

Advisory Committee on Dangerous Pathogens



# Biological Agents Bulletin

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HSE BOOKS

## Control of Substances Hazardous to Health (COSHH) 2001

The last issue of *Biological Agents Bulletin* featured an article on the proposed changes to the biological agents provisions of COSHH. A draft of the new proposed COSHH Regulations and a draft revised Schedule 3 have now been prepared to take account of the proposals, and to emphasise that the provisions apply to chemical **and** biological agents.

### Key changes

The main changes proposed are:

- ◆ the general provisions on the assessment and control of biological agents will be moved into the main COSHH Regulations; and
- ◆ specific measures relating to deliberate work with biological agents (eg laboratory establishments and large-scale use plants) will continue to be addressed in a slimmed-down Schedule 3, and supplemented by a biological agents appendix to the main COSHH Approved Code of Practice (ACOP).

Other changes planned are:

- ◆ the extension of the facility to develop and use HSC guidelines to allow the selection of containment measures for different kinds of work. This will allow the current unsatisfactory use of exemption certificates to be phased out. Clear guidance on how to apply the derogation will be provided in the biological agents appendix to the main ACOP, and in the future revision of the Advisory Committee on Dangerous Pathogens' (ACDP's) guidance on *Categorisation of biological agents* according to hazard and categories of containment;
- ◆ the clarification of definitions used, eg 'use' and 'handling'; and
- ◆ the simplification, clarification and extension of the notification duties required for biological agents.

The Health and Safety Commission will be undertaking formal consultation on the proposals in due course.

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## Freedom of information

The Data Protection Act 1998 came into force on 1 March 2000. It replaces the Data Protection Act 1984. It protects the privacy of living individuals in respect of the personal data that are held on them, and gives new rights to know who holds information on you. The new Act continues to cover electronic data, but now also extends to manual (ie records on paper) data that are readily accessible. 'Data controllers' must inform all individuals that they are 'data subjects'. Government advisory committees (such as ACDP) and all government departments/agencies are obliged to reveal what information they hold on private individuals.

The Act gives everyone the right to request and expect from data holders:

- ◆ confirmation that they hold personal data on them;
- ◆ information about the identity of the person in a business or government department who is nominated as responsible for data protection issues;
- ◆ access to a photocopy of the data held in an understandable format; and
- ◆ correction of any mistakes held in the data.

There are new rules to prevent data being sent to a foreign country outside the European Economic Area to escape the legislation. There is also a new range of non-compliance rules which can lead to individuals being held personally responsible for breaches.



## Transport of infectious substances

The Health and Safety Executive (HSE) has issued a certificate of exemption to permit consignors handling certain diagnostic specimens with a low risk of contamination to receive exemption from parts of the carriage of dangerous goods legislation until the end of 2003. The exemption follows discussions with carriers about the practical difficulties being experienced when sending diagnostic specimens by post.

The exemption enables diagnostic specimens which may contain human or animal pathogens in biological agent Hazard Groups 2 and 3 to be packaged and sent in a less onerous and more efficient way. Details of the packaging requirements which must be followed to ensure that specimens continue to be consigned safely are provided in the schedule to the certificate of exemption. These include that the packaging shall either comply with standard EN 829:1996 or meet a number of conditions (eg that the primary receptacles shall not contain more

than 100ml; that the outer packaging shall not contain more than 500ml; and that the primary receptacles shall be leakproof). Further information is also given on the requirements for diagnostic specimens which are applied on test sticks or test strips.

The exemption is allowed under Multilateral Special Agreement M96, which has been co-signed by the UK and the Czech Republic. The agreement covers domestic carriage between the two signatories and may be extended to other countries which apply. If the agreement is terminated by any signatories before that date, the exemption will be revoked for that particular territory by a further certificate in writing.

