Control of Biological Hazards

Safety Guide Number 14 Part 2
Legal Duties
**Safety guide 14: Control of biological hazards**

**Part 2: Legal Duties**

1 **INTRODUCTION**

There are various legal duties that apply to anyone undertaking work with “biological materials”, whether these be microorganisms; living “higher organisms” or materials obtained from them. This Part of the Guide gives an overview of these legal duties, and a more detailed explanation of the requirements of the most important Regulations that are relevant to those undertaking such work.

The main specific duties arise from the **Control of Substances Hazardous to Health [COSHH] Regulations** (Ref. 1). The Management of Health and Safety at Work Regulations and other “general” regulations such as the Personal Protective Equipment Regulations and The Provision and Use of Work Equipment Regulations (etc.) will also apply in many situations, but these are not specific to the use of biological agents or biological materials.

Depending on the type of work involved, other specific legislation may apply, for example the **Ionising Radiation Regulations** where the work involves the use of radioactive materials, but users should refer to the relevant University Safety Guides in such cases. This Guide is
primarily concerned with the hazards to health which may be encountered in “biological” work, and the risks which might therefore arise as a consequence.

2 THE CONTROL OF SUBSTANCES HAZARDOUS TO HEALTH REGULATIONS (COSHH)

Within the terms of the COSHH Regulations, microorganisms and cell cultures, etc, are regarded as “substances hazardous to health” if they create risks to human health. The Regulations also apply to the use of human and animal tissues - such as blood and other body fluids (which themselves fall outside the definition of “biological agent”), because of the possibility of their contamination by biological agents. Any such contaminants, especially those of human origin, will present a risk to human health.

2.1 Definitions used in COSHH

Within the terms of this Guide, the most important definitions are

1. “Biological Agent.”:
   “biological agent” means a microorganism, cell culture, or human endoparasite, whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health”.

   The essence of the definition is that the hazards and risks relate to humans – if an organism poses no health risks to humans it falls outside the definition of “biological agent”, even though it may present severe risks to animals or to plants (these are regarded as environmental risks).

   Note that there are other risks besides infection, and also that the hazard categorisation for microorganisms is primarily based on the ability to infect humans and cause disease. It is therefore entirely possible for an organism in Hazard Category 1 (i.e., unlikely to cause disease by infection) being classified as a Biological agent because of properties such as toxicity or allergenicity.

2. “Microorganism”:
   “microorganism” means a microbiological entity, cellular or non-cellular, which is capable of replication or of transferring genetic material”,

   and

3. “[Hazard] Group”:
   “Group”, in relation to a biological agent, means one of the four Hazard Groups specified in paragraph 2 of Schedule 3 to which that agent is assigned.”

2.2 Essential requirements of the COSHH regulations

The COSHH Regulations require that an employer shall:

a) undertake a "suitable and sufficient" assessment of the risks to health is undertaken before any work is done which could cause exposure to substances hazardous to health (Reg. 6);

b) prevent exposure to substances hazardous to health, or where exposure cannot be prevented, put systems in place to adequately control exposure (Reg. 7);
e) **ensure** that all control measures are properly used or applied (Reg. 8);

d) **regularly maintain**, examine and test control measures (Reg. 9);

e) **monitor exposure** in particular circumstances (Reg. 10);

f) **undertake health surveillance** on exposed individuals in particular circumstances; (Reg. 11) and

g) **provide information, instruction and training** for anyone who might be exposed to substances hazardous to health.(Reg. 12)

h) **For work with biological agents**, there are also requirements for classification of the agents, and notification of “First Use” and (for certain specified agents) each subsequent use.

The notification requirements are detailed in Schedule 3 to the Regulations: “**Additional provisions relating to work with biological agents**”. Schedule 3 also gives details of the classification scheme, by which biological agents are allocated to groups according to their ability to cause human disease, the risk to the individual and to the human community. The Scheme is explained in greater detail in Part 3 of this Guide.

### 2.3 Notification requirements

Prior notification is required for all “**First use**” activities with agents in hazard groups 2, 3 and 4; in addition each subsequent use of any agent specified in Part V of the Schedule must be notified at least 20 days in advance of starting work with that agent.

Part V of the Schedule lists the following agents as requiring notification:

*Any Group 3 or 4 agent*

*The following Group 2 agents:*

- Bordetella pertussis
- Corynebacterium diphtheriae
- Neisseria meningitidis.

As organisms in both Hazard Groups 2 and 3 were already in use at the University when the current COSHH Regulations came into force, the University was not required make a “First Use” notification. However, each subsequent use of a specified agent must be notified in advance.

If a notification is required, it must contain details as specified in the Regulations, including details of where the work will be undertaken; the results of the risk assessment, and details of the preventive and protective measures to be taken.

