Control of Biological Hazards

Safety Guide Number 14 Part 5
Practical Aspects

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Safety Guide 14, Part 5

Practical aspects of work involving the possible exposure to hazardous biological agents.

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INTRODUCTION
The COSHH Regulations (Reference 1) require that the risks of exposure to hazardous biological agents are properly assessed before any such work is undertaken (SG14, Part 2). The Regulations apply, whether or not there is any intention to work with the agents – the possibility of incidental exposure is also covered by the Regulations. Sections 2 to 3 of this Part of the guide apply to intentional work with such agents; and Section 4 relates to work where there is a possibility of incidental exposure. Procedural aspects (University procedures) are dealt with in Part 1 to this guide.

INTENTIONAL WORK
All “Intentional Work” must be preceded by a risk assessment, which should identify:
- the risks pertaining to the work, and
- the measures necessary to adequately control those risks.

Safe working with biological agents includes (but is not limited to) identifying the Hazard Group(s) of all agents to be used; selecting the containment facilities to be used; checking that the physical requirements are available for the highest hazard category of agent to be used, and then following the associated procedural requirements. The risk assessment forms BiolAgRA-2 and BiolAgRA-2i have been designed to assist in undertaking COSHH assessments for work involving intentional or incidental exposure to hazardous biological agents.

2.1 Hazard Groups and containment facilities
All intentional work with biological agents must follow the guidance given in the relevant ACDP publications (References 2a/ 2b/ 2c).

The containment facilities required for work with a given biological agent are normally commensurate with the hazard. For organisms in any Hazard Group, the principles of Good Occupational Safety and Hygiene (GOSH - see Section 5) apply to working practices. These basic requirements are overlaid with specific recommendations, which differ according to the Hazard Group of the agent concerned. Where the work involves agents in more than one Hazard Group, the containment facilities must be able to accommodate the highest category of agent to be used.

The use of “Good Microbiological Laboratory Practice” (GMLP) is the minimum requirement for work with all microorganisms. These minimum requirements are given in the Health and Safety Services leaflet, “Good Microbiological Laboratory Practice” (also reproduced in Appendix 1 to this Part of the Guide. ). Remember also that good hygiene techniques can also help to protect experimental material from contamination originating from the environment or from the experimenter!

2.2 Physical requirements
An outline of the physical requirements for each containment level, including work in

1 In particular circumstances (as indicated by a risk assessment), it may be possible to omit one or more control measures that would normally apply to a given containment level – for example, the use of a Microbiological Safety Cabinet may not be essential if the agent concerned is not infectious by inhalation of aerosol droplets containing viable organisms. Such a derogation from the requirements would only be granted by HSE in writing (normally on a case-by-case basis). Applications should be made via the Biological Safety Officer.
laboratories and animal rooms and in industrial processes is given in the Regulations (Schedule 3, Part II and Part III respectively). Detailed recommendations for physical and procedural requirements for Containment Levels 2 and 3 are given in pps 23 - 42 of Reference 2a.

In general, for each containment level, recommendations are made for both the design of the facility, and the procedures to be used. These include:

- **hygiene** - e.g., ease of cleaning benches, floors, walls, ceilings etc; prohibition of eating, drinking, chewing, etc, in laboratories;
- **the use of personal protective equipment** - e.g., the wearing of properly fastened laboratory coats of a design that affords the wearer protection, etc;
- **the use of effective disinfectants** and procedures for the control of contaminated wastes;
- **the use of techniques and equipment** designed to minimise the production of and/or contain contaminated aerosols (especially at higher hazard levels); and
- **the use of dedicated equipment** for the exclusive use within a containment laboratory (where appropriate).

### 2.3 Information and record keeping

COSHH Regulation 12(1) (Reference 1) requires an employer to provide his employees with “such information, instruction and training such as is suitable and sufficient for him to know the risks to health” created by exposure to biological agents. This includes information on the identity of, and the nature of the hazards associated with, biological agents that are stored or used within the laboratory. Details of the following must always be recorded for each project involving the use of hazardous biological agents:

1. **Risk assessments**

Records of risk assessments must be kept (e.g., completed copies of form CRA-2), together with any changes to those risk assessments. Staff must be informed of the results of those risk assessments, and in particular, instructed on the proper use of any control measures identified by the risk assessment. Assessments should be kept for a minimum of 3 years after work has ceased with a particular biological agent, and should be reviewed on an annual basis.

2. **Hazardous biological agents in use: the Laboratory Inventory**

Each laboratory storing or using hazardous biological agents\(^2\) should keep a detailed inventory [approximate quantities, locations] of all such agents within the laboratory. **This also applies to material likely to be contaminated by hazardous biological agents** - thus, for example, human tissues samples and body fluids (such as blood) should be included in the inventory.

Note that the need for an inventory only applies to agents in Hazard Groups 2 and 3 – Hazard Group 1 organisms are not considered to pose a risk of infection (although they may pose other risks such as toxicity or allergenicity).

\(^2\) Note that the names of organisms, particularly bacteria, are subject to change as more information is gained about their taxonomic relationships. It is possible therefore, that a culture may be known in a Department under a different name from that currently recognised by the regulatory authorities. This may well be the case where a culture has been maintained within a School/ Department for a long time. This may lead to a false assumption regarding the hazard classification of the organism, as “old” names may not occur in the lists of biological agents. Laboratory Supervisors should therefore regularly review the hazard classification status of all the cultures they maintain. A convenient time to do this would be as part of the annual survey of hazardous biological agents undertaken by the Biological Safety Officer.
The inventory should record details of the:

- identity of each organism [or potentially contaminated sample + details of its provenance];
- name of the person in charge;
- amount stored (in long-term storage, such as freeze-dried culture); and
- location and type of storage.

Given that quantities of agents in use are liable to change on “day to day” basis, laboratory supervisors should record figures for the average quantities of agents in use.

For security reasons the detailed inventory should be kept in a secure location, but be accessible to all persons authorised to enter the particular laboratory. Note that this represents a change from previous practice, in which each laboratory was required to exhibit a list on the door of all the hazardous biological agents used in the laboratory. This applies especially where any of the organisms are named as “Schedule 5” substances in the Anti-Terrorism Crime and Security legislation. See reference 3. (Please contact the BSO for further advice on this topic if necessary.)

A copy of each laboratory inventory should be stored centrally, i.e., each School or Department should have secure central records showing the type and location of all hazardous biological agents used/ stored within the building. The aim of the Departmental inventory is provide a central record in case of an emergency affecting one or more laboratories in the building, or in situations when the laboratory supervisor cannot be contacted. The central record would be in addition to individual records maintained by each laboratory supervisor. Records must be updated if there are any significant changes - for example, addition of new biological agents, or removal of existing agents from the inventory.

There would be no need to list details of individual strains or isolates, unless particular strains had a higher hazard classification. For example, many laboratory strains of *E. coli* are regarded as "disabled"; are accorded Hazard Category 1 status, and therefore need not be listed. By contrast, wild-type *E. coli* strains (especially hospital isolates) are Hazard Category 2, and some toxigenic strains, such as VTEC<sup>+</sup> O7H157, are Hazard Category 3. In this case, the quantities and locations of the different hazard category materials should be recorded separately.

Note that all Hazard Category 3 organisms must be stored in containment level 3 facilities where practicable. Where specialised storage is required (e.g. -80° storage) and CL3 storage is impracticable, then stocks should be kept securely in appropriate storage, for example, inside a locked (“biohazard”-labelled) box within the store. Ideally, the box should be fixed to a shelf in the store, so that it is not capable of being removed. This should only be accessible to authorised personnel.)

- **Biohazard Warning Signs**

For the purposes of warning emergency or security personnel, the outer door of each Containment laboratory (Containment level 2 or higher) or suite should bear a Biohazard warning sign which identifies the containment level of the laboratory (see the “Signs” page of

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3 Note that in some cases, newly acquired agents must be notified to HSE and the notification acknowledged before any work may be undertaken with the agent. See Part 1 – University Procedures.
the Health & Safety Services website, via “S” in the A to Z). The sign should also state that access is permitted only to named authorised personnel. The sign should also carry the name/ emergency contact details of the relevant responsible person, and where appropriate, contact details for an alternative responsible person.

Where a laboratory is shared between different groups, each of which uses their own particular biological agents, all laboratory staff should be made aware of the risks to which they could be exposed. Members of each group should therefore be able to access details of the biological agents in use by others in the same laboratory. However, it is not good practice for different groups to share the same laboratory if the two groups use organisms with very different hazards – such work should be undertaken in separate laboratories.

For Containment Category 3 laboratories, in addition to the above, the door should be kept locked when the laboratory is not in use, and the key kept in secure storage. It may also be necessary to add additional security measures (such as swipe card access; CCTV) as advised by the relevant authorities. Similar controls apply where stocks of the Scheduled toxins (Schedule 5 of the antiterrorism legislation, as above) are kept.