Copies of the Multilateral Special Agreement M96 under marginals 2M and 10 602 relating to the carriage of diagnostic specimens are available on the HSE website ([www.hse.gov.uk/spd/m96dial.pdf](http://www.hse.gov.uk/spd/m96dial.pdf)).

# Laboratory containment of polio virus

Following the successful eradication of smallpox in 1988, the World Health Organisation (WHO) launched a global initiative to eradicate polio by the end of 2000. Since the launch, the number of cases has fallen by more than 90%; the number of countries in which polio has not been eradicated has fallen from 125 to 30; and paralytic polio has been prevented in around three million people in the developing world because they have been immunised against the disease.

Once polio is eradicated worldwide, the only source of the virus will be in laboratories. As an increasing number of countries become polio-free, the virus needs to be safely and securely stored to ensure no inadvertent release occurs after eradication.

In 1998, WHO issued a global action plan for the safe handling and maximum laboratory containment of wild polio virus and potentially infectious material post-eradication. There are a number of tasks that must be carried out as part of this process:

- ◆ firstly, laboratories which hold wild polio virus infectious material, or potentially infectious material, have to be identified and a national inventory prepared;
- ◆ laboratories must then put in place enhanced containment measures for the safe handling of all such infectious material;
- ◆ national plans will have to be developed for the implementation

of more stringent containment measures post-eradication (when polio virus will have to be handled at Containment Level 4).

In the UK, the work is being overseen by a joint Advisory Committee on Dangerous Pathogens (ACDP) and Joint Committee on Vaccination and Immunisation (JCVI) working group. The group is in the process of developing the UK plan, and it is expected that work on the inventory will begin later this year. Further details will be given in a future special issue of the *Bulletin*. If there are any queries in the meantime, please contact the joint ACDP/JCVI working group via the Public Health Laboratory Service (polio@phls.nhs.uk).

## The Special Pathogens Programme at CAMR

### *Diagnostics*

The Diagnosis Laboratory at the Centre for Applied Microbiology and Research (CAMR) provides UK laboratory diagnostic services for pathogenic viruses, and other Hazard Group 3 bacteria (particularly anthrax). This involves the investigation and identification of such infections in UK nationals (or animals, where appropriate) returning from endemic areas, by combinations of serology, immunoassays, culture and molecular techniques. A comprehensive range of reference Hazard Group 3 and 4 viruses, bacterial strains, antisera, and other specific diagnostic agents is available. Advice is provided to healthcare professionals and dialogue is maintained with the Ministry of Agriculture, Fisheries and Food (MAFF), HSE, ACDP and European groups (eg the Comité Européen de Normalisation (CEN), the European Network for the Diagnostics of Imported Virus Diseases (ENIVD)) on aspects of biosafety.

### *Research and development*

Continual research and development is needed to maintain the effectiveness of diagnostic services. In addition, it is a guiding principle that dependence on the use of Containment Level 4 facilities for laboratory diagnosis should be reduced to a minimum. One theme is based on the successful RT-PCR-based assay for Lassa virus infection,<sup>1</sup> which was a joint development with the Central Public Health Laboratory. The Department of

Health is currently funding work to extend this approach to some of the other viruses circulating in Africa (Ebola, Marburg and Crimean-Congo haemorrhagic fever), which can give rise to similar clinical presentations.

Other ongoing research includes formal microbial risk assessment, a powerful approach which is now being applied to various serious infectious disease scenarios; and, in addressing one of the most discussed risks of xenotransplantation, an investigation of the transmissibility of porcine endogenous retroviruses to small laboratory animals.

### *National collection of pathogenic viruses*

The Office of Science and Technology (OST) and the Wellcome Trust are jointly supporting the new National Collection of Pathogenic Viruses (NCPV) sited at CAMR. It forms an integral part of the UK National Culture Collection. The NCPV is being built up as an archive of well-characterised, authenticated human pathogens which will resource the supply of viruses, and materials derived from them, to the scientific community. Viruses assigned to ACDP Hazard Groups 2 and 3 will form the major part of the collection, but Hazard Group 4 viruses will also be accommodated. Strict controls on the distribution of unusually hazardous infectious material will be implemented following legislation based on the recommendations of the Australia Group of countries.

