding issues may be discussed, responsibility for decisions in this area would continue to rest with the individual departments and agencies.

4.3 However, decisions on the group's terms of reference and agenda items are premature. As the Committee noted, Professor Griffin, Chairman of the Advisory Committee on Dangerous Pathogens, is leading a review to assess the provision of facilities for human and animal diagnostics and research at the highest biological containment levels. He is also considering a number of associated issues, such as skills requirements, the scope for collaboration with others (within the UK and internationally) and likely future needs.

4.4 Professor Griffin's review has been commissioned by the Health Protection Agency following a proposal from the Medical Research Council (MRC). Defra, the Department of Health (DH), the HSE, the MRC and the Biotechnology and Biological Sciences Research Council (BBSRC) are represented on the review's Steering Committee. The review is due to conclude in October 2008 and should provide a good basis for determining the subsequent work of the inter-agency group. Detailed consideration will therefore be given to the terms of reference and the issues for the inter-agency group once we have received Professor Griffin's report.

4.5 The Government does not agree with the Committee's conclusion that having started the process of identifying gaps in the UK's provision of high containment facilities, Defra did not act to address these gaps. A series of detailed discussions took place between senior representatives of Defra, the HSE, Institute for Animal Health/BBSRC, Ministry of Defence and DH specifically on the provision of ACDP 4 large animal high containment facilities. The conclusion of those discussions was that there is not a gap in the provision of this type of facility and that Defra would be able to undertake any new work, if a new disease emerged, within existing facilities of other Government departments.

Ministerial responsibility

We are disturbed that Ministers have not met to discuss the issue of biosecurity, especially given that no organisation or Government department has oversight in this area or responsibility for planning for

future requirements, for example in the areas of surge capacity and anti-terrorist provision. We do not accept the view held by Lord Rooker that it is satisfactory for no Minister to have overall responsibility for biosecurity. We recommend that in view of the cross-cutting nature of these issues, the Government establish a ministerial group to meet periodically to discuss issues of biosecurity. A single Minister, for example the Minister for Science and Innovation, should take responsibility for co-ordinating biosecurity and the provision of high containment laboratories and should act to convene this ministerial group and the inter-agency body we have recommended be set up. (Paragraph 82)

4.6 Much of the work of the inter-agency group of Government and Research Council officials will comprise relatively technical issues relating to scientific capacity and capability. Where scientific and technical issues are involved, the Chief Scientific Advisers' Committee is best placed to oversee cross-cutting issues and receive reports from the inter-agency group from time to time.

4.7 We agree with the Select Committee that a collective Ministerial overview would be appropriate, at least until Ministers are confident that coordination by officials and Chief Scientific Advisers is working well. We will therefore establish a Ministerial group, to be convened when the need arises. Where wider considerations (policy, resource, etc.) need to be taken account, Ministerial involvement will be appropriate and officials and departmental Chief Scientific Advisers will alert their Ministers to significant issues as appropriate. For non-controversial issues, agreement to key decisions and plans or resolution of differences will be obtained through periodic write-rounds to the Ministerial group.

Single Ministerial responsibility

4.8 The Ministerial group will comprise Ministers from the departments with the most significant interest in biosecurity issues (Defra, DH, the Department for Innovation, Universities and Skills, the Department for Work and Pensions, the Home Office and the Ministry of Defence). In the short term, the Minister for Science and Innovation will take responsibility for coordinating biosecurity issues and writing round to or convening the Ministerial group. In the longer term, the agenda may indicate that it would be more appropriate for another Minister to lead. Alternatively, if the other coordinating arrangements are working well, there may no longer be a need for a Ministerial group.

Report to Parliament

We recommend that every two years the Government present to Parliament a report outlining the UK's readiness in the face of the threat posed by dangerous pathogens. This should include an analysis of the capacity and capability for research at high containment, set out the contingency plans for unexpected outbreaks of disease or the emergence of novel pathogens and how UK facilities will be used following such an event and include an updated long-term strategy

for research and surveillance, accounting for climate change and other factors affecting the pathogens threatening the UK. (Paragraph 80)

4.9 We note the Committee's recommendation that the Government should present to Parliament every two years a report outlining the UK's readiness in the face of the threat posed by dangerous pathogens.

