

1. The Academy welcomes the opportunity to respond to the Innovation, Universities and Skills Committee inquiry regarding 'Biosecurity in UK Research Laboratories'. The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are translated as quickly as possible into benefits for society.
2. Overall, the Academy considers that existing regulations and standards of security and safety in UK laboratories are good. We emphasise that it is essential for the UK to maintain its excellent reputation for highly competitive research into dangerous pathogens and to attract the best researchers from around the world. The Academy also stresses that high quality research into dangerous infectious agents is essential to equip the UK to deal with public health emergencies and any bioterrorist threats; the risks associated with this research are low and far outweighed by the benefits. However, we are aware that the consequences of accidental release of a hazardous pathogen may be severe, thus, measures must be taken to ensure that all high category facilities are adequately monitored, managed and well maintained.

**3. The current capacity for research on dangerous pathogenic material in the UK and the capability to conduct research on the causative agents of disease that may emerge at a future time**

The UK maintains a competitive edge in fields of research concerning dangerous pathogenic material. However, whilst the current capacity of category 2 and 3 labs in the UK is sufficient, the Academy considers that capacity in category 4 labs should be improved for continued prominence in these research fields. At present, the majority of category 4 facilities are focused in the South of England and provision of a greater number of such facilities in the North of England would be beneficial. We consider that these facilities should be fully integrated with reference and research laboratories.

4. The uncertain nature of future threats and continuing risk of emerging zoonotic diseases also underscores the need for adequate infrastructure in the UK that can support a broad range of human and veterinary research, despite the considerable cost of building and maintaining category 4 units. A system of upgrading category 3 facilities to category 3+ could be considered in line with an assessment of the need to develop a greater number of category 4 facilities. We also note that a balance must be maintained between capacity for both hazardous bacterial pathogens and pathogenic viruses.
5. UK expertise was mobilised rapidly during the outbreak of Severe Acute Respiratory Syndrome (SARS) in 2002-3, particularly by HPA, but this would not necessarily have been possible for other pathogens. Additionally, in this case, funds for SARS research were mainly mobilised from University sources. The time required to fulfil containment regulations would have made it difficult to initiate a SARS primate study rapidly in the UK, if it had been necessary. Thus, the use of a generic Home Office project licence for the UK could be considered in order that imperative research may proceed, should the public health need arise.<sup>1</sup> The emergence of SARS in 2002, combined with the recent outbreak of Foot-and-Mouth Disease virus (FMDV), demonstrate the need to mobilise expertise with speed. Thus, in addition to developing sufficient

<sup>1</sup> Academy of Medical Sciences, 2003. Severe Acute Respiratory Syndrome (SARS). Accessed January 2008 at: <http://www.acmedsci.ac.uk/p99puid21.html>

infrastructure to capitalise on the expertise currently available, the need to prepare the next generation of expertise and to maintain a cadre of appropriately trained staff must be considered.

## **6. The state of biological containment facilities in the UK**

Overall, the safety record of UK laboratories is good and inspections carried out by the Health and Safety Executive (HSE) ensure that bio-containment facilities are functioning appropriately. However, the accidental release of FMDV at the Pirbright laboratories in August 2007,<sup>2</sup> demonstrates the need for effective governance, clear ownership of research sites and allocation of adequate funds for the maintenance of high category sites. Maintaining negative pressure required in a category 3 research laboratory is more challenging in older buildings and new designs of negative pressure laboratories within existing rooms may need to be considered, despite the costs entailed. Inspections should include appropriate checks that infrastructure is safe and well maintained.

## **7. Laboratory inspection regimes and the rationale and practicalities of the licensing system**

The Academy welcomes the proposal to develop a single regulatory framework for the regulation of laboratories covering the handling of human and animal pathogens.<sup>3</sup> Use of a single independent regulatory body will improve the clarity of messages delivered and will unify approaches to research on human and animal pathogens.

8. The Academy is aware that there is rigorous attention to compliance with HSE regulations by safety officers and high safety levels will be assured by good working relationships between safety officers and HSE representatives. However, we also note that whilst inspections are a necessary component of ensuring laboratory safety, a multiplicity of inspections can unduly affect continuity of research, owing to the need to fumigate and clear laboratories. Nevertheless, inspection regimes for high containment laboratories must continue to ensure that access is secure, movements are recorded and that equipment is functioning appropriately.
9. We are concerned that there is a tendency for the rationale used by the HSE and relevant bodies regarding regulations for high containment laboratories to be based on the concept of preventing aerosol or droplet dissemination. Yet, a number of hazardous pathogens, such as HIV, are not airborne thus regulations must take account of other methods of dissemination.