- **Annual Survey of hazardous biological agents**

The Biological Safety Officer conducts an annual survey of all Schools liable to be using or storing materials containing hazardous biological agents. A current print-out of the Departmental Inventory will be sufficient response. This allows the BSO to keep an up to date list of all such agents within the University.

2.4 **Emergency Response planning (etc.)**

At present, there are no organisms kept or used within the University that would require the preparation (and subsequent execution) of an Emergency Response plan were an accident to occur. The BSO will advise on whether such a plan should be prepared when considering new proposals for work with high-hazard biological agents. If such a plan is required, a copy must be included within the Emergency Folder for the building, and relevant local authorities informed.

3 **INTENTIONAL WORK WITH BIOLOGICAL AGENTS:**

**PRACTICAL ASPECTS**

Safe working with biological agents requires a sound knowledge of the hazards and risks associated with the work. All those involved must operate in such a way as to minimise those risks. The following guidance should be included in departmental information that is distributed to all staff and students intending to work with biological agents at the University.

3.1 **Before starting work**

All workers wishing to undertake work at Containment level 3 must gain prior medical approval, and be able to prove their competence in required techniques to the satisfaction of the prospective Supervisor (see Part 8 to this guide – the former Safety Note 17 has now been withdrawn). Training must be fully documented, and validated by the Supervisor.

For work at lower containment levels, prior medical approval is not required, unless the work also involves the use of Genetically Modified Microorganisms (GMMs - see Safety Guide 15). Workers must however register with Health and Safety Services if they are using Hazard Group 2 organisms, and project details must have been approved by the Sub Committee for Biological...
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Safety (SCBS) before work may start (See SG14, Part 1 – University Procedures).  

Prospective workers should however seek medical advice from the University Occupational Health Service before starting work with biological agents if they have any ongoing medical condition, or are receiving treatment that renders them more susceptible to infection, e.g.:  

- immunosuppressive treatment;  
- eczema or other condition that damages the protective barrier of the skin;  
- HIV infection; or  
- pregnancy.  

The need for specific vaccinations should be discussed with the laboratory/project supervisor and/or the Occupational Health Service before starting work. Contact details for the Occupational Health Service may be obtained from the Health & Safety Services website on [http://www.rdg.ac.uk/Safety/Contacts_page3.htm](http://www.rdg.ac.uk/Safety/Contacts_page3.htm).  

All workers should make sure that they are familiar with the Local Rules for their laboratory. Particular attention should be given to the procedures to be adopted in case of an accident or emergency such as the spillage of a culture, or contamination of a piece of equipment such as a centrifuge. Any aspect of the Local Rules that appears unclear should be discussed with the supervisor before starting work.  

See Part 7 to this Guide for recommendations relating to Undergraduate students engaged on either project work, or fully supervised practical classes.  

3.2 During work  

- Wherever possible, workers should sit at the bench on a suitable stool: prolonged standing can be tiring, and can increase the chances of accidental spills. Any seat used should be capable of being decontaminated in case of a spill of infectious material.  
- All techniques/procedures used should aim to prevent the generation of infected aerosols or dust. If aerosols cannot be prevented, the work should be done within the confines of a microbiological safety cabinet. (This is a legal requirement for Hazard Group 2 and higher.) Operations that can generate aerosols include:  
  - “blowing out” pipettes;  
  - “Whirlimixing” or centrifuging open tubes of culture;  
  - opening stoppered vials or bottles, where the lid is contaminated with a viable culture of a microorganism; and  
  - using a Bunsen burner flame to sterilise a wire loop loaded with culture.  
- If a safety cabinet is used, the worker must know how to use it properly, and check that the alarms (for low air flow, etc) are working properly both before starting and after finishing work. (This is to check that failure has not occurred during the work.) The interior of the cabinet should be kept free of all unnecessary equipment and materials - they can severely disrupt the airflow patterns, and lead to “spill” of contaminated air from the front of an open-fronted cabinet. See Part 6 to this Guide for more details on Microbiological Safety Cabinets.  
- Note that use of equipment such as a centrifuge in an open-fronted microbiological safety cabinet can create seriously disrupt the airflow pattern, and lead to loss of containment.
Similarly, any traffic or passage of people behind the operator can affect the containment offered by an open-fronted safety cabinet, especially Class 2 cabinets which have a low inward airflow velocity. Eddy currents can be generated by people walking past the cabinet, leading to a serious disruption of the airflow. It is especially important to consider this aspect when deciding the siting of cabinets (See Part 6 of this Guide. Note that Part 4 of BS 5726 (Reference 6) gives advice on siting cabinets.)

- **A laminar flow cabinet should never be used with a viable culture of a microorganism.** This applies to all microorganisms, whether they are recognised as human pathogens or not. A laminar flow cabinet is designed to protect the work, and not the worker: it is NOT a safety cabinet. A horizontal laminar flow cabinet directs a flow of HEPA filtered air over the work area, directly towards the operator, thus any aerosol of viable microorganism, or fine dust containing spores will be directed straight towards the operator’s breathing zone. By contrast, a Class II safety cabinet directs a flow of sterile air over the work, but is also designed to pull air in from the front of the cabinet and prevent dispersal of aerosols towards the operator. (See Part 6 of this guide for further information.) However, the use of such a laminar flow cabinet for plant cell culture may be acceptable if certain criteria are met. Unlike the use of mammalian cell cultures, any contaminating microorganisms are likely to be regarded as Hazard Group 1, i.e., "unlikely to cause human disease by infection." Contaminants or components of the medium could however be allergenic or toxic, hence it is a condition for such a use of a laminar flow cabinet that the cultures are **demonstrably free of human pathogens and allergenic or toxic components.**

- Disinfection procedures must **always** be suitable for the material being used, and should be detailed in the Local Rules for the laboratory. Sufficient time should be allowed for the disinfectant to act before discarded material is collected. For example, if discard pots for pipettes are emptied daily, no pipettes should be placed in the pot less than 2 hours before the collection. (In practice, this means the last pipette should be put in the pot the previous night for a “morning collection”.)

- Discard containers should be placed within easy reach of the working position; they should not be placed where they could be knocked over or create hazards to others working within the laboratory.

- If autoclave bags are used for collecting discard material, they should be held in proper bag stands, fitted with drip trays to prevent leaks contaminating the floor. Autoclave bags should not be taped to the edges of benches.

- All contaminated material must be discarded in a safe manner. If it is to be collected for autoclaving, it must be transported safely in such a way that spills can be quickly and safely dealt with.

- All pipettes or disposable pipette tips used for viable cultures should either be completely immersed in an appropriate disinfectant, or discarded into an autoclaveable “sharps bin” for ultimate disposal by incineration. (see below)

- Discard containers must never be overfilled: laboratory attendants should be instructed to refuse to collect containers that they consider to be overfilled.

- Contaminated “sharps”, such as scalpel blades, hypodermic needles, broken glass, etc, should be discarded into a “sharps bin”. Such bins should be leakproof (even when wet), so that any residual culture fluid from pipette tips, etc, is contained within the bin. The design
of the bin should prevent the hand from coming into contact with the contents, even when the bin is full. Full bins should be autoclaved promptly, then sent for incineration.

- **Hypodermic needles must never be recapped before being discarded** - they should always be discarded directly into the bin. The greatest single cause of “needlestick” injuries is the attempted recapping of needles after use! Users should make sure the bin flap closes after discarding the needle, and never overfill the bin.

- Everyone should make sure he/ she knows how to use a required piece of equipment, and assures himself or herself that it is working properly. If in doubt, they should ASK someone who does know how to use it properly, and/or read the manual!

- **Workers should keep a tidy workbench**: the more untidy the bench, the easier it is to lose things, or to have accidental spills trying to find them. The more materials present, the greater the chance of making mistakes for example, using the wrong culture, solution or reagent in a test.

- At all containment levels, Laboratory notebooks should be kept/ used in a separate writing area, whenever possible, to avoid the possibility of contamination due to culture spills, etc. Laboratory users should always bear in mind the possible need to effectively decontaminate any personal items kept or stored in a laboratory. Not many notebooks (or computers!) can withstand disinfection without a severe degradation of the contents! Write-up areas should (where possible) be physically segregated from bench areas, for example, by partitions.

- At containment level 2, the use of separate write-up areas in the laboratory should be restricted to writing up daily results into the laboratory notebook. Analysis or processing of results should be done in an office area that is segregated by a closable door from the laboratory area. It should be possible to enter or leave the office without passing through the containment laboratory. Laboratory coats must not be worn or stored in such an office: they must be removed (and hands washed, etc.) as when leaving the laboratory.

- For Containment level 3, notebooks etc., should be disinfected before removal from the laboratory - but, ideally, a system of data recording and transfer should be used that avoids physical removal of the storage medium from the laboratory. (For example, a computer terminal or data link to a computer outside the laboratory.)