4.10 Much of the information that the Committee wished to see will be classified, particularly where it relates to containment level 4 facilities, and there would be security concerns if it were to be made publicly available. Nevertheless, Parliament will wish to be reassured that biosecurity issues are being addressed and kept under review. The Government therefore intends to report to the Select Committee before the end of September 2009 to explain how the new mechanisms (inter-agency group, scientific overview by Chief Scientific Advisers and the Ministerial group) are delivering their objectives. At that time, we will also consider whether there continues to be a need for collective Ministerial overview and whether there would be value in providing subsequent reports to Parliament.

4.11 In addition, the Government has recently published for the first time a National Risk Register. The National Risk Register sets out the Government's assessment of the likelihood and potential impact of a range of different risks that may directly affect the resilience of the UK and is designed to encourage individuals and organisations to think about their own preparedness. It also includes details of what the Government and emergency services are doing to prepare for emergencies. It draws upon the National Risk Assessment, a classified cross-government document which assesses the impact and likelihood of the major risks that the country could face over a five year period.

Location of facilities

We consider that there is no reason in principle why CL4 laboratories should not be built in urban areas, provided that the correct risk assessment is undertaken and biorisk is managed appropriately. As each case will be unique, we recommend that such applications be treated on an individual basis. (Paragraph 95)

We recommend that the HSE be a statutory consultee in any planning application for a CL3 or CL4 laboratory. (Paragraph 96)

4.12 The Government supports the Committee's view that there is no reason in principle why containment level 4 laboratories should not be built in urban areas, and that such applications should be treated on an individual basis. Whatever the location, it is essential that the facilities have robust security measures in place and that they are appropriate to the location. Those measures must be sufficient to minimise hazards to health and the environment in the event of a breach.

4.13 The Anti-terrorism, Crime and Security Act 2001 requires laboratory operators to notify the Home Office if they intend to work with any of the pathogens listed in Schedule 5 of the Act (ie those at containment levels 2, 3

and 4). Counter Terrorism Security Advisers review the security of the facilities and sites and provide any necessary advice on measures relating to personnel and physical security. If an operator fails to introduce suitable measures, the Act provides powers for the counter-terrorism security adviser to dispose of the pathogens and/or require closure of the facility.

4.14 NaCTSO and the Home Office have produced specific guidelines for laboratories which will handle pathogens at containment levels 2 and 3. This document is entitled 'Security Standards for Laboratories Subject of Part 7 of the ATCSA 2001'. It is currently being reviewed to take account of the Part 7 of the Anti-terrorism, Crime and Security Act 2001 (Extension to Animal Pathogens) Order 2007, which brings animal pathogens as well as human pathogens within the scope of the Act. Generic advice is not produced for containment level 4 laboratories; instead the National Counter Terrorism Security Office provides bespoke advice on all aspects of the facility (such as the structure, security equipment and staffing).

4.15 The Government acknowledges the recommendation that HSE should become a statutory consultee in planning applications for laboratories at containment levels 3 and 4. Although we do not propose to amend the current requirements for planning permission, in developing proposals for the new single regulatory framework the HSE will consider the information that should be provided to the regulator. As part of this, the HSE will consider, with other Government departments and the devolved administrations, the extent of any consultation which may be required for a new facility or a change of use of an existing facility.

5. Resourcing

Funding

The costs to human or animal health and to the economy of a breach of biosecurity at a high containment laboratory are devastating, as seen at Pirbright in 2007. We urge all those who fund high containment research to consider more seriously the cost of maintaining and running high containment laboratories. All funders of high containment laboratories must ensure that long-term funding for running costs is provided, sustained and protected to ensure risk management can take place effectively. The Government has a particular responsibility in this regard. UK research laboratories should be maintained by their operators to a high, internationally acceptable standard. (Paragraph 103)

5.1 The Government fully accepts the need to ensure funding for modern research and surveillance facilities and agrees that they should be maintained and operated to an internationally acceptable standard. The Government has recognised the need for improved research facilities. The Science Budget, which funds research in universities and Research Council Institutes, has doubled in real terms since 1997 and will be £4bn a year by 2010.

Redevelopment of the Institute for Animal Health, Pirbright

The Pirbright redevelopment is of considerable national importance. We recommend that as a matter of urgency DIUS (via the BBSRC and Large Facilities Capital Fund) and Defra settle how they are to share the cost of the Pirbright redevelopment project as it now stands. At the very least, the final settlement should be announced by the time the Government responds to this report. (Paragraph 107)

5.2 The Government agrees with the Committee that the redevelopment of the Institute for Animal Health at Pirbright is of prime importance. It has been the subject of significant capital investment in recent years and the BBSRC is spending £22 million to improve facilities there prior to the redevelopment of the site. The current building programme is progressing, but since the outbreak of foot and mouth disease and the need for increased biosecurity measures, the costs of the redevelopment are being re-examined.