1 AH Demby, JC Chamberlain, DWG Brown and JCS Clegg Early diagnosis of Lassa fever by reverse transcription-polymerase chain reaction (RT-PCR) *J Clin Microbiol* 32 1994 2898-903.

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# The Memorandum on Rabies Prevention and Control

The *Memorandum on Rabies Prevention and Control* was published on 8 February 2000 and replaces the edition issued in August 1977. The memorandum was prepared by the Department of Health in conjunction with the Ministry of Agriculture, Fisheries and Food, the Public Health Laboratory Service, the Health and Safety Executive, and others. The Advisory Committee on Dangerous Pathogens was consulted and endorsed the contents.

The memorandum describes the rabies virus in both animals and humans; outlines the means by which human rabies is prevented; and advises on the management of a human patient with rabies and the actions needed to protect public health. The chapter on the management of human patients with rabies includes information on such

matters as the treatment and care of patients, protection of health care professionals, laboratory practice, diagnostic methods, disinfection, the carriage of dangerous goods and clinical waste. It reminds readers that the COSHH Regulations 1999 apply to the rabies virus, which is classified as a Hazard Group 3 biological agent.

The Memorandum is intended primarily for the use of local public health services, but it is available to others (medical and allied professions or the general public) free of charge from the Department of Health, PO Box 777, London SE1 6XH, fax 01623 724524 (e-mail: [doh@prologistics.co.uk](mailto:doh@prologistics.co.uk)). It is also available on the Department of Health's website ([www.doh.gov.uk/memorandumonrabies/](http://www.doh.gov.uk/memorandumonrabies/)).

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## Containment of cell cultures

ACDP has recently reconsidered its advice to users on containment requirements for work with cell cultures, in the light of the advice set out in the proposed new Genetically Modified Organisms (Contained Use) Regulations. Current ACDP guidance on the hazards associated with cell cultures recommends that work with all cell cultures is undertaken at a minimum of Containment Level 2, and the use of a microbiological safety cabinet for all work is advised, even where the risk is considered to be low.

With a view to standardising the guidance from ACDP and the Advisory Committee on Genetic Modification (ACGM), the current ACDP guidance will be amended to allow work with cell lines that are well characterised or authenticated, including those of human and primate origin, to be handled in future at Containment Level 1. Such work will no longer require notification. ACDP has also agreed to clarify the degree of authentication or characterisation that is required for a cell line to be considered to be 'well authenticated/well characterised'.

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## Current ACDP publications

ACDP has produced a number of free and priced publications which may be obtained from either HSE Books or the Stationery Office (see past issues of *Biological Agents Bulletin* for a complete list, or contact HSE Books or TSO directly). Brief summaries of selected ACDP publications are also featured on the Health and Safety Executive website and on the ACDP homepage within the Department of Health website. (See list of contacts and addresses below.)

Previous issues of the *Bulletin* are available from HSE Books and a copy is posted on the HSE website. You may also join up to receive copies via the free subscription mailing service - send details to HSE Books at the address given below.

HSE Books, PO Box 1999, Sudbury, Suffolk CO10 2WA Tel: 01787 881165; Fax: 01787 313995  
website: [www.open.gov.uk/hse/hsehome.htm](http://www.open.gov.uk/hse/hsehome.htm)  
The Stationery Office, PO Box 276, London SW8 5DT Tel: 020 7873 9090; Fax: 020 7873 8200  
website: [www.tso-online.co.uk](http://www.tso-online.co.uk)

### Coming up...

Progress on guidance on the management, design and operation of microbiological containment laboratories  
Legionella plans  
WHO polio containment campaign update  
Appointment of members to ACDP  
Guidance on Hendra and Nipah virus