- Back-up copies of electronic records should be made and kept in a separate area (in case of damaging events, such as a fire), and computer equipment should be kept well away from any possible contamination by liquids, cultures, etc.

- Finally, medical advice should be sought from the Occupational Health Service if:
  - a female worker wishes to conceive, or becomes pregnant (etc.), or
  - if a course of immunosuppressive treatment, is commenced, or
  - a worker has any reason to suspect that he/ she may have been infected by contact with a biological agent at work.

  (All cases of occupationally-acquired disease must be reported to the Health and Safety Executive).

3.3 **At the end of the working day:**

- Benches must be tidied and swabbed with an appropriate disinfectant (which should be
specified in the Local Rules).

- All cultures, plates, chemicals, reagents, etc must be safely stored or safely discarded if not required. Waste awaiting collection must also be stored without risk. All storage facilities used for cultures or contaminated waste should be easy to clean, impervious to water and resistant to the effects of acids, alkalis and disinfectants. It is a legal requirement that Hazard Group 2 agents must be safely stored. If "storage" (which includes incubation) is outside the main laboratory area (for example in communal equipment such as a freezer in a containment level 1 laboratory), then the “storage” should be lockable.

- Unless specifically authorised and properly trained in appropriate procedures, cleaners are not permitted to enter Category (containment level) 2 or 3 laboratories – any waste paper for collection should be rendered “safe” before being taken out of the laboratory for disposal. Ideally, lab. staff should undertake the treatment and disposal of all waste from Category 2 and Category 3 containment laboratories.

- For laboratories at Containment level 1, cleaners have specific instructions not to touch items on laboratory benches. Floors should be kept clear of obstructions, and laboratory users should remember that items close to the edge of a bench could be knocked off. The laboratory should be left in a safe condition at the end of the working day.

- Laboratory coats must be removed and stored in a safe place away from outdoor clothing before leaving the laboratory.

- Hands should be washed with a suitable disinfectant soap, rinsed well and then properly dried before leaving. Any hand cream should only be applied once the worker is outside the laboratory - hand cream is regarded as a "cosmetic", and is banned at all containment levels. It should not be stored in the laboratory, because of the risk of contamination. If surgical latex gloves are routinely worn, hands should be washed before removing the gloves, then again after removing them.

- Note that some people may become sensitised to latex proteins (etc.) in the gloves, and may subsequently develop skin irritation or eczema. Glove users should regularly check their hands for signs of irritation. If in doubt, they should ask Health and Safety Services for a copy of the HSE leaflet "Latex and you" and/or consult the University Occupational Health Service (See “contact details” on the Health and Safety Services website http://www.fmd.rdg.ac.uk/safety/contacts.asp

  Skin irritation or eczema caused in this way is reportable under RIDDOR.

4 WORK LIKELY TO ENTAIL INCIDENTAL EXPOSURE TO BIOLOGICAL AGENTS

There are many areas of work where people may be exposed to biological agents, although there is no deliberate intention to work with them. Examples are:

- work with human blood or tissue samples;
- work with animals that may be carrying or infected by biological agents, or parasites that can themselves be infected by and/or transmit biological agents. (For example, sheep may pick up ticks infected with *Borrelia burgdorferi*, the causative agent of Lyme disease)
- work with materials liable to be contaminated with biological agents - e.g., soil, (especially if recently manured, or of exotic origin), and
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- service or maintenance work on equipment or buildings liable to be contaminated with biological agents, etc. (N.B. - this includes the possibility of contamination by Legionella - see Part 7)

In all cases, the requirements of COSHH apply, i.e., the risks created by the work must be properly assessed, and, where necessary, appropriate control measures put in place before the work is commenced. In some cases, as, for example proposals to use wild-caught rodents, the proposals should be fully discussed with the Biological Safety Officer (extension 8887) before the projects are initiated. In order that the risks may be properly assessed, the potential hazards must be identified, i.e., there must be a general awareness of the problems likely to be associated with particular types of work. There must also be knowledge of the provenance (or otherwise) of any biological materials used in the work. (See Appendix 2 to this Part for a "worked example" of risk assessment involving incidental exposure to biological agents.)

4.1 Tissues and body fluids of human origin

All tissues or fluids of human origin have a risk that they may be contaminated with viable biological agents. Samples at greatest risk are blood and primary human tissues, for example, human placental tissues, umbilical cords, and pathological specimens. Other human body fluids, such as cerebrospinal fluid, serum, sputum, and, to a lesser extent, saliva, may also pose a risk. Biological agents liable to be present include:

- Blood-borne viruses such as HIV and the Hepatitis viruses B, C (etc.) (See reference 2c)
- Bacteria such as Mycobacterium tuberculosis, etc., depending on the type of sample, and the source.

Note - all of these biological agents are Hazard Group 3.

As a minimum, all material of human origin should be handled under Containment Level 2 conditions, for example, blood samples that have been obtained from apparently healthy volunteers, either within the University, or from the public. This recommendation applies unless the samples are known to be free from blood-borne biological agents. For example, blood that had been obtained from a blood bank, and which could have been given by transfusion, can be assumed to be free of blood-borne viruses, inssofar as screening methods exist for them. Note there are no effective screening methods (to date) in place for some of the newly described blood borne viruses, such as Hepatitis E - however, this agent is thought to be rare in the general population.

By contrast, if the source (provenance) of the material indicates that there is a high probability that the sample could be contaminated by a Hazard Group 3 agent, it must be handled at Containment Level 3 until the absence of contamination has been confirmed. This is especially so for clinical specimens, where the case history of the particular patient indicates the likely presence of an agent such as HIV for a blood sample, or M. tuberculosis for a sputum sample.

- If the status of a particular sample is in doubt, always regard it as potentially contaminated until shown to be free of all hazardous biological agents.

4.2 Zoonoses

(i.e., diseases which could be transmitted to humans by contact with infected animals).

Animals may harbour (or be infected by) biological agents that can be transmitted to humans and cause disease. Such diseases are known as zoonoses. Occupationally-acquired zoonoses must be reported to HSE under the requirements of RIDDOR (see below)
Note that animals may carry or be excreting viable pathogenic microorganisms without (initially, at least) showing overt signs of disease. Farm animals may have been infected following contact with wild animals carrying pathogenic organisms. For example, the increase in the incidence of TB in cattle has been attributed to transmission from badgers carrying *Mycobacterium bovis* to cattle. (Fortunately, bovine tuberculosis is currently uncommon in the local farm animal population (and requires stringent control measures if it is diagnosed) but it can have serious consequences if transmitted to humans.)

In the context of the University farms, etc, the possibility of latent or sub-clinical infection should always be borne in mind whenever new stock is “bought in”. If such an infection is demonstrated in a farm animal, consider that the animal may have spread the infection to others, and may have contaminated stock holding areas, etc. Appropriate decontamination procedures may be required.

All work-related zoonoses, for example, diseases such as:

- leptospirosis;
- Q-fever; and
- Chlamydiosis

are reportable (to HSE, via Health and Safety Services) under the Reporting of Injuries, Diseases and Dangerous Occurrences, (RIDDOR) Regulations, 1995⁴ (Reference 5). See Safety Guide 9, which contains a full list of “reportable” diseases

- **Enteric pathogens**
  
The majority of potential zoonotic diseases are caused by Group 2 pathogens, some of which may not cause overt disease in the animal(s) carrying them. For example, many enteric pathogens, such as: *Salmonella, Enterococcus, Escherichia*, and *Streptococcus* can be carried asymptomatically by animals, and are commonly found in their digestive tracts, and/or in faeces. In addition, because of the common practice of including growth-promoting antibiotics in animal feed, it is common for such bacteria to be resistant to one or more antibiotics. Having acquired resistance, they are often able to transfer it to other, potentially more pathogenic bacteria in the appropriate circumstances. Occupationally acquired infections of this type could have serious consequences if the organism were to be resistant to antibiotics normally used to treat the disease. Particular areas of risk would be intensive animal husbandry, where animals were reared indoors at high densities - typically, chicken broiler houses, etc. These may also present additional risks from dust containing feather débris, faeces and particles derived from the foodstuffs - all of which could contain viable organisms or spores, as well as potentially allergic materials.

- **Overt disease outbreaks in farm animals**
  
All cases of overt disease in farm animals should be referred immediately to a veterinary surgeon, and appropriate precautions taken if the animal is confirmed to be suffering from a

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⁴ The Regulations require that “any infection reliably attributable to … work with animals or potentially infected material derived from [them]” must be reported to HSE. This definition would include work such as removing pigeon droppings and other debris from building rooftops and other areas they have infested, as well as work on farms or in the Grounds Department which may involve exposure to contaminated material. There does however have to be a clearly demonstrable connection between the animal/ material, the work undertaken and the disease.
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Pathogen that can be transmitted to humans. In some cases, there will be a need to notify the Department of the Environment, Food and Rural Affairs, DEFRA (formerly Ministry of Agriculture, Fisheries and Foods, MAFF) of the occurrence of certain, specified diseases. Where possible, animal bedding that is potentially contaminated should be removed and destroyed by incineration; and “contact” animals monitored to check for disease development. Such animals should be treated as potentially infected until proven otherwise.