### 3 THE MANAGEMENT OF HEALTH AND SAFETY AT WORK REGULATIONS

These Regulations (Ref. 2) may be regarded as a general requirement to manage health and safety in the workplace. This includes making such arrangements as are necessary to plan, organise, control, monitor and review all protective and preventive measures employed for this purpose. They apply as a “**default condition**” unless they are superseded by other, more specific regulations (such as COSHH). They would thus apply to activities as diverse as animal handling (see Part 4 of this guide) and undertaking field-work to collect biological
samples (see Safety Guide 32 – Fieldwork). The requirements include matters such as requiring a prior risk assessment of the work to be done; provision of training; provision of information about hazards and the risks associated with the work, etc. There are also special provisions for new and expectant mothers, and in respect of “young persons” employed in the workplace.

4 **RISK ASSESSMENT**

This is the most important requirement of both sets of Regulations, and which form the basis for any requirements which follow. The risks must be assessed before any work is commenced.

4.1 **The stages of risk assessment**

In the leaflet “Five steps to Risk Assessment” (HSE – ref. 3), the essential steps of a risk assessment are:

1. Identify the hazards;
2. Decide who might be harmed, and how;
3. Evaluate the risks, and decide whether the existing precautions are adequate, or whether more should be done;
4. Record your findings, and
5. Review your assessment and revise it if necessary.

(Revision would be necessary if there were any significant changes to the activity, or if evidence was obtained that the existing assessment is not adequate.)

Note that:

- if there is no hazard, there will be no risk, and consequently, no need to put any control measures in place; and that
- failure to identify an evident hazard may be regarded as evidence of failure to undertake a “suitable and sufficient risk assessment” - which is a criminal offence.

The magnitude of the risks to health or safety will depend both on the hazard and also on the extent of (and consequences of) exposure to the hazard.

4.2 **Biological Agents: Hazard categories and containment**

For any work entailing possible exposure to biological agents, correct identification of the hazard category of an agent is an essential element of the risk assessment. See Part 3 of this Guide for details and examples of the hazard categorisation scheme for biological agents.

For “intentional work” [e.g., in a laboratory], the COSHH Regulations require that the level of containment to be used is [normally] numerically equal to the hazard category of the agent(s): thus Containment level 1 (the lowest level) is required for Hazard Group 1; Containment level 2 for Hazard Group 2 etc. The “normal” level may be modified by detailed consideration of the risks associated with the work and the particular properties of the agent concerned – for example, if a hazard category 3 agent does not pose a risk by inhalation of infected aerosols (because it does not infect by this route), then full containment category 3 conditions would not be required. This is enshrined in the law by means of a derogation granted by the enforcing authority (HSE).
The containment measures are designed to limit the exposure of workers to the agent, and to prevent or minimise the dispersal of the agent from the laboratory. The higher containment levels take into account the ability of a microorganism to replicate in a susceptible host, and are thus more stringent in terms of minimising or preventing exposure. Where the hazard is not primarily that of infection (i.e., where there are toxic or allergenic hazards), Containment level 1 is normally sufficient to control risks to humans unless the agent produces a potent toxin that is readily dispersed into the environment. However, environmental considerations may require a higher level of containment than is necessary to protect human health – for example, Foot and Mouth Disease Virus (FMDV) is not regarded as a biological agent, as it does not infect humans, and is not a hazard to human health – Containment level 1 is therefore sufficient to protect human health. However, work with the virus requires level 4 containment because of the pathogenicity towards animals such as cattle, sheep, pigs, etc. and it is listed as being subject to controls under DEFRA legislation (not detailed here.).

4.3 Hazardous materials of biological origin.

The COSHH Regulations apply to all substances that may be hazardous to health. This definition therefore covers substances that are contained within (or produced by) living organisms, and which may be hazardous in the absence of living biological agents. Thus, toxins produced by plants or animals (neither of which are biological agents) are covered, as well as allergens, and substances that may be irritant, harmful or corrosive etc. A risk assessment must be undertaken, but is more akin to a “chemical” risk assessment than one for biological agents. Such biological materials however are unlikely to be accompanied by a safety data sheet, unless they are obtained from a supplier “by means of trade.” Anyone undertaking extraction and purification of hazardous biological materials from original source material (e.g., plant and/or animal tissue) must undertake a full COSHH assessment. For substances where the hazards are “unknown” where possible, an estimate should be made of the nature of the hazards by analogy to “known” materials of similar function.

Details of how to undertake risk assessments (including suggested forms for recording assessments) are given in Part 1 of this Guide (University Procedures).

4.4 Exposure

For work involving the possibility of incidental exposure to a biological agent, the risk assessment should identify all measures necessary to prevent or minimise exposure of the worker to the agent, and (if appropriate) minimise the consequences of exposure if it were to occur.

