

Safety Services

Guidance on completing COSHH assessment and application form for handling biological materials

The University's Biological COSHH form provides a means of assessing the risk in accordance with the Control of Substances Hazardous to Health Regulations, a means of monitoring which biological materials are in use across the University, and a way of obtaining formal approval to work with certain substances that represent a higher risk to health.

These notes should be read in conjunction with the form, and the numbers in bold tally with the boxes numbered on that form.

General References

1. Biological agents: Managing the risks in laboratories and healthcare premises; available only at <http://www.hse.gov.uk/biosafety/biologagents.pdf>
2. The management, design and operation of microbiological containment Laboratories, HSE Books 2001 ISBN 0 7176 2034 4

Notes

- 8 Containment level of area(s)** See Reference 1, Table 2, page 15; Reference 2
- 9 Hazard Group of agent(s)** See COSHH 2002 (as amended); ACDP (2004); The Approved List of biological agents" at <http://www.hse.gov.uk/pubns/misc208.pdf>
- Detailed safety data sheets are available at <http://www.phac-aspc.gc.ca/msds-ftss/> but *note this is a Canadian website and legal statutes may be different to those in English law*
- 13 Nature of biological agent** - include source, strains, maximum amount and concentration to be handled and frequency of use.
Could a safer agent or strain be substituted, for example a clinical strain of pathogen with one that is lab adapted?
- Potential Hazard to humans and/or animals including:**
- 14 Pathogenicity** - How severe is the disease caused - morbidity vs. mortality; acute vs. chronic? Are any groups of people at greater risk, e.g. new and expectant mothers, those whose immune system is not fully functioning (e.g. because they are undergoing medical treatment or they have had their spleen removed). Can the agent cause harm by other means, i.e. cause an allergy, produce a toxin? See references as Note 9
- 15 Epidemiology** - Consider the natural hosts of the agent and what is known about the incidence of laboratory acquired infection – see also <http://www.ebsaweb.eu/Resources/LAI-p-26.html> and <http://www.phac-aspc.gc.ca/msds-ftss/>
- 16 Infectious dose** - Remember that data on infectious doses may be useful but be aware that they can be a function of the immune status of the exposed individual.
- 17 Routes of transmission** - Remember to consider both natural and potential

routes of laboratory transmission e.g. an agent that is transmitted naturally via an insect vector could be transmitted in the laboratory via a penetrating sharps injury.

- 18 Medical data** - Consider whether there are prophylactic treatments available and also whether there is any known resistance to such treatment. Consider also if there are vaccines readily available and their side-effects. Consider the symptoms of the infection and if such information can be used for health surveillance purposes.
- 19 Environmental stability** - Consider what is known about the agent's survival outside the host, e.g. can it form spores; how susceptible is the agent to disinfectants (what kinds?); and what are the physical inactivation methods?
- 20 Possible involvement of non-laboratory personnel** - Consider those who may not be in the workplace all of the time, e.g. cleaners, engineers, maintenance/service workers, students; and members of the public, e.g. visitors.
- 21 Special Containment procedures** - other than those standard for the appropriate level of containment (include details of extra precautions needed to contain procedures likely to produce significant aerosols - shaking, blending, centrifugation, sonication – e.g. the use of safety cabinets).
- 21A Plants:** List the measures to be used to protect personnel and the environment against higher plants and plant products that cannot be controlled by working with containment level 1, 2 or 3 procedures as defined for microbial materials. Even for non-GM plants, precautions might be selected from measures suggested for use with GM plants (see Part 4 of the Compendium of Guidance at <http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/>).
- 21B Prions:** see *Advisory Committee on Dangerous Pathogens Transmissible spongiform encephalopathies: Safe working and the prevention of infection* Internet only, 2003
www.advisorybodies.doh.gov.uk/acdp/tseguidance/index.htm
- 21C Supplementary measures for Microorganisms:**
1. Assignment of organisms to a Hazard Group is only the first step in Risk Assessment. Research with biological agents which are appropriately assigned to Hazard Group 2 on clinical criteria and on the basis of the strict definition for that Group can present a significant risk of serious infection in some laboratory operations unless supplementary containment measures are employed.
 2. COSHH requires that agents in Group 2 are handled in the laboratory at Containment Level 2 as a minimum. In general, work with agents in Group 2 may be conducted on the open bench although care must always be taken to minimise the production of aerosols. For manipulations such as vigorous shaking or mixing and ultrasonic disruption etc, a microbiological safety cabinet or equipment which is designed to contain the aerosol must be used. All manipulations involving infectious agents should be addressed in the risk assessment and specific local rules developed to ensure that the work is conducted safely. In some cases, the nature of the work may even dictate the need for full Containment Level 3 conditions to protect adequately against Hazard Group 2 organisms.
 3. Although most agents in Group 2 fit the epidemiological and clinical criteria reflected in the definition, certain members of this group, including those that are infectious by inhalation and others classified as blood-borne infections, should always be handled in a safety cabinet or be otherwise