4.3 Work involving exposure to contaminated soils.

Many soils, especially those exposed to or treated with animal manures, have a high probability of containing spores of the Hazard Group 2 agent Clostridium tetani. This organism, the causative agent of tetanus, produces spores that can survive for a long time even in dried soil samples. As the organism is an obligate anaerobe (i.e., it grows in the absence of oxygen), situations carrying an enhanced risk are those where a deep penetrating puncture wound introduces contaminated soil into the body tissues. The damage of the puncture wound may create local areas of tissue death, which will create ideal conditions for any spores to germinate and multiply. The disease is caused by a potent toxin produced on germination of the spores. Because the organism is ubiquitous, it is advisable that tetanus immunisation is a requirement for anyone liable to be exposed. This would include Grounds Department staff, staff and students from the Soil Science and Archaeology Departments (etc.). Any case of serious injury involving contamination of the wound by dirt or soil may require additional anti-tetanus treatment, especially if it has been several years since the last anti-tetanus inoculation.

In addition to spores of Cl. tetani, soils may also contain other viable biological agents or their spores, including bacteria; fungi or parasites: the likelihood will depend upon the past history of the sample. Various types of fungi form an integral part of all productive soils (as the presence of fungi is essential for degradation of dead plant material, and the recycling of the nutrients they contain.) Most fungi however are not regarded as being biological agents, i.e., they are not capable of infecting humans (but they could be allergenic.) See http://www.hse.gov.uk/pubns/misc208.pdf for fungi that are recognised as biological agents. Common fungi found in soil that are recognised as Category 2 biological agents include Candida spp; Trichophyton spp and Aspergillus fumigatus – see below for an example involving this organism.

Note that soils brought back from overseas (especially from the Tropics) may contain "exotic" biological agents (viable organisms, and/or their spores or cysts), including Hazard Category 2 and/or 3 species of bacteria, parasites and fungi. (The presence of viable viruses cannot be excluded, but is less likely.). Such soils must only be imported under licence (from DEFRA), and any conditions attached to the licence must always be observed. They should always be handled with extreme care.

4.4 Service or maintenance work

In some situations, as in service or maintenance work on equipment used in a containment laboratory, it is predictable that the equipment may be contaminated. Appropriate procedures must be put in place to ensure that the equipment is decontaminated before any service or maintenance work is undertaken. If the work is to be undertaken by an external engineer, he/she may well ask for a signed statement that decontamination has been effected. It would be good practice to provide such a statement whether requested or not.

In many situations, however, there is a possibility of contamination by hazardous biological agents, but it may not be immediately obvious to those undertaking the work. A thorough risk assessment must be undertaken in advance of the work commencing. This assessment can only
be undertaken if there is information available regarding the past history of use of the equipment or building – the equivalent of knowledge of the provenance of a sample to be studied in the laboratory.

If there is any suspicion that (for example) an air conditioning duct or basement is contaminated with biological agents, it is advisable that samples such as surface swabs be taken and analysed by a competent (preferably UKAS-accredited) laboratory. If biological agents are shown to be present, a risk assessment should identify what precautions and remedial action should be taken before the work is commenced.

For example, confirmation of the presence of Aspergillus fumigatus\(^5\) would require that appropriate precautions and control measures be taken:

If the spores were isolated from the fabric of a building due to be renovated, the potential for exposure to the fungus could be reduced by adequate ventilation and dust control (“Engineering controls”). The use of appropriate personal protective equipment (including gloves; respiratory protective equipment and disposable overall) would also be required for all work where individuals could be exposed to large numbers of spores.

As moulds such as Aspergillus spp. are common in the environment, it is important to take special care in situations where such moulds could proliferate and release large numbers of spores. These are places with high humidity and little air movement, and the presence of readily degradable plant material, including marshland and bogs, forests, compost heaps, grain stores, any rotting vegetation, piles of dead leaves, and soils.

People with asthma, a suppressed immune system, or a history of lung disease should avoid places where the Aspergillus fungus is likely to be, as they are likely to be more susceptible to developing allergies or infections.

4.5 Special Considerations

**Agents responsible for Transmissible Spongiform Encephalopathies (TSE agents) Scrapie, BSE and CJD – are they Zoonotic agents?**

The TSE agents are responsible for fatal degenerative brain disease in a variety of mammalian species, including cattle (BSE); sheep (Scrapie) and humans (Creutzfeld-Jakob disease - CJD). The agents are known as "prions" ("protein infectious agents"), and are thought to be species-specific structural variants of a cellular protein (PrP) which is present in brain cells. The function of the cellular protein is unknown, but the variant appears to aggregate in the affected cells to form insoluble complexes. The structural variant (isoform) is thought to catalyse the conversion of the cellular form to the isoform, resulting in a "pseudoreplication" of the agent. Aggregation apparently disrupts the cellular architecture, leading to irreversible loss of function - thus in the whole animal (or person) there is a progressive neurological degeneration, leading to dementia, paralysis and death. The overall picture is complicated by the existence of genetic factors, which can be mapped to the structural gene for the cellular PrP protein. It is presently unclear whether these genetic factors control the disease itself, or susceptibility to infection (or both).

Based on information gained from Scrapie (a spongiform disease of sheep and goats), the agents

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\(^5\) A Category 2 Biological Agent, based on its ability to both cause infections and provoke respiratory sensitisation (by inhalation of spores).
are thought to be extremely resistant to heat and chemical disinfectants, and are reportedly stabilised by treatment with formaldehyde. They tend to be species-specific, i.e., there is a natural barrier which renders infection of one species by the TSE of another very difficult. However, the barriers can be overcome in the laboratory if there is repeated passage of material through the new species. (For example, Scrapie can be transmitted (and eventually adapted) to mice by intracerebral inoculation.)

- In the case of the Scrapie agent, there is no evidence that humans are susceptible to infection, as there is no epidemiological association between incidence of Creutzfeldt-Jakob Disease (CJD) and prevalence of Scrapie in sheep.

- By contrast, Bovine Spongiform Encephalopathy (BSE) in cattle is thought to be transmissible to humans (by consumption of contaminated meat). BSE has been attributed to be the cause of "variant CJD" (vCJD), which differs from "classical" CJD by age of onset of the disease and the duration of the disease. At present there is considerable uncertainty about matters such as the infective dose and the incubation period, and the possible incidence of the disease in the population at large. However, there is (currently) no evidence that the agent can be transmitted to humans either directly from cattle to man, or via contaminated cattle feed. It is possible that human infection could occur during handling of infected carcasses or "high risk" brain or spinal cord material, but there is currently no epidemiological evidence (e.g., amongst slaughterhouse staff) to support this supposition.

Controls put into place during the 1990's ensure that any beef intended for human consumption is only produced from cattle less than 30 months old (the "30 month scheme"). (This is on the basis that even if an animal were incubating BSE asymptptomatically, the levels of agent present at slaughter are likely to be very low.) In addition, all the "specified risk materials" (brain, spinal cord, spleen, etc. where the highest concentrations are found in infected cattle) must be removed from the human food chain during the slaughtering process. It is therefore extremely unlikely that anyone now handling raw meat (e.g., catering staff) would be exposed to high-risk material, and in any case, the risks appear to be associated with consumption of infected meat rather than handling it.

The BSE agent is now regarded as a Hazard Group 3 biological agent, despite the fact that vCJD is a non-treatable fatal disease. See Reference 4 for further information.

There is currently no evidence of direct occupational transmission of any TSE from animal to human, and they are therefore not zoonoses as defined above.

5 PRINCIPLES OF GOOD OCCUPATIONAL SAFETY AND HYGIENE (GOSH)

The prime aim of GOSH is to protect the health and safety of workers by adopting working practices that minimise exposure to hazardous agents in the workplace.

6 REFERENCES


2. (a) The Management, design and operation of microbiological containment laboratories. HSE Books 2001 ISBN 0 7176 203 4 ...Also, see Http://www.hse.gov.uk/biosafety/diseases/entericpathogens.htm


These references may be obtained from HSE Books or by download from the HSE website.


6. Microbiological Safety Cabinets – BS 5726:2005. Information to be supplied by the purchaser to the vendor and to the installer, and siting and use of cabinets – Recommendations and Guidance. British Standards Institution, London, 2005. Note: this Standard is an update of Parts 2 and 4 of the former BS5726: 1992, which have been withdrawn. This Standard (which does not have the status of a European Standard) must be read in conjunction with BS EN 12469: 2000 “Performance Criteria for microbiological safety cabinets”.
Appendix 1: Good Microbiological Practice

1 INTRODUCTION: LEGAL AND OTHER REQUIREMENTS

1.1 This code of practice applies to all work where there is a deliberate intention to work with microorganisms, human endoparasites or cell cultures.