- The potential for exposure will depend on the nature of the operations conducted during the work activity, and how these operations are effected.
- The nature of the work to be done will control the likelihood of exposure to the agents in question, and the risks to health will depend upon the consequences of exposure.
- The extent of the risk will depend upon the numbers and susceptibility of those exposed to the risk. If individuals are particularly susceptible to adverse effects of exposure, the consequences of exposure will be greater, and the risks will increase. Although it is
normally assumed that the "exposed population" is in good health, this may not in fact be the case.

To be acceptable as a "suitable and sufficient risk assessment", the assessment must identify:

- All the potential risks to health created by the work (the nature of the risks to health, their magnitude and consequences, and the likelihood that those risks may be realised);
- those at risk from the work, and the nature of the risks to health; and
- all measures (both physical and procedural) required for the control of those risks.

It is essential to include consideration of any reasonably foreseeable situation in the risk assessment. This would include "accident scenarios", such as accidental spillage or leakage of a biological agent, and the procedures adopted to contain and control any such spill. The process of risk assessment should be iterative, i.e., if there are any residual risks at the "end" of the assessment process, consideration should be given as to whether any additional measures are necessary to control those risks. The test of "reasonable practicability" should be applied to determine whether such additional measures are necessary.

5 EXPOSURE PREVENTION AND CONTROL FOR BIOLOGICAL AGENTS

COSHH Regulation 7 requires that “Every employer shall ensure that the exposure of his employees to substances hazardous to health is either prevented, or where this is not reasonably practicable, [be] adequately controlled ....”

The need for exposure prevention or control results in the following steps:

1. If the intention is to work with a specific biological agent, then any risks of exposure cannot be prevented. (The only assured way of preventing exposure to a particular biological agent is not to use it.)

2. If a less-hazardous agent (or an attenuated strain of the agent) can be used to substitute for a more hazardous agent, then it should always be used. (Note that this requirement would not extend to genetically modified strains of the agent, unless there is definitive evidence that such strains are less hazardous than the parental organism.)

3. If it is not reasonably practicable to prevent exposure (and hence any risks), then the exposure must be adequately controlled, by whatever combination of measures as is necessary to minimise the risks to health.

Adequate control of exposure also involves:

- Ensuring that all persons liable to be exposed have appropriate information, instruction and training;
- Minimising numbers of people likely to be exposed (this minimises the extent of the risk);
- Restricting entry to areas in which biological agents are used to named, authorised personnel;
- Designing work processes and engineering control measures to prevent or minimise the
release of biological agents into the workplace.

Other control measures (which can reduce inadvertent exposure of others not directly involved in the work) include:

- Displaying the Biohazard warning symbol and other relevant warning signs at the entrance to areas where biological agents are in use;
- Drawing up plans to deal with accidents involving biological agents;
- Specifying appropriate decontamination and disinfection procedures;
- Having systems in place for safe collection, storage and decontamination of contaminated waste, etc.;
- Using procedures for safe handling, processing and transport of biological agents (and samples that may contain them);
- Providing collective protection measures, and appropriate protective clothing and equipment for individual protection;
- The use of vaccination procedures where appropriate;
- Adoption of suitable hygiene measures aimed at reducing the accidental spread or release of a biological agent from the workplace. (This latter topic is dealt with in more detail in Part 6, Good Occupational Safety and Hygiene.)

Most of these features should be incorporated into the Local Rules for the laboratory – See Part 5 of this guide

Consideration of the risks should therefore lead to identification of the measures needed to adequately control the risks. All activities involved should be considered.

- For example, any operation that leads to the generation of an infectious aerosol of droplets containing viable microorganisms will create a high potential for exposure via the inhalation route. If this activity is done in the open laboratory, it would be regarded as an unacceptable risk for a high-hazard organism known to cause infection by the aerosol route. However, if the operation is done within the confines of a Class III (total enclosure) safety cabinet, the potential for exposure will be much reduced or eliminated altogether. In this case, the Class III cabinet is regarded as a “control measure” under COSHH, the need for which had been identified by the “unacceptable” nature of the "open laboratory" operation considered during the risk assessment process. (Note that this would not be the only control measure required for a high-hazard organism.)

5.1 Use and maintenance of control measures

The main control measures used in intentional work with biological agents are those related to the Containment Laboratory. As the level of hazard increases, the extent of control required also increases, and is reflected by the containment level of the laboratory. All control measures must be:

- **properly used** (Regulation 8); and (where appropriate) be
- **properly maintained, examined and tested** at regular intervals by a competent person
Proper use requires that those using the control measure(s) be given sufficient information, instruction and training to be able to use them properly and safely. Employees are also required to