suitably contained. In some cases, gloves and eye protection should be used routinely and procedural controls on the use of sharps. Historically there has been a notional '2 +' level of containment adopted for such agents; however, it should be recognised that this description has no legal status under COSHH and therefore where additional control measures are used that are not described in the Table of Containment (see references as Note 8), these should be listed in section 21. Examples of the pathogens that should be included in this group are those known to have been the cause of serious or even fatal infections when involved in such simple operations as making suspensions for serotyping or simply opening centrifuge containers. Some Hazard Group 2 agents are known to infect via apparently intact mucosae or through skin contact and can present an enhanced risk.

4. Depending on the nature of the intended work, examples of agents that are likely to require additional containment and control measures are:

Bordetella pertussis
Borrelia burgdorferi
Borrelia duttoni
Borrelia recurrentes
Chlamydia trachomatis
Clostridium botulinum
Corynebacterium diphtheriae
Cryptococcus neoformans
Legionella pneumophila
Leptospira interrogans var. *Ictohaemorrhagiae*, *canicola*, *hebdomadis*

Neisseria meningitidis

Sporothrix schenckii
Streptobacillus moniliformis
Treponema pallidum and other treponemes
Vibrio cholerae (including El Tor)

It should be noted that additional containment and control measures may be required for other micro-organisms not listed above depending upon the nature of the activity.

5. *Advisory Committee on Dangerous Pathogens Guidance on work with Hazard Group 3 enteric pathogens* Internet only
<http://www.hse.gov.uk/biosafety/diseases/entericpathogens.htm>
6. Viruses (especially Blood Borne Viruses), fungi and parasites should also be considered in this context (see also Protection against blood-borne infections in the workplace: HIV and hepatitis, The Stationery Office 1995 ISBN 0 11321953 9.) . Extra precautions for work with blood-borne infections, or clinical samples that may contain them are discussed in detail and summarized in a table in paragraph 142 (pages 34-35). Also see the supplement to this document entitled Revised Advice on Laboratory Containment Measures for work with Tissue Samples in Clinical Cytogenetics Laboratories (available from http://www.rcpath.org/resources/pdf/dh_acdp.pdf) which describes in paragraph 8 the extra precautions that may be needed at CL2.
7. Technical advice on selecting the most appropriate containment measures can also be obtained from the Health & Safety Executive's Biological Agents Unit (Tel: 0151 951 4000)

- 24 Animal work** - Consider the possibility of allergies or zoonotic infections and work with deliberately infected animals, including those that might have been infected with GM agents. Some cross-referencing with the relevant GM forms may be required.
- 25 Protective clothing and equipment** - include type of lab-coats, gloves, glasses, face-masks, etc. Face fit testing may be needed for face masks.
- 26 Storage & transport arrangements** - include where they are stored, under what conditions and whether appropriate signs are displayed. There are 3 aspects to transport, (a) from outside the University; (b) within the University; (c) to destinations outside the University.
- 27 Disinfection & disposal procedures** - include concentration of validated disinfectant and minimum contact time for decontamination of equipment and surfaces, and details of disposal methods
- 28 Immunisation & health surveillance** – following discussions with Occupational Health, consider all staff/students who may be exposed to the biological agent. Personal medical details cannot be provided as they are confidential and not accessible to non-medical personal. The [Clinical and Laboratory Workers Questionnaire](#) is available
- 29 Environmental monitoring** - This is rarely necessary and only required for HG3 or above or very large scale HG2. This would almost certainly be discussed with the Regulatory Agency (e.g. HSE or DEFRA) as part of the process of getting permission to work with the material.
- 30 Emergency procedures** - include details of how you would handle a major spillage, accidental exposure or infection. As in **Section 29**, this is only necessary for HG3 or above and very large scale HG2. How would the incident be reported and to whom?

- 31 & 32** Ensure these workers are covered by any appropriate immunisation and health surveillance as identified in **Section 28**
- 33** **PI Signature** - In signing this box, the PI must recognise their commitment to comply with all 4 parts of the box.
Ethical Approval - see
- 33(d)** <http://www.campus.manchester.ac.uk/researchoffice/researchethics/>
- 38** HSE approval - is required for first use of agents in Hazard Groups 2, 3 or 4 at a particular premises and subsequent use of any of the agents listed in part V of Schedule 3 "Approved Code of Practice and guidance", Control of substances hazardous to health (Fifth edition, 2005). These are currently any Group 3 or 4 agent and the Group 2 agents *Bordetella pertussis*, *Corynebacterium diphtheriae* & *Neisseria meningitides*
Anyone contemplating using any of these agents should download HSE form CBA1 from <https://www.hse.gov.uk/forms/notification/cba1.pdf> , fill it in, and append it to their application to handle biological materials.