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HEALTH AND SAFETY COMMISSION

Approved List of Biological Agents

A Paper by Jillian Deans

Advisor(s): Dr Jim Neilson

Cleared by Jane Willis on 23 January 2004

Issue

1. Approval of the latest (fifth) edition of the Advisory Committee on Dangerous Pathogens' (ACDP) Approved List of biological agents.

Timing

2. Routine.

Recommendation

3. The Commission is invited to approve publication of the Approved List (Annex 1).

Background

4. ACDP has been responsible for preparing a classification of biological agents since a list was first published in 1984 as a result of recommendations in the Shooter Report of 1980 on a third death from laboratory-acquired smallpox. A second edition was published in 1990. This took into account the introduction of the Control of Substances Hazardous to Health Regulations 1988 (COSHH) - micro-organisms being regarded as substances hazardous to health. The fourth edition¹ was published in 1995. This reflected the implementation of two European Directives concerned with biological agents:

- a) 90/679/EEC² on the protection of workers from risks related to exposure to biological agents at work was implemented by COSHH in 1995
- b) 93/88/EC - a Community classification of biological agents, which was implemented by means of an Approved List made under Section 15 of the Health and Safety at Work etc Act 1974.

¹ The third edition was an interim document only containing just the Approved List of Biological Agents in order to implement the Biological Agents Directive.

² The two Directives and their various technical adaptations have now been consolidated into a single Directive 2000/54/EC.

5. The Approved List classifies biological agents (bacteria, viruses, parasites and fungi) into one of four hazard groups (HG) according to the following criteria (only agents in Groups 2-4 are listed):

- Their ability to cause infection (in otherwise healthy individuals);
- The severity of the disease that may result;
- The risk that infection will spread to the community; and
- The availability of effective vaccines and treatment.

Argument

6. ACDP agreed that as part of the project to revise their guidance *Categorisation of biological agents and categories of containment*, the ACDP working group responsible for the revision should take the opportunity to review the current Approved List of biological agents. The review ensured that the list took into account the most up-to-date information about the nature of the agents. The scope of the review was limited to those agents appearing in the UK list' but not the EC Classification Directive, and those agents which are classified in a higher hazard group in the UK than in the rest of Europe.

7. A number of agents have either been reclassified, removed or added to the revised list following the review by ACDP and external consultation (see paragraphs 8-15 and Annex 1).

8. ACDP also recently set up a working group to consider the classification of severe acute respiratory syndrome (SARS). The SARS Working Group recommended the classification of the agent as Hazard Group 3; but stressed the need to revisit this classification once further information becomes available. This includes data on:

- Treatment: The development of possible immunoglobulin therapy (currently underway in Hong Kong) and information on the viral burden (whether it peaks early or late during infection).
- Infection: Further information on the viral load, burden and titre required for infection to occur.
- Further information about the routes of infection.

SARS therefore appears in the Approved List for the first time, and is classified as a HG3 agent. Guidance has already been published on the HSE website on working with the SARS agent.

9. The revised list also contains a number of other changes:

- A new title – previously the List was a supplement to the *Categorisation of biological agents according to hazard and categories of containment* guidance. The List is now entitled *The Approved List of Biological Agents* and is a stand alone publication that should be read in conjunction with COSHH and relevant ACDP guidance.

- Following changes to the biological agents provisions of COSHH 2002, the exemption certificate in the current edition has been removed.
- Removal of Appendix 24 – the advice on work with HG3 enteric pathogens remains current but will appear in new ACDP guidance (*Biological agents: managing the risks* - in preparation). In the interim, it will be available on the HSE website.

Consultation

10. In addition to seeking views from the ACDP and the working group, an external consultation was carried out seeking the views of a number of expert professional bodies/individuals on the following issues:

- The rationale for the current classification of agents in a higher hazard group in the UK Approved List than in the EC Directive.
- The evidence (or otherwise) for agents on the UK Approved List but not the EC Directive being listed.
- Any new evidence about recently classified agents which would enable ACDP to either reclassify or confirm the current classification.
- New/emerging/existing agents that should be classified.
- Any changes in nomenclature and/or taxonomy of any of the agents on the Approved List.

11. Responses were received from a number of bodies (list at Annex 2).

12. A number of suggestions for removal of agents, addition of new agents and reclassification into lower HGs were proposed and subsequently approved by ACDP.

13. There was one proposal to increase the HG of an agent; Duvenhage virus (from HG2 to a HG3) on the basis of its similarity to rabies. As this could increase the burden on those working with the virus, a further targeted consultation was carried out. This determined that all work with rabies-like viruses must be carried in accordance with the requirements of The Specified Animal Pathogens Order (SAPO), in addition to requirements imposed by COSHH. As SAPO imposes stricter containment measures than those required by COSHH, there were no objections to increasing the HG of Duvenhage virus.

14. In finalising the text of the revised list, an inconsistency was noted in the classification of a particular arenavirus – Mobala. One of the respondents to the consultation had noted that this virus and another related virus, Mopeia, have different classifications: Mobala was in HG2 whereas Mopeia was in HG3. When the Approved List was first issued in 1995, a consultation was carried out which resulted in a number of agents being added to the list and Mobala was added at the suggestion of two respondents. However, their recommendation was to classify the virus in HG3. In the absence of any record of a specific discussion about the classification of Mobala, it appears that its final classification in the Approved List was the result of an editorial oversight. ACDP and relevant researchers in the UK and USA were therefore asked to reconsider the classification of the virus.

15. The consensus was that because of the lack of human data and the close relationship of Mobala with other HG3 and HG4 arenaviruses, the precautionary principle should apply

and this virus should also be classified as a HG3 agent. When the key players in the UK were consulted about this classification, they indicated that increasing the classification of the virus would not impose an undue burden, as similar agents are already handled at the higher containment level.

Presentation

16. The revised Approved List will be published on the ACDP website (<http://www.hse.gov.uk/aboutus/meetings/acdp/index.htm>). Hard copies of the Approved List will also be available to individuals without Internet access.

17. The target audience for the publication will be those working in the microbiology (and related disciplines) sector – in academic, healthcare and private research establishments.

18. General media interest is likely to be low. The potential audience has already been made aware of the on-going revision of the list by means of articles in the ACDP's Biological Agents Bulletin. A further article will be prepared to announce the publication of the list. A Press Notice will also be issued.

Costs and Benefits

19. There are no additional costs to those already complying with the legal obligations imposed by the list. Increasing the HG of Duvenhage virus will not impose extra costs on laboratories because stricter control measures are already required under animal health legislation. The removal or reclassification of certain agents ensures consistency with European laboratories.

Financial/Resource Implications for HSE

20. None.

Environmental Implications

21. None.

Other Implications

22. None.

Action

23. The Commission is invited to approve publication of the Approved List.

Consultation respondents

Association of the British Pharmaceutical Industry
Association of Clinical Microbiologists
Association of Medical Microbiologists
British Veterinary Association
Central Public Health Laboratory
National Collections of Industrial, Food and Marine Bacteria
National Institute of Biological Standards and Control
Public Health Laboratory Service
Royal College of Pathologists
Society for General Microbiology
UK National Committee for Microbiology