## **10. Biosafety training provision for staff working in containment facilities**

The Academy considers that biosafety training provision for staff is generally of a good standard across the board and supports HSE requirements to ensure adequate standards of training and record keeping. The majority of training is likely to take place at the research site, thus standards may vary markedly between institutions. Nevertheless, laboratory inspections would ensure that training is appropriate by quickly identifying poor safety standards.

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<sup>2</sup> Professor Brian Spratt CBE FRS (August 2007). Independent review of the safety of UK facilities handling Foot-and-Mouth Disease Virus. Accessed January 2008 at:

[http://www.defra.gov.uk/animalh/diseases/fmd/investigations/pdf/spratt\\_final.pdf](http://www.defra.gov.uk/animalh/diseases/fmd/investigations/pdf/spratt_final.pdf)

<sup>3</sup> <http://www.defra.gov.uk/corporate/ministers/statements/hb071213.htm>

## **11. The maintenance and recording practices surrounding the storage and transportation of dangerous pathogens**

Overall, we believe these practices to be adequate but highlight that responsibility for good practice remains with the University or research institute. Adequate recording procedures are assured by logging of samples both prior to entrance into containment 4 facilities and within containment 4 facilities. Monitoring of such practice would present significant logistical issues. Despite this, effective recording of the use and storage of pathogens could be improved by using currently available monitoring software. Additionally, both national and international rules for transport of dangerous pathogens and material assure that samples can only be shipped if they are properly packed and accompanied by appropriate documentation. One caveat is that it has become progressively more difficult and more expensive to transport dangerous pathogens and improvements could be made to address this. Further barriers to efficient transport of pathogens would unduly affect collaboration and the progression of scientific research.

## **12. Measures implemented when pathogenic material cannot be accounted for**

Samples stored in category 4 facilities are routinely audited on a monthly and quarterly basis, which would highlight whether any pathogenic material cannot be accounted for. Further investigation by the Safety Officer and reporting to the Home Office and Police would ensure that any discrepancies are reported and appropriately managed.

13. Continuing dialogue between the HSE and researchers and/or Safety Officers is important for ensuring that all pathogenic material is accounted for and appropriate laboratory practice and waste disposal maintained. Requirements for appropriate sealing and detailed labelling of transported material prevents any hazard from being presented in the event of material being lost during transit.

## **14. The role of universities in overseeing security clearance for research students working with dangerous pathogens**

The Academy is concerned by the ability of universities to refer certain applicants, suspected of attempting to further knowledge that could threaten national security, to the UK Government's Foreign and Commonwealth Office (FCO) for security checks through the Voluntary Vetting Scheme. Between 1998 and 2004, 2419 individuals were volunteered under this system and the FCO advised that 260 individuals be declined admission between 2000 and 2004.<sup>4</sup> We stress that international researchers make an immensely valuable contribution to the enhancement of scientific knowledge and emphasise the importance of attracting talented researchers from around the world to UK research universities. Thus, we consider it essential that security clearance does not unduly exclude or delay applications from students or post-doctoral scientists with a particular nationality. We stress that free international movement of scientists is critical to scientific collaboration and activity. We also note that the voluntary nature of referral to this FCO scheme inevitably creates wide variation between institutions in the extent to which further security checks are performed.

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<sup>4</sup> <http://www.fco.gov.uk/Files/KFile/VVS.doc>

15. The Academy also wishes to highlight that free exchange and sharing of scientific findings through peer-reviewed journals are central to scientific discovery and must not be limited by further regulation. We stress that the benefits of enhanced and applied knowledge through the sharing of research findings far outweigh any risks.

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### **The Academy of Medical Sciences**

The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are converted into healthcare benefits for society. Our Fellows are the UK's leading medical scientists from hospitals and general practice, academia, industry and the public service.

The Academy seeks to play a pivotal role in determining the future of medical science in the UK, and the benefits that society will enjoy in years to come. We champion the UK's strengths in medical science, promote careers and capacity building, encourage the implementation of new ideas and solutions – often through novel partnerships – and help to remove barriers to progress.

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