



## ADVISORY COMMITTEE ON DANGEROUS PATHOGENS

### Callaghan review and the new regulatory framework for animal and human pathogens

#### Issue

1. Consideration of a common set of containment measures for animal and human pathogens as recommended by the Callaghan review

#### Background

2. The Callaghan Review on the regulatory framework for handling animal pathogens led by Sir Bill Callaghan was published on 13 December 2007. The Secretary of State announced that the Government accepted all of the recommendations of the review.
3. Members of ACDP will recall that the review recommended a three-phased approach to implementing changes to strengthen the regulatory framework for controlling animal pathogens, briefly:

**Phase 1:** formalise HSE's support of Specified Animal Pathogens Order (SAPO) inspections by January 2008.

**Phase 2:** changes to SAPO regulations to designate HSE as inspection and lead enforcement body under the Order by April 2008, Defra remain as the licensing authority until the introduction of the single regulatory framework.

**Phase 3:** single risk based regulatory framework to govern work with human and animal pathogens by the end of 2008, with full cost recovery. Defra would expect to pass full responsibility for regulation of these pathogens to HSE at this point, as a single, independent body with the appropriate expertise and experience for this technical work.

#### Phase 1

4. HSE's support of Specified Animal Pathogens Order (SAPO) inspections was formalised in January 2008. This milestone was met and the inspections under this phase completed.

#### Phase 2

5. Defra and HSE worked closely to revise the Specified Animal Pathogens Order (SAPO), which was placed before Parliament in early April and came into force on 28 April 2008 (see Annex 2). The Order provides HSE inspectors with a wide range of powers that are substantively very close to the powers they use under the Health and Safety at Work Act, including the ability to issue formal improvement and prohibition notices. This measure

provides the legal means to effect the transfer of inspection and enforcement responsibility to HSE. The Order is complemented by an Agency Agreement which formally delegates enforcement responsibility to HSE and a Memorandum of Understanding which sets out the practical working arrangements between HSE and Defra. These documents are published on the website at:

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

6. During phase 2, Defra will remain the licensing authority, but HSE will take responsibility for inspections and enforcement using their established protocols. This work will be carried out in accordance with the Health and Safety Executive's Enforcement Policy and principles of HSE operational procedures and its Enforcement Management Model. This arrangement is now well established and working effectively.

### Phase 3

7. Phase 3 focuses on developing a Single Regulatory Framework (SRF) to govern work with human and animal pathogens. This incorporates three sets of regulations, namely SAPO, COSHH and the GMO (CU) Regulations and the outcome of legal advice will impact on the implications for the approach for Phase 3. The Callaghan Review implies a consistency of regulatory model and consistency of enforcement powers.
8. The SRF will operate at full economic cost recovery and provide the benefit of a single, understandable regime that reflects government policy to transfer delivery of work to those best qualified to deliver it.
9. Phase 3 is split over six identified workstreams to take this phase forward and positive progress has been made against each workstream:
  1. Development of a single regulatory framework for work with human and animal pathogens
  2. Development of a cost recovery regime
  3. Stakeholder engagement and a communications plan
  4. Production of a common set of containment measures to apply to both human and animal pathogens
  5. Development of an integrated notification system
  6. Engagement of the Devolved Administrations (DA)
10. The central issue revolves around developing a framework that is legally feasible and practicable; that is understood by dutyholders and that the regulations within can be enforced by regulators: the aim being to ensure that dutyholders have a clear understanding of what is required of them when seeking to work with biological agents.
11. Sir Bill Callaghan's review recommended that a common set of containment measures be formulated that provide a clear indication of the essential control measures to be taken by any laboratory dealing with human and animal pathogens, and this has been clearly defined as a workstream for phase 3. ACDP currently formulates guidance in respect of the hazards presented by human pathogens and the measures necessary to contain them in a laboratory context and there is already close collaboration between ACDP and Defra's veterinary experts.

12. Given ACDP's relevant technical and scientific expertise, the Callaghan Review recommends that ACDP is best placed to develop a single set of containment measures to apply to facilities handling human and animal pathogens.
13. To this effect, a formal invitation was sent to Professor Griffin, ACDP Chair, to consider undertaking this work. A copy of the invitation and terms of reference are attached at Annex 1.

**Action**

- Members are asked to consider the formal request for a working group to be set up to commence work on producing a common set of containment measures as proposed by the Callaghan Review.