

Advisory Committee on Dangerous Pathogens

Single regulatory framework for work with human & animal pathogens, new Biosafety guidelines

Issue

Members are aware of the review led by Sir Bill Callaghan in December 2007, which proposed several recommendations to improve the way animal pathogens are regulated in the UK. ACDP have been asked to take forward the recommendation of a common set of containment measures applicable to both animal and human pathogens and as such formed a "Containment working group" to consider all issues and produce new biosafety guidelines in support of the new regulations. The Secretariat has provided the working group's first draft (Annex1) for information and asks members for their initial comments on the approach taken. .

Background

The introduction of "The Biological Agents and Genetically Modified Organisms (Contained Use) Regulations 2010", will result in revocation of COSHH, GMO(CU) and SAPO, thereby implementing the concept of a single regulatory framework, advocated by the Callaghan review of 2007. Members are reminded that the new regulations will cover deliberate work with wild type pathogens (human and animal), currently regulated under COSHH and SAPO and all GMOs currently covered by the GMO(CU) regulations. The framework set out in the current GMO(CU) regulations will be adopted in the new regs, thereby introducing the risk based approach the "Callaghan review" recommended for deliberate work with these pathogens.

Members will wish to know that the working group have made considerable progress in discussing the commonalities between the current legislative requirements for containment of human, animal and GM pathogens, whilst also taking into account the limitations imposed by the requirements to meet the minimal standards established by European Directives for biological agents (COSHH), genetically modified organisms (GMO(CU)) and foot & mouth disease virus. Agreement has been reached within the group that a set of common containment measures (for containment levels 1 to 4) is feasible. However, more difficulty was encountered in identifying a set of common criteria for assigning human and animal pathogens to common hazard groups. The intention being that the hazard groups would be used as a starting process in the selection of containment measures appropriate to the risk. Four new hazard group definitions have

been defined by the working group and this has provided a platform for brigading of existing containment measures within COSHH, GMO (CU) and SAPO into a common list of control measures for each of the hazard groups, thus resulting in 4 common levels of containment for activities involving laboratory scale work, animal experimentation and large scale processes.

The new regulations will also require ACDP to review the existing "Approved list of pathogens which currently lists human pathogens only. From April 2010, however, the list will need to combine human pathogens and those animal pathogens currently covered by SAPO.

This first draft has been prepared by the working group and represents progress to date. The Secretariat recognises further work is needed consequently additional meetings of the working group are planned for the middle of March and early May. A final draft of these new guidelines will be available for ACDP members to consider in full, at the meeting in June 2009.

Action

Members are invited to note the draft at Annex 1 and are invited to comment on the approach taken.