Governance of the Institute for Animal Health

5.3 In addition, the BBSRC Council recognised in 2006 that the governance of the Institute for Animal Health needed to be re-examined. The Institute for Animal Health is a private company limited by guarantee with charitable status. It is constitutionally autonomous. However, the BBSRC employs all of the Institute's staff, and provides the bulk of funding. The Beringer report advised that this arrangement was not appropriate because it was not clear whether accountability for decisions lay with the BBSRC or the governing board of the Institute. To address this, the BBSRC has agreed to become corporate trustee for the Institute for Animal Health.

Future funding and governance

5.4 DIUS, Defra and the BBSRC have been in discussion over the best way forward for the longer-term ownership and management of the Pirbright site and how best to ensure the provision of long-term core funding for its redeveloped laboratories. Decisions will take account of the recommendations from the Anderson and Beringer Reviews. Although the Government is keen to make a decision as quickly as possible, the issues are complex and it is important that they are resolved appropriately.

Future structures for animal health

The future of the Pirbright site and IAH and the question of its merger with the VLA must be settled as a matter of priority and in any case by April 2009 in line with the Beringer report recommendation on the ownership and management of the site (see below). Whilst Pirbright is undergoing redevelopment, we urge the Government to use the opportunity to develop a long term plan for animal health, considering the recommendations of the Anderson and Beringer Reviews. (Paragraph 111)

The question of the creation of a national centre at Pirbright, a national research strategy for animal health with a new funding body and a new national agency for animal health arose late in our inquiry and does not

fall strictly within our terms of reference. However, we recognise that it is an issue of great importance and we recommend that as a matter of urgency the Government produce a White Paper to clarify its strategy for the future of animal health and welfare in the UK, provision of containment laboratories for research and diagnostics and how these would be used in an outbreak. (Paragraph 112)

We support the provision of long-term core funding for the redeveloped laboratories at Pirbright. Whatever the future of the Pirbright site, we support Sir John Beringer's recommendation that by April 2009, Defra and BBSRC should settle the long-term ownership and management of the Pirbright site; otherwise the issue should be referred to the Cabinet Office for resolution. (Paragraph 117)

5.5 Although not a focus of its report, the Government recognises the Committee's desire to see a clear strategy for the future of animal health and welfare, including the provision of containment laboratories for research and diagnostics and their use in a disease outbreak. As part of its responsibility and cost-sharing agenda, Defra is proposing to consult in the late autumn on future governance and funding arrangements for animal health in England. The consultation is likely to explore the option of establishing a new independent public body that would exercise the functions currently exercised by the Secretary of State in respect of animal health. If established, such a body would assume Defra's customer requirements for research and diagnostics in this area. Animal health and welfare policy is a devolved matter within the UK, although the Animal Health Agency (an executive agency of Defra) operates on a GB wide basis, working closely with the devolved administrations in Wales and Scotland. In order for the EU single market to operate effectively, animal health and welfare policy is made in Brussels. The UK plays an active role in helping to shape this policy.

5.6 The Animal Health and Welfare Strategy for GB was published in 2004 with the aim to: "develop a new partnership in which we can make a lasting and continuous improvement in the health and welfare of kept animals while protecting society, the economy, and the environment from the effect of animal disease". The England Implementation Group is an independent advisory group appointed by the Government to drive forward delivery, in England, of the Strategy. The Group is currently being reviewed by David Evans CB and will report in December 2008. His recommendations will inform Defra's decision, in early 2009, on the future of the Group.

Clarity of governance and funding

The Government should set out clearly its policy on the provision of core funding to research institutes with reference to the Research Council Institute and Public Sector Research Establishment Sustainability Study. (Paragraph 118)

5.7 The Government notes the Committee's desire for clarification of its policy on the provision of core funding to research institutes, with reference to the Research Council Institute and Public Sector Research Establishment

Sustainability Study. Responsibility for Research Council Institutes and Public Sector Research Establishments rests with an individual Research Council or Government department. In those circumstances, the sponsors, as part of their normal management activities, should consider how the Institutes or Establishments can deliver the science required in both the short and longer terms.