1.2 Where such organisms present hazards to human health, they are defined as biological agents: i.e., hazardous substances subject to the Control of Substances Hazardous to Health Regulations (2002). See Reference 1 for information on the COSHH Regulations and Biological Agents Approved Code of Practice.

1.3 Biological agents have been categorised by the Advisory Committee on Dangerous Pathogens (ACDP) into four hazard categories, according to the hazard they present to workers (Reference 2). This categorisation scheme is based on the ability of the organism concerned to cause human disease, and on the likelihood of serious consequences both for infected individuals and for the community at large. Use of organisms in the highest hazard group (Category 4) is not permitted at the University. Note that variants of an organism which show reduced or no pathogenicity are likely to have a lower hazard category than their virulent ancestors.

There is a legal requirement to notify HSE of all new work with any organism in Hazard Group 3, and of “work for the first time” with specified agents in Hazard Group 2. This requirement also applies to the intended acquisition of a specified HG2 or any HG3 agent (i.e., “storage” is equated with “intending to use”). At least 20 days prior notice is required.

To ensure compliance with this requirement, all work involving intentional work with organisms in both Hazard Group 2 and Hazard Group 3 must be approved by the Sub Committee for Biological Safety (SCBS) in advance. Anyone intending to undertake work of this type must submit a project proposal (form BiolAgProjform) to SCBS, via the BSO at the Health & Safety Services office. The project proposal form incorporates the risk assessment form BiolAgRA-2.

2 RISK ASSESSMENT

2.1 The COSHH Regulations require that risks to health occasioned by the work must be assessed prior to starting work. If the risk cannot be prevented, then it must be adequately controlled.

Good Microbiological Practice

For work with biological agents, this is by controlling exposure to the agents.

The magnitude of the risk will depend on both the magnitude of the hazard (hazard category) and the consequences of exposure to the organism in any operation.

The potential for exposure depends on the type of operation and the quantity of organisms being handled. Operations liable to create aerosols (e.g., blowing out pipettes; vortex mixing or centrifuging liquid cultures) have a high potential for creating exposure to viable organisms.

2.2 The assessment must include a statement of the hazards; the risks (including identification of those at risk), and the measures necessary to control those risks. They must specify the safe working practices and procedures (e.g., “local rules”) for:

• Prevention or control of dispersal of viable microorganisms into the laboratory or into the wider environment.
• Disposal of waste and decontamination of apparatus and equipment etc.

If disinfectants are routinely used for decontamination, the local rules should specify which disinfectants are suitable, the dilution(s) to be used, and the minimum contact times required. (Note that use of disinfectants alone may require validation of the procedures).

- Procedures for dealing with an accidental spill of viable material etc.
- Ensure that these procedures are understood by anyone working with the particular organism concerned. If the laboratory is shared with another group, it is important that each group is familiar with the hazards and risks posed by all work undertaken within the laboratory. If emergency spill procedures differ between the different groups, ensure that the members of each group are familiar with the procedures adopted by the other group(s).

2.3 A copy of the risk assessment must be submitted with any notification made to HSE.

2.4 Reference 3 gives information on laboratory containment levels, which are laboratory procedures and facilities necessary to minimise the risk from working with biological agents. This guidance must be followed within the University for all work with biological agents.

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6 These Regulations apply to employers and to employees, but not directly to students. Students however may be affected by the work undertaken by others, and – like infectious agents (!) – this guide makes no distinction between students and employees.

7 This takes into account the route(s) of entry into the body and the number of organisms required to initiate an infection.

8 Take special care when defining safe working practices with organisms in the higher hazard groups (groups 2 or 3) for example, a pathogen transmitted by aerosol droplets would require very careful control of all activities likely to cause the formation of aerosols.

9Information on Containment levels 2 and 3 only.
2.5 Each individual is responsible for his/her own safety and also for the safety of others who may be affected by their work - this includes the staff responsible for collecting discarded contaminated waste and those responsible for general laboratory servicing and cleaning. The laboratory supervisor or project leader has overall responsibility for safety in the laboratory but the ultimate responsibility rests with the Head of School. He or she will be advised by the Area Health & Safety Co-ordinator (AHSC) and the University Biological Safety Officer (BSO) on matters relating to biological safety.

2.6 Use form CRA-2 to record the risk assessments for intentional work with hazardous biological agents.

3 BEFORE STARTING WORK

3.1 For new projects involving Hazard Category 1 agents, no prior University approval is required. All other work must be specifically approved by the Sub Committee for Biological Safety (SCBS). A project application form is available via page “B” [“biological safety”] of the A to Z on the Health & Safety services website. Any project planning to acquire a new HG2 or HG3 agent must be approved by SCBS, and then notified to HSE where appropriate.

3.2 Ensure that you have been given appropriate training for the work you intend to do. Training should be given by a competent person, and should involve appropriate practical experience. You may be required to demonstrate your competence before being accepted as properly trained.

3.3 For work at containment level 3 training must be validated by the project supervisor and/or the University Biological Safety Officer (UOHMA). With the project supervisor and/or the University Occupational Health Medical Advisor (UOHMA). See Reference 5.

3.4 All those working with agents in Hazard Category 2 and 3 must be registered with the Health & Safety Services database, and (for Category 3 projects) must obtain prior medical approval from the Occupational Health service.

3.5 For work with some microorganisms, vaccination may be appropriate as a means of reducing the risks of an infection by the organism. Consult Reference 2 for information on the organisms for which an effective vaccine is available.

3.6 If you have (or acquire) a medical condition, or are under any form of medical treatment) that may affect your susceptibility to infection by microorganisms, you should discuss the advisability of commencing or continuing work with microorganisms with your GP and/or the Occupational Health Service.

4 PRINCIPLES OF GOOD OCCUPATIONAL SAFETY AND HYGIENE (GOSH)

4.1 The primary aim of GOSH is to protect you and those around you from contamination by hazardous agents, e.g., biological agents used in the laboratory. Secondary but no less important aims are to prevent the dispersal of organisms from the laboratory into the community at large, and to minimise the risk to others who may be affected by your work.

4.2 You must wear a suitable laboratory coat when working in the microbiology laboratory: this should be either side-fastening, or back-fastening, and should protect the arms, neck and lap.

4.3 Before starting work, cover any wounds or skin abrasions with a waterproof dressing and/or suitable gloves.

4.4 NEVER:

- Pipette by mouth. Pipetting aids must be used.
- Store food or drink intended for human consumption in the laboratory. All such materials used for experimental purposes must be clearly marked “Not for human consumption”.
- Eat, chew gum, drink, apply cosmetics, take snuff or smoke within the laboratory. If there is a need to apply an emollient hand cream after washing your hands, make sure that this is done outside the laboratory.

4.5 ALWAYS:

- Treat spills of infectious materials promptly with an appropriate disinfectant.
- Swab your bench with a suitable disinfectant at the end of the working day. Details of suitable disinfectants and procedures must be specified in the local rules.
- Wash your hands with a suitable disinfectant soap before leaving the laboratory AND whenever there is a suspicion that you may have contaminated them with viable microorganisms. If you routinely wear gloves, wash and dry them before removal and then wash your hands.
- Remove your labcoat before leaving the laboratory suite, and properly store it out of contact with outdoor clothing. Coats used for work with Hazard Group 2 agents (or higher) must be autoclaved before being cleaned.
- Ensure a supply of suitable disinfectant is available for immediate use in case of a spill of viable material.

5 ADDITIONAL POINTS ON TECHNIQUE

5.1 Keep the laboratory door closed when work is in progress. Access to the laboratory should be

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10 The advisability of vaccination should be discussed with the project supervisor and/or the University Occupational Health Medical Advisor (UOHMA). For example, HIV infection; eczema; treatment with immuno-suppressive drugs; pregnancy.

12 Some people may develop skin irritation as a result of prolonged contact with latex gloves. The UOHMA should be consulted at the first signs of such a problem developing. See Reference 5.
5.2 Keep workbenches and the laboratory clean and tidy.

5.3 Familiarise yourself with the laboratory local rules, which should, as a minimum, specify the disinfection and decontamination procedures, both for normal work, and in case of accidents.

When a disinfectant is routinely used for decontamination of equipment or waste, make sure that all items are completely immersed for the appropriate time as detailed in the rules.

5.4 You may work on the open bench at Containment levels 1 and 2. However, for operations that have the potential to create an aerosol of a biological agent of Hazard group 2 (or higher), you must use a suitable containment procedure. (For example, work within the confines of a Microbiological Safety Cabinet.)

When centrifuging viable cultures of such organisms, use sealed tubes or a sealable rotor. These must then be opened in a Microbiological Safety Cabinet. NEVER operate a centrifuge in an open-fronted Safety Cabinet, as the air currents created will disrupt the air flow in the cabinet.

5.5 If you intend to use a safety cabinet, you must know how to use it, and check that it is working properly before starting work. The interior should be kept free of unnecessary equipment and the use of Bunsen burners should be avoided. If a wire loop must be sterilised, use an electric loop heater - but consider if disposable loops can be used instead.

5.6 If the use of glass pipettes is essential, always use the appropriate pipetting aids. For pipetors with disposable tips [eg, Gilson], make sure that the tips are disposed into an appropriate disinfectant, or into an autoclavable "burn bin".

5.7 Contaminated materials and apparatus must be decontaminated before either disposal or recycling. If disinfectants are used as a primary method of decontamination, the procedure must be validated, and regular monitoring checks made on the efficacy.

- All contaminated material that is awaiting collection for sterilisation/disposal must be stored safely, in suitable leak-proof containers. These should not be overfilled - this includes pipette discard containers. Particularly hazardous items must be dealt with by the person generating the waste, and not left for general collection with other contaminated waste.
- Remember that the person who collects your waste may not have your technical knowledge, and that YOU are responsible for his/her safety.

6 EMERGENCY SPILL PROCEDURES

6.1 Everyone should be familiar with what they should do in the event of a spill or other accidental release of microorganisms. It is already too late to read up on the procedures when a spill has occurred.

6.2 Emergency plans are essential when dealing with organisms in the higher hazard groups: if there is no risk of exposure, treat the spill and then report the event to the laboratory supervisor. If immediate treatment would involve a risk of exposure to high hazard (Category 3) microorganisms, ensure that all staff evacuate the room in which the spill occurred. See also 6.4, below.

Seal the room to allow time for aerosol droplets to settle (at least 2 hours should be allowed.) For containment level 3 laboratories, arrange for fumigation of the room with formaldehyde vapour - or other appropriate disinfection procedure.

6.3 Appropriate protective clothing must be worn if it is necessary to enter the room to initiate fumigation. This must then be discarded for decontamination on leaving. It may also be necessary to shower after leaving.

6.4 A spill of a hazard Category 2 or 3 organism should be regarded as a "Reportable Incident", which MUST be reported [via the AHSC] to the Health and Safety Services office as soon as possible after the event. The BSO will investigate the circumstances of the spill, and will arrange for appropriate decontamination procedures to be effected if not done immediately. (Such a spill may also be reportable to the Health and Safety Executive.) If in doubt, contact the BSO at the Health and Safety Services office (ext. 8887). In the absence of the BSO, contact the most appropriate Deputy BSO on Ext. 8460 (AMS building) or 6332 (PS building).

7 GENETIC MODIFICATION WORK

7.1 A separate set of regulations applies to work with GMOs, including genetically modified microorganisms (GMMs).

7.2 Everyone wishing to work with GMOs MUST first complete a registration form and, if appropriate a health questionnaire. Written approval must be given by the BSO before an instance.

13 Suitable methods of microbiological decontamination are autoclaving; use of a suitable disinfection regime, and disposal by incineration [currently, via a specialist contractor].

14 In some cases of work with high hazard organisms, details of emergency plans must be notified to HSE and the Local Authority. This is unlikely to be required in the University of Reading.

15 A risk assessment should identify whether an accidental release of a biological agent is likely to require room fumigation. If this is the case, such work may only be done in a Containment level 3 laboratory, as only laboratories of this (or higher) standard are designed to be sealable for fumigation.
individual may commence GM work, which must be on an approved project.

7.3 All GM workers must attend a training seminar (organised by Health and Safety Services) on the GMO (Contained Use) Regulations as a condition of their approval. Approval is limited to a maximum of 3 years for postgraduate students, and 5 years for members of staff.

7.4 All project proposals for work with GMOs must first be approved by the University Sub-Committee for Biological Safety (SCBS). Details of procedures are given in Safety Guide 15: Genetic Modification work.

7.5 Application forms for both workers and GM projects may be obtained via the “Safety forms” page of the Health and Safety Services website, http://www.fmd.rdg.ac.uk/safety/forms.asp

8 USE OF ANIMALS
For any microbiological work involving the use of laboratory animals, make sure you have been appropriately trained, and hold the appropriate Home Office licences where these are required. See also Part X of this guide for information on the health & safety risks of working with animals.

9 FURTHER INFORMATION
See appropriate sections of Safety Guides 14 and 15 for more detailed information on the use of biological agents and GMOs. Both may be accessed via “Safety Guides” (page “S” of the Health and Safety Services website “A to Z”, http://www.fmd.rdg.ac.uk/safety/az.asp?letter=S)

10 REFERENCES
Contact your AHSC if you require access to a hard copy of these references:

1 General COSHH ACOP, Carcinogens ACOP and Biological Agents ACOP, Approved Codes of Practice for the Control of Substances Hazardous to Health Regulations 2002 (as amended). Ref. L5, HSE Books, Sudbury, Suffolk.

2 The Approved list of biological agents. HSE, 2005: www.hse.gov.uk/pubns/misc208.pdf

3 "The management, design and operation of microbiological containment laboratories"; Advisory Committee on Dangerous Pathogens HSE Books, Sudbury, Suffolk, 2001.


Part X of this Guide includes animals subject to Regulated Procedures [e.g., vertebrates such as mammals] and non-Regulated animals such as insects within the definition of “laboratory animals”.
Part 5, Appendix 2: Worked Examples of Risk assessments

Appendix 2: Worked Examples of Risk assessments

Introduction:

This Appendix contains worked examples of (a) a project involving the intentional use of hazardous biological agents in hazard category 2 (HG2 agents), and (b) work involving the possibility of incidental exposure to HG2 agents. Intentional work requires that a project proposal be made to SCBS via the Biological Safety Officer, who may give approval for the work to commence, subject to the scrutiny and approval of the proposals by an independent assessor (see this part of the Guide, section 2, and Part 1 (University Procedures), section 2.2). The project proposal form incorporates the risk assessment form for the use of hazardous biological agents. (Form BiolAg-RA2)

Work which involves the possibility of incidental exposure to hazardous biological agents requires that a COSHH assessment be done (Part 1, Section 3). The form “BiolAg-RA2i” has been designed to ease the process of assessing the risks of such activities.

Both risk assessment forms may be downloaded from the Health and Safety Services website, currently [http://www.fmd.rdg.ac.uk/For_University_staff/Health_and_safety/Forms/](http://www.fmd.rdg.ac.uk/For_University_staff/Health_and_safety/Forms/)

Part A: Intentional work with Hazardous Biological agents.

This part contains the relevant parts of a completed Project Proposal form for work with hazardous biological agents, giving an example of the level of detail required to undertake a risk assessment and the information that the Sub Committee for Biological Safety would require in order to consider the proposals.

All applicants should complete:

Section One - Project information.
Section Two: Hazard information and Risk Assessment
The Summary Statements.

Section 1: Project information

All proposers must complete this section

<table>
<thead>
<tr>
<th>1. Area or School where the work is to be carried out. Please delete as appropriate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbiotics</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Project Supervisor, i.e., Member of staff responsible for directing the work.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
</tr>
<tr>
<td>Surname</td>
</tr>
<tr>
<td>Initials</td>
</tr>
<tr>
<td>Tel.</td>
</tr>
<tr>
<td>e-mail</td>
</tr>
</tbody>
</table>
Part 5, Appendix 2: Worked Examples of Risk assessments

3. Staff involved operationally on the project, and details of their qualifications/experience in microbiological techniques. If appropriate, give numbers of previous HG2 or HG3 projects.

NB: Each worker having any practical involvement with the project MUST complete the appropriate worker’s registration form (HG2std or HG3std) and await written confirmation of approval from the BSO before starting work.

See individual forms for instructions for submission.

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Qualifications/experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Novice</td>
<td>Postgraduate student</td>
<td>B.Sc. Microbiology and. M.Sc Biotechnology</td>
</tr>
</tbody>
</table>

Undergraduate class? [ ]

For undergraduate student classes or projects, please tick box, and attach separate lists of participating students and demonstrators; appropriate lists should be resubmitted each year the project is run. NB: only fully supervised activities are permitted for undergraduate classes. Demonstrators must have appropriate experience with HG2 organisms.

4. Number / location, and containment level of laboratory facilities proposed for project.

<table>
<thead>
<tr>
<th>Room number</th>
<th>Containment level</th>
<th>Building</th>
</tr>
</thead>
<tbody>
<tr>
<td>225</td>
<td>2</td>
<td>MicroScience</td>
</tr>
</tbody>
</table>

5. Please tick box and give reference number if this project is to be considered as an extension to a previously-approved project.

Extension? [ ] Previous Ref. No. [ ]

Please then complete appropriate sections in the remainder of this form, so as to emphasise the connection between the original project and this application.

6. Title of project

Investigation of the growth, antibiotic resistance and genetic profile of selected enteric pathogens isolated from leaf surfaces in fields treated with sewage sludge as fertiliser prior to sowing sugar beet.
### 7. Purpose of the project, stated in layman's terms.

This project is intended to assess the potential impact on both animal health and human health of the practice of treating fields with sewage sludge. Survival and transfer of enteric pathogens arising from sewage sludge injected into soil will be assessed by sampling leaves of newly-emerged sugar beet which will be sown at various times after the sludge injection.

### 8. The scope and expected results of the project.

We hope to track the survival of pathogenic bacteria originating in sewage sludge via the soil to the leaf surface of crop plants sown in fields which have been treated by injection of sewage sludge into the top 15 cm of the soil. In particular, we will look for the presence of enteric pathogens such as *Salmonella* spp., *Enterococcus* spp. and *E. coli* on the leaves of sugar beet plants which will have germinated through the injected soil. Sampled leaves will be homogenised and viable bacteria will be cultured and enriched for the organisms of interest, prior to being identified. They will then be subjected to antibiotic resistance profiling and genetic profiling and compared with standard strains of these organisms as a reference. We hope to be able to identify survival times for these enteric pathogens in this environment with a view to examining the animal and public health implications of the practice of sewage sludge injection.

Sampling of fields will be undertaken in conjunction with and with the co-operation of farm management staff on selected farms that are contracted to the sewage works to take sewage sludge for injection into the fields. All the sewage sludge will be supplied by the Green Park sewage works, which accepts domestic sewage from approximately 750,000 households; sludge will be supplied at the stage when it would previously have been disposed of by dumping at sea.
Section 2: Hazard Information and risk assessment

[Remember: cell cultures are classified as microorganisms.]

This section provides the basic information for preparation of the summary statements. It is also available as a separate form (ref. CRA-2), which should be used for all reassessments of projects using hazardous biological agents, and for activities involving incidental exposure to hazardous biological agents.

- Please give sufficient detail to allow the independent assessor to confirm your risk assessment. Provide supporting references where necessary.
- If organisms are to be imported into the University from elsewhere (e.g., a culture collection), the information on the “identity” of the organism (Q2) must be obtained from the prospective supplier. [N.B.: it is permissible to use a risk assessment prepared by the supplier, provided that this gives the information required in the headings below.]

A: Identifying hazardous biological agent(s) and existing controls

<table>
<thead>
<tr>
<th>1. Brief summary of work activity or project assessed</th>
<th>Survival of enteric pathogens on leaf surfaces in fields treated by sewage sludge injection prior to sowing sugar beet.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organism</td>
<td>Nature of the hazard</td>
</tr>
<tr>
<td>Microorganisms isolated from leaf samples and used for enrichment cultures (conditions selected to enrich for Escherichia coli; Salmonella enterica, and Enterococcus faecalis)</td>
<td>Infection, with possibility that non-enteric pathogens may also be present at early stages of the procedure, but not expected to be in high numbers. Non-enteric pathogens may cause infection by unexpected routes, leading to unusual disease outcomes. Culture conditions should preclude isolation of organisms in Hazard Category 3.</td>
</tr>
</tbody>
</table>
2. Pure cultures of bacteria under study
   Escherichia coli (nonVTEC)
   Salmonella enterica (various serotypes)
   Enterococcus faecalis

Pure cultures to be used are all enteric pathogens with well-known hazards, and the risk of laboratory-acquired infection.

3. List all who might be exposed to the microorganism(s), how often and to how much. (e.g. staff, students, visitors, cleaners & consider numbers at risk)

Staff involved with project – maximum exposure estimated to be to $10^8$ organisms if tube breakage were to occur during centrifuging, or concentrated culture spilt onto bench or floor. Max 2 staff.

Staff not involved in project, but working in same lab: maximum exposure estimated to be to $10^6$ organisms during scenarios above. Max 10 staff.

Cleaners and visitors not permitted without prior arrangement, and only when lab. certified as safe to enter.

5. How might they be exposed?

Consequence: Is infection possible by this route?
(Routes of entry or areas of the body likely to be exposed; identify any injuries or health problem that might result)

<table>
<thead>
<tr>
<th>Route of exposure</th>
<th>‘X’ if yes</th>
<th>Consequence of exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>Theoretically possible with concentrated aerosols, but not a recognised normal route of infection</td>
<td>Infection as above</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Most important route of infection</td>
<td>Infection causing temporary gastro-intestinal upset; more severe disease regarded as unlikely.</td>
</tr>
<tr>
<td>Absorption</td>
<td>A possible risk with sharps</td>
<td>Infection, causing bacteraemia and possible systemic infection (“blood poisoning”)</td>
</tr>
<tr>
<td>Injection</td>
<td>Possible from direct contact with infected material</td>
<td>Skin infection possible, ultimately causing bacteraemia as above.</td>
</tr>
<tr>
<td>Skin</td>
<td>Possible from concentrated aerosols or direct contact with infected material</td>
<td>Infection possibly resulting in damage to the eye and blindness</td>
</tr>
<tr>
<td>Eyes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6. List control measures in place to reduce risks

Assess whether these controls are adequate, actually used in practice and regularly checked, where appropriate:

**Hierarchy:**

1. **Eliminate the need**
2. **Substitute substance**
3. **Enclose the process**
4. **Engineering controls** (e.g., LEV)
5. **PPE**

<table>
<thead>
<tr>
<th>Engineering controls</th>
<th>Personal Protective Equipment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbiological safety cabinet</td>
<td>□ Gloves (Specify type neoprene examination gloves to be used where contact is more likely e.g. in preparing microscope slides)</td>
</tr>
<tr>
<td>Not required – no operations liable to generate infectious aerosol except centrifuging – this done with sealed tubes.</td>
<td>□ Safety Glasses/Goggles/ Face Shield (Specify type)</td>
</tr>
<tr>
<td>Other Local exhaust ventilation</td>
<td>□ RPE (Specify Type… …………..)</td>
</tr>
<tr>
<td>Other containment (please specify)</td>
<td>✅ Protective clothing (Specify Type Howie Lab coat)</td>
</tr>
</tbody>
</table>
| Work restricted to room 225, Category 2 laboratory. Cultures grown in flasks, capped tubes used during centrifugation. Waste is autoclaved. | Other (Specify Type) ………………...……
| **Procedural controls** | ……………………… |
| Limitation of Access | ✅ Restriction of quantities |
### Part 5, Appendix 2: Worked Examples of Risk assessments

**B: Assessing the level of risk and further action needed**

<table>
<thead>
<tr>
<th>7.1 How severe is any health effect likely to be? [Severity can be equated with ACDP or other hazard category]</th>
<th>Tick one box (S = score given in brackets)</th>
<th>Minor (1)</th>
<th>Serious (2) <strong>X</strong></th>
<th>Major (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.2. How likely is exposure to the organism? Take account of possible exposure during accidental spills, etc. For possible environmental exposure, consider susceptible hosts in the vicinity.</td>
<td>Tick one box (P = score given in brackets)</td>
<td>Very unlikely (1)</td>
<td>Unlikely (2)</td>
<td>Possible (3) <strong>X</strong></td>
</tr>
<tr>
<td>7.3. Calculate the risk score by multiplying the 2 scores in Q7.1 &amp; 7.2</td>
<td>Risk Score ((S \times P) =)</td>
<td>Low (1–3)</td>
<td>Medium (4–6) <strong>X</strong></td>
<td>High (8–9)</td>
</tr>
</tbody>
</table>

N.B.: If score is 8 or more, the activity must not go ahead until additional measures to control exposure have been installed and the activity has been reassessed.

<table>
<thead>
<tr>
<th>8. Further action/control measures to be taken to make the situation safe / reduce risk to health (Use additional sheets if necessary)</th>
<th>Action to be taken by whom?</th>
<th>Implementatio n Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. Is health surveillance required?</td>
<td>Y/ N if &quot;Yes&quot;, specify type: Y - Reporting of cases of diarrhoea etc to supervisor, with follow-up by Occupational Health.</td>
<td>Ongoing</td>
</tr>
</tbody>
</table>

10. Emergency Procedures (First aid actions, spill action, fire etc - Refer to local rules if in place)

Spilt material to be flooded with 10% Virkon and left for 10 min. Liquid to be absorbed on paper towelling. All material including any broken glass to be placed in an autoclavable container and autoclaved before disposal. If a dustpan and brush is used to gather up broken glass this must also be autoclaved. In case of spillage on the person remove contaminated clothing and soak in disinfectant or autoclave; wash affected areas with antimicrobial soap and water. In case of accidental ingestion, injection etc. refer to GP. For information of fire-fighters a list of organisms is posted on the laboratory doors and copies held by the area safety coordinator.

11. What are the inactivation and disposal requirements?

Pipettes and other disposables to be deposited in autoclave bags contained in upright cylinders on benches. These bags to be sealed for autoclaving by researchers. Sharps to be disposed of in dedicated containers. Microscope slides and glass Pasteur Pipettes in Disposafe Jars to be autoclaved. Petri dishes to be placed in autoclave bags at end of bench. All contaminated material to be taken to discard area for autoclaving by researchers.
Part 5, Appendix 2: Worked Examples of Risk assessments

<table>
<thead>
<tr>
<th>Name (please print)</th>
<th>B.H. McKinley</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature</td>
<td>Date: 8/06/06</td>
</tr>
</tbody>
</table>

Approved by Head of Dept/School/Unit

<table>
<thead>
<tr>
<th>Signature</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date for Review (maximum 12 months from date of assessment)</td>
<td>Date: 7/06/07</td>
</tr>
</tbody>
</table>

After assessing the risks, please complete the summary statements below:

**Summary Statements**

The main sources of information for "lay" members of the Committee are the "Statement on overall risks" and the Lay Summary. They will be copied and submitted to the Committee for formal approval. Sufficient detail, in **non-technical terms**, should therefore be given to allow them to understand the aims of the project, and to confirm the risk status of the project.

**Statement on the overall risks associated with this project**

- Use the information provided on form BiolAgRA-2 to draft this statement. You should identify the most hazardous elements of the project, and any procedures necessary to control the associated risks. Extend the section as necessary.

<table>
<thead>
<tr>
<th>A: Risks to human health &amp; safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>All the organisms of interest occasionally cause laboratory acquired infections. Use of good microbiological practice and containment procedures, together with appropriate training for all staff for all operations liable to create an infection aerosol should be sufficient to control these risks.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B: Risks to the environment (if relevant)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All the organisms to be studied are very common in the environment and there would be no additional risk of a general nature as a consequence of its release. Clearly if any contaminated material were to be disposed of without autoclaving there would be health implications to anyone handling such material.</td>
</tr>
</tbody>
</table>
Lay summary of the project

<table>
<thead>
<tr>
<th>Outline the aims and expected results of the project. Where possible, avoid the use of acronyms and abbreviations, and explain or spell out any used.</th>
<th>This project is intended to assess the potential impact on both animal health and human health of the practice of treating fields with sewage sludge. Sugar beet will be used as a model leafy plant for this study.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clearly identify the risk class for the project.</td>
<td>A crop of sugar beet will be sown according to normal commercial practices on field which had been treated by sludge injection (a) 6 months; (b) 3 months (c) 1 month and (d) 1 week before sowing.</td>
</tr>
<tr>
<td>Describe the measures to be put in place to control the identified risks, including those taken to decontaminate waste /equipment and/or prevent dissemination of biological agents from the laboratory.</td>
<td>Leaf samples will be taken at specified times after emergence of the seedlings (4-leaf; 10 leaf and 20 leaf stages.), using a total weight of approximately 10g. for each sample. Leaves will be homogenised in 50 ml of nutrient medium, and then 1 ml volumes plated out on appropriate media for analysis of total viable count; total enteric pathogen count and selective medium for <em>Salmonella, Enterococcus</em> and <em>E. coli</em>. Individual colonies [max 10 per plate] will be picked into 5 ml growth medium and incubated to the mid-log phase. Cultures will then be centrifuged in sealed tubes and used for (a) antibiotic resistance profile analysis; (b) gentic profiling by various analytical techniques on DNA isolated from the cells.</td>
</tr>
</tbody>
</table>

*Salmonella; Enterococcus* and *E. coli* are classed as hazard category two organisms and are occasionally associated with laboratory acquired infection.
Part B: Work involving the possibility of incidental exposure to hazardous biological agents.

Such work does not need to be approved by the Sub-Committee for Biological Safety in advance, but a “biological” risk assessment is still required by the COSHH Regulations. The example given (on form BiolAg-RA-2i) identifies the potential hazards, and the potential for exposure and hence the risk. Note that the risk is also dependant on the provenance of the materials used, as this will have a great effect on the probability that the samples may contain hazardous biological agents.

<table>
<thead>
<tr>
<th>School / Dept / Unit</th>
<th>MicroBioScience</th>
</tr>
</thead>
</table>

A: Identifying hazardous biological agent(s) and existing controls

1. Brief summary of work activity or project assessed
Analysing human blood plasma for cholesterol content/ HDL:LDL ratio, plus lipid profile of saturated vs. unsaturated fatty acid.

2. Describe the type(s) of sample, quantity and provenance of the material(s) to be used
Samples consist of 3ml volumes of blood plasma obtained from apparently healthy human volunteers taking part in the study of the effect of dietary fats on blood lipid profile. Study members are members of the public who have volunteered to take part in this study.

3. List the hazardous biological agents that are liable to be present in the materials used and the hazard(s) relating to them.
Organism: Possible presence of blood-borne viruses such as Hepatitis B C/ Delta agent, and Human Immunodeficiency virus (HIV)
Nature of the hazard: All Hazard Group 3 pathogens – CL3 required if agents known to be present; CL2 plus GMLP sufficient for unscreened samples of this nature

4. How might they be exposed?
(Routes of entry or areas of the body likely to be exposed; identify any injuries or health problem that might result)

<table>
<thead>
<tr>
<th>Route of exposure</th>
<th>‘X’ if possible</th>
<th>Consequence of exposure: is infection possible by this route?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ingestion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absorption</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection/ sharps injury</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eyes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
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</tr>
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</table>

November 2006
Part 5, Appendix 2: Worked Examples of Risk assessments

<table>
<thead>
<tr>
<th>6. List control measures in place to reduce risks</th>
<th>Engineering controls</th>
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<tr>
<td>Assess whether these controls are adequate, actually used in practice and regularly checked, where appropriate:</td>
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<td>□ Microbiological safety cabinet</td>
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<tr>
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<td>Other containment (please specify)</td>
</tr>
<tr>
<td>□ Other containment (please specify)</td>
<td>Hierarchy:</td>
</tr>
<tr>
<td></td>
<td>Eliminate the need</td>
</tr>
<tr>
<td></td>
<td>Substitute with less hazardous organism or strain</td>
</tr>
<tr>
<td></td>
<td>Minimise quantity</td>
</tr>
<tr>
<td></td>
<td>Enclose the process</td>
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<td></td>
<td>Engineering controls (e.g., LEV)</td>
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<td>PPE</td>
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<td>□ RPE</td>
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<td>□ Protective clothing</td>
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<tr>
<td></td>
<td>□ Other (Specify Type)</td>
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</table>

<table>
<thead>
<tr>
<th>Procedural controls</th>
<th>□ Limitation of Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Limitation of Duration/ exposure of non-involved personnel</td>
<td></td>
</tr>
<tr>
<td>□ Restriction of quantities (state max. volume)</td>
<td></td>
</tr>
<tr>
<td>□ Prohibition of sharps</td>
<td></td>
</tr>
<tr>
<td>□ Prophylactic vaccination (if “x”, please specify:</td>
<td></td>
</tr>
<tr>
<td>........................................................................</td>
<td></td>
</tr>
<tr>
<td>□ Provision of specific training (Give details)</td>
<td></td>
</tr>
<tr>
<td>........................................................................</td>
<td></td>
</tr>
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### Part 5, Appendix 2: Worked Examples of Risk assessments

#### B: Assessing the level of risk and identifying further action needed

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<tr>
<th>8. Further action/control measures to be taken to reduce risk to health (Use additional sheets if necessary)</th>
<th>Action to be taken by whom?</th>
<th>Implementation Date</th>
</tr>
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<tbody>
<tr>
<td>9. Is health surveillance required?</td>
<td>Y/ N If “Yes”, specify type:</td>
<td></td>
</tr>
<tr>
<td>10. Emergency Procedures (First aid actions, spill action, fire etc - Refer to local rules if in place)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11 What are the inactivation and disposal requirements?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Assessor [Project Proposer]

<table>
<thead>
<tr>
<th>Name (please print)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature</td>
<td>Date:</td>
<td></td>
</tr>
</tbody>
</table>

| Date for Review (maximum 12 months from date of assessment) | Date: |
Part 5, Appendix 2: Worked Examples of Risk assessments

Approved by:
Area Health & Safety Co-ordinator

<table>
<thead>
<tr>
<th>Signature</th>
<th>Date:</th>
</tr>
</thead>
</table>

or:
Head of Dept/School/Unit

<table>
<thead>
<tr>
<th>Signature</th>
<th>Date:</th>
</tr>
</thead>
</table>

Notes for Users

1. This form should be used to assess the risks of work involving the use of materials which may contain hazardous non-modified [non-GM] biological agents\(^{17}\), but where there is no intention to work with those agents.

2. When assessing the likelihood of exposure, take into account both the likelihood of exposure, and the likelihood that the samples may contain hazardous biological agents. The former will depend on the techniques to be used and the containment procedures during work, and the latter will depend on the provenance of the samples.

3. The risk assessment must be reviewed at regular intervals not exceeding 12 months, or earlier if any aspects of the work/ workers change.

---

\(^{17}\) A biological agent is defined in law as a “micro-organism, cell culture or human endoparasite whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health”. For the purposes of this risk assessment, “environmental risks” created by use of Controlled pathogens are also included.