University procedures for work involving hazards of biological origin

Safety Guide 14, Part 1:

University Procedures for work involving hazards of biological origin

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March 2006
Amended November 2006
This Safety Guide forms one part of a series that together provide guidance on the control of Biological Hazards, Safety Guide 14. Part 5 sets out management responsibilities and identifies the controls and procedures that must be followed by all who work with, or may be exposed to, biological agents.

1 Introduction

There are several types of work that may involve the potential for exposure to biological hazards, i.e., “biological materials” that pose a hazard to human health and/or safety. In this context, “biological materials” includes hazardous microorganisms (which are legally defined as “biological agents”) and tissue or components derived from living organisms, both microorganisms and higher organisms (see below). As described in more detail in Part 2 to this Guide (Legal Requirements), the main Regulations applying to such work are the Control of Substances Hazardous to Health Regulations (COSHH, Ref. 1). These Regulations require that the risks arising from such work must be adequately assessed, and appropriate control measures put in place before the work is undertaken. This Part of the Safety Guide sets out the procedures that should be followed to ensure that there is compliance with these requirements.

Where hazardous properties are due to materials produced by, or contained within and/or comprising the body of the (micro)organism, such organisms could remain hazardous even after death. The COSHH Regulations require that any risks must be assessed, and appropriate control measures put in place. However, unlike the majority of hazardous chemicals, there are unlikely to be safety data sheets for biological materials, which makes the assessment process more difficult.

Before any work is undertaken (including that involving “biological material”), it is therefore essential to undertake a risk assessment of the proposed work. The purpose of the risk assessment is to identify:

- all the hazards that may exist;
- the ways in which exposure to the hazards may occur;
- the risks that might thereby arise and those who may be exposed to them, and
- the methods that must be adopted to adequately control the exposure so that any risks are either eliminated or otherwise reduced to an acceptable level.

For microorganisms, this process commences with the identification of the hazard category of all microorganisms which may be encountered in the course of the work. Where the organisms are recognised as biological agents (see SG 14 Part 3), then consideration of all operations likely to cause exposure to the organisms must follow. This in turn will lead to identification of all measures necessary to adequately control the exposure. Note however that organisms that do not pose a hazard by infection (i.e., are most unlikely to cause an infection in a human) are not listed as biological agents, but by reason of other properties, they may still pose a hazard to those who work with them – for example, many mould spores are allergenic or may contain toxins, but are

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1 Microorganisms that do not pose any risks to human health are (by definition) not biological agents. The definition of “biological agent” includes genetically modified microorganisms (see Safety Guide 15), and is irrespective of whether the hazard is one of infection (causing disease or other adverse effect); or illness due to allergy; toxicity, etc. Higher organisms are also not biological agents.

2 See the Approved List of Biological Agents at http://www.hse.gov.uk/pubns/misc208.pdf
not capable of infecting humans. It is therefore essential to consult relevant literature to determine whether any hazard is associated with a particular “unlisted” microorganism.

For “biological materials”, the hazards to health presented by the material can be classified according to the scheme used for chemicals, i.e., Harmful; Corrosive; Irritant; Toxic/ Very Toxic; Sensitising; Carcinogenic/ Mutagenic, etc. Of these hazardous properties, probably the most common is that of allergenicity – the material is capable of “sensitising” an exposed person, causing them to become allergic and react to subsequent exposures (Risk Phrase R42 / R43 – See SG 28, Annex 2 for a list of Safety and Risk Phrases.) See also Section 4.1 below for further information.

The results of the risk assessment should be recorded, and be reviewed at regular intervals – preferably on an annual basis, and on each occasion when there are changes made to the procedures, or if new information on the hazards becomes available.

2 Intentional Work with hazardous microorganisms

2.1 Introduction

This Guidance applies to all proposals to undertake intentional work with hazardous biological agents in any hazard category\(^3\) (See Part 3 to this Guide for information on hazard categorisation.)

Note that work with agents in hazard Category 4 is not permitted under any circumstances, as the University does not possess any facilities that would permit the safe handling and use of such agents.

All proposals to undertake work with hazard category 3 agents must be notified on an individual basis to the Health and Safety Executive, after they have been approved by the Sub-Committee for Biological Safety (SCBS). Notification must be made a minimum of 20 days before work is commenced, thus permission to commence work on the project will only be given once the project has been approved by SCBS; the details have been notified to HSE, and the requisite 20 days have elapsed.

2.2 Proposals to undertake work with hazardous microorganisms

Anyone proposing to undertake intentional work with hazardous microorganisms in Hazard Group (HG) 2 or HG3 must complete the appropriate project proposal form, and submit it to the Biological Safety Officer (BSO) for initial assessment. Because of legal requirements relating to responsibility for the health and safety of workers, only employees of the University are acceptable as Project Supervisors. Normally, this is interpreted as members of the permanent Academic Staff, although others such as Research Fellows may be acceptable with the written consent of the Head of School\(^4\).

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\(^3\) As microorganisms are categorised on the basis of the infectivity and transmissibility, the categorisation scheme does not take account of any hazardous properties derived from the presence of toxic or allergenic components, but such hazards must not be overlooked when conducting the assessment.

\(^4\) The project proposal form includes a space for signature by the Head of School: signature in such circumstances indicates assent to the project proposer being named as the project Supervisor.
The procedures for project approval closely mirror those put in place for GM projects, the main difference being that in most cases, the legal requirements for non-GM organisms are less rigorous than for their GM counterparts. Note however that the GM procedures take precedence. As noted in Part 3, the project supervisor must keep an inventory of all stocks of hazardous microorganisms in Hazard Categories 2 and 3, whether or not they are genetically modified. (For genetically modified organisms, this requirement also applies to those in Hazard Category 1. See Safety Guide 15, The Contained Use of Genetically Modified Organisms.)

Where the project involves both GM and non-GM biological agents, the proposals will be treated as a standard GM project proposal. Any risk assessment undertaken in compliance with the GMO (Contained Use) Regulations 2000 (as amended) should be extended if appropriate to cover the non-GM aspects. Where the project does not involve the use of any GM microorganisms, it will be treated as a non-GM project – see below. Where a GM project supervisor wishes to add the use of one or more new biological agents in HG2 or higher (or pathogens of animals or plants that are subject to statutory control) to an approved GM project, he/ she must complete a risk assessment form (ref. BiolAgRA2) and submit it to the BSO for assessment and approval. Work with the new agent must not commence until the supervisor has received written approval of the assessment. Details of the assessment will be recorded with the original GM project details.

- **Proposals for work with hazard category 1 agents**

Where organisms are not hazardous by infection (Hazard Group 1), the main risks may arise from other hazardous properties of the organism. For such organisms, the procedures of Good Microbiological Practice (GMLP) and Good Occupational Safety and Hygiene (GOSH) should suffice to control any risks that may arise by preventing or minimising exposure. This supposition should be confirmed by a risk assessment, which should be recorded in a suitable form, and reviewed at annual intervals. No formal project proposals are required for such work, and approval by SCBS is not necessary. If any hazardous properties such as toxicity or allergenicity may be associated with the organism(s), the project supervisor is advised to consult both the BSO in respect of additional precautions required, and the Occupational Health Service in respect of health surveillance.

- **Proposals for work with hazard category 2 agents**

Anyone proposing to undertake intentional work with hazard category 2 agents must complete the appropriate project proposal form (Reference HG2proj) plus the risk assessment form (ref. BiolAgRA2) and send them to the BSO. On receipt of the forms, the BSO will ask an independent assessor to review the proposals and recommend a course of further action. This may be a temporary approval by the BSO (which is subject to ratification by the next meeting of SCBS), or a referral back to the proposer for amendment or for more information.

Note that proposals for work with notifiable HG2 Agents (Corynebacterium diphtheriae; Bordetella pertussis or Neisseria meningitidis) will be treated as if they were HG3 agents as far as University Procedures are concerned.

If the BSO gives his approval for work to commence, all workers on the project must be registered with the Health and Safety Services database, and will be required to undergo such occupational health surveillance as is deemed appropriate by the Occupational Health Service. If the project is referred back to the Proposer, the proposals must be resubmitted in a form.

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5 The standard project proposal form could be used for this, as the form is designed to lead Proposers through the steps required for the risk assessment.
acceptable to both the BSO and an independent assessor before temporary approval may be given.

- **Proposals for work with hazard category 3 agents.**

  Full details of University procedures for work with hazard category 3 agents are given in Safety Note 17, and only an outline is given here.

  On receipt of the project proposal form (Ref. HG3proj) and the risk assessment form BiolAgRA2, the BSO will convene a specialist technical assessment group to assess the proposals. The Proposer will be required to give a presentation to the group, outlining the main intentions of the proposals, and giving details of the methods to be used to control any potential exposure to the agents to be used. After due deliberation, the group will recommend to SCBS whether or not the proposals should be accepted, and/ or if any changes should be made in the interests of health and safety. A summary of the project, outlining the intentions and risk control measures to be adopted, will then be circulated to SCBS members for comment and a decision on approval. If SCBS approve, the details of the project, and the associated risk assessment will be notified to the Health and Safety Executive, as required by Schedule 3 of the COSHH Regulations.

  All workers on a project involving hazard category 3 agents must have had documented, validated training in Containment Level 3 procedures, and must be registered as “Category 3 workers” with both Occupational Health and with the Health & Safety Services database. (Details of the registration process are given under “biological safety” on the HSS website at [http://www.fmd.rdg.ac.uk/safety/az.asp?letter=B](http://www.fmd.rdg.ac.uk/safety/az.asp?letter=B). The project proposal forms and worker registration forms may be downloaded from the “Forms” page of the website at [http://www.fmd.rdg.ac.uk/safety/forms.asp#genetic](http://www.fmd.rdg.ac.uk/safety/forms.asp#genetic).)

  Appropriate occupational health surveillance will be required: note that for certain types of work, this may require a “pre-exposure” serum sample to be taken and stored. If this is the case, a “leaving sample” will also be required when the worker leaves the University.

### 3 Incidental exposure to hazardous microorganisms

Several types of work may entail the risk of **incidental exposure** to hazardous microorganisms, even though there is no intention to work with such agents.

Examples of such incidental exposure include:

- work with human blood or tissue samples (*See Part 5 of this guide*);
- 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
- service or maintenance work on equipment liable to be contaminated with biological agents, etc. (*N.B.* - this includes the possibility of contamination by *Legionella* - *see Part 8*)

In general, there is no requirement for SCBS to approve work with the possibility of “incidental exposure” in advance of the work starting. **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 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 of Part 5 for a "worked example" of a risk assessment involving incidental exposure to biological agents.)

See Part 5 of this Guide for advice on practical aspects of work of this nature, including work with:

- Tissues and body fluids of human origin;
- Diseases which could be transmitted to humans by contact with infected animals (i.e., zoonoses);
- Work involving exposure to contaminated soils; and
- Service or maintenance work.

4 Exposure to hazardous substances of biological origin

"Hazardous substances of biological origin" may be defined as (complex) by-products or components of one or more living organisms (including higher animals and plants). They may have one or more of the hazardous properties normally associated with chemicals/chemical products – i.e., they may be toxic/very toxic; corrosive; carcinogenic; mutagenic; irritant or harmful. (It should be remembered that the most toxic substances known are of biological origin, such as Botulinum toxin.)

As with other substances which are hazardous to health, their use is subject to the COSHH Regulations. This is the main formal requirement of University procedures applicable to the use of “materials of biological origin”. Just as for work with the possibility of incidental exposure to hazardous microorganisms, there is no requirement to submit project proposals for approval, although the BSO and SCBS are willing to assist in the risk assessment process if requested. Note however the requirement (below) for occupational health surveillance for all work with biological materials regarded as “sensitisers”.

4.1 Risk Assessment

The COSHH Regulations require assessment of the risk, and identification and adoption of adequate control measures. As noted in the Introduction, the lack of safety data sheets for biological materials makes the assessment process more difficult and complex than that for chemicals/chemical products. Remember also that some biological materials may be carcinogenic, for example hardwood dust, or be extremely toxic, for example ricin or strychnine.

The risk to health arises mainly if the substance is inhaled, or enters the bloodstream directly, such as by injection. Dusts which are (or contain) hazardous materials would normally present the greatest risk.

Probably the greatest hazard of biological materials is that of allergenicity. Many biological materials are known to be respiratory sensitisers, in that exposure by inhalation can lead to the development of an immune response and may lead to the development of asthma. Some materials
may also affect the skin - for example, they are classified as irritants or skin sensitisers. Other materials may induce a severe response in the form of anaphylactic shock – a life-threatening condition that requires prompt treatment – where once an individual has become sensitised, any subsequent exposure to the material is an extreme risk. (For example, bee stings and nut allergies.)

Examples of allergenic biological materials include:

- Grain dust
- Flour
- Hardwood and softwood dust
- Enzyme preparations (e.g., subtilisins) as used in enzyme washing powders;
- Insect cuticle protein and faecal material (frasse);
- animal dander (N.B. - this includes urinary proteins, as well as skin particles and animal fur).

For respiratory sensitisers, further exposure to the agent (at work) can lead to an allergic response that is expressed by elicitation of bronchial spasm and narrowing of the airways - i.e., the development of (occupational) asthma. Skin sensitisation may be accompanied by the development of (occupational) dermatitis (including eczema), where further exposure leads to cracking and irritation of the skin, etc.

- For example, exposure to *Hevea* (rubber) proteins in latex gloves is now well known as a source of problems, including both Type 1 and Type IV allergic reactions. (For details, see the HSE safety leaflet, "Latex and you" (reference 4), which is available for download from the HSE website.)

In some cases, sensitisation may be so severe that an anaphylactic, life-threatening response may occur on subsequent exposure to even minute quantities of the agent involved. In such cases, an individual would have to be removed from all possibility of further contact with the agent and may even be permanently disabled by the disease.

For some sensitisers commonly found or produced within the workplace, workplace exposure limits ("W.E.L.s") have been set for exposure of employees to these dusts. (See "EH40", Reference 5.) Note that these limits are not applicable to employees who have already been sensitised (for whom any further exposure may trigger an attack); the limits are set with a view to preventing sensitisation of those who may be exposed.

In other cases (those which are less common in industry), such as with insect cuticle proteins (which are also known to be potent respiratory sensitisers), there are presently no legally defined exposure limits for such material. (There is little evidence of the level of exposure that is harmful, and no agreed criteria for analysis. There is usually, however, sufficient evidence of harm arising from exposure - in the form of allergies and occupational asthma - for the substances to be included within the term “harmful”.)

- Any employee of the University whose work brings him/ her into regular contact with allergenic materials should be under occupational health surveillance.

The essential feature of the control regime to be adopted is that of controlling exposure, where exposure cannot be prevented. The normal hierarchy of control measures applies (see Part 2), with the priority being given to “engineering controls” which aim to control exposure at source by either enclosing the hazardous substance/ process, or applying a measure such as local exhaust ventilation to remove the hazardous substance from the vicinity of the worker..
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The use of Personal Protective Equipment (PPE) such as Respiratory Protective Equipment (RPE - for example a filtering face mask) is normally considered to be a “last resort” under the COSHH hierarchy of controls (see SG14, Part 2). Control should be achieved by "engineering means" where this is reasonably practicable. However, where it is not possible to define any "control limits" for some substances (such as animal dander), both administrative controls and PPE should normally be used in addition to the use of "engineering controls". Where limits have been set (e.g., as with wood dust), "engineering means" would be the methods of choice of achieving adequate control, backed up as appropriate by “administrative controls” to limit the time a worker may be exposed to the substance. The use of PPE could, however, be acceptable on a temporary basis e.g., during maintenance, repair, or whilst additional controls (and an agreed maintenance schedule) were being put in place.
References


2. The University of Reading Safety Note 17: Work at Containment Level 3.