5.8 The “PSREs and the Science Base: A Policy for Sustainable Trading and Joint Strategic Investment in PSRE Infrastructure” report explained that -

“Research Council Chief Executives and Permanent Secretaries of Government departments, working through Chief Scientific Advisers, 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. Once agreed, those joint strategic plans should be deemed to place a commitment on a Government department’s science budget holder to honour the joint agreement. The Research Councils UK and the Chief Scientific Advisers’ Committee should jointly review such strategies every five years.”

5.9 The “Science & Innovation Investment Framework 2004-2014” noted that the Government supported the report’s recommendations.

5.10 To help the Institutes and Establishments assess their long term sustainability, DIUS runs a regular annual Research Council Institute and PSRE Sustainability Study monitoring exercise. This assessment, which research establishments agree with their sponsor department, enables research establishments to identify changes in their funders’ priorities and help assess their long term sustainability in terms of their delivery of strategic profile, income, infrastructure and staff.

HPA Porton Down

It is not acceptable that scientists at HPA Porton Down are asked to work in such ageing facilities. We recommend that the Department of Health consider the redevelopment of the HPA’s Porton Down site a priority. Any redevelopment could be viewed as an opportunity to look at the UK’s likely future wider requirements for containment facilities. (Paragraph 120)

5.11 The Government notes the recommendation that the Health Protection Agency’s site at Porton Down should be redeveloped as a priority. The Department of Health has already considered a strategic outline case for this redevelopment and the Health Protection Agency is currently developing a detailed business case for the project. The Department of Health expects to receive the business case in the second half of 2009 and will then consider it in the light of both the Health Protection Agency’s and wider national strategic requirements.

6. Staff working on dangerous pathogens

Supply of staff

The specialist field of high containment biology is critical to the national interest of the UK. We recommend that, through the inter-agency body we have recommended be set up, the Government review the retention of staff and the incentives available for those working in this area to ensure that supply is sufficient for current and future needs. (Paragraph 124)

6.1 The Government agrees with the Committee that the recruitment and retention of suitably qualified staff is an issue that should be addressed by the inter-agency group. The group's discussions will be informed by Professor Griffin's review of issues relating to the UK's capability for research into the highest containment levels of human and animal pathogens.

Training

We recommend that the Government co-ordinate the funding and development of training schemes for those working with dangerous pathogens, building on schemes currently in existence. These should provide certification that a minimum level of competency has been reached and should be designed as a base from which staff can be further trained locally in the safe use of specific pathogens in a particular laboratory. Training programmes should be tailored to the needs of laboratory staff, principal investigators or BSOs whose training needs differ. (Paragraph 131)

We recommend that DIUS engage with the higher education sector to ensure that undergraduate and masters programmes in relevant subjects include instruction in biorisk management. (Paragraph 132)

6.2 The Government agrees that adequate training is essential if staff are to work with dangerous pathogens safely and competently. Although the responsibility for training staff must rest with the operators of laboratories, the Government recognises that there may be merits in providing more formal training and qualifications as well. We therefore welcome the development of a certification scheme for Biological Safety Officers. In the light of Professor Griffin's recommendations on the skills requirements for research into the highest containment levels for human and animal pathogens, the inter-agency group will review the need to encourage the industry to extend this scheme to others working with or supervising work with dangerous pathogens. The group will also consider the level of training that might be required as part of undergraduate and Masters programmes and, if appropriate, DIUS will engage with the higher education sector to take this forward.

Vetting of staff

Security-vetting is intended to minimise the risks of deliberate misuse of dangerous pathogenic material. This risk exists regardless of the ownership and governance of a laboratory or the country of origin of researchers and other staff. We therefore recommend that the Government provide access to Government vetting programmes so that all those working with CL4 pathogens can be reliably security vetted to a consistent, high standard. (Paragraph 139)

6.3 The Government agrees with the need for a consistent, high standard of security vetting for all those working with dangerous pathogens, including the application of national security vetting for those working in laboratories handling containment level 4 pathogens. National security vetting is a requirement for laboratories handling containment level 4 pathogens covered by the Anti-terrorism, Crime and Security Act 2001. Those working in laboratories handling level 4 pathogens covered by the Specified Animal Pathogens Order are not currently required to undergo national security vetting unless the pathogens are also listed in Schedule 5 to the Act. However, the Government will review the arrangements in place for such laboratories.

6.4 While the vetting of staff is obviously important, subsequent and on-going awareness of security issues is essential. Thus laboratory managers are advised to maintain personnel security by way of on-going good management and reporting and the creation of a 'security aware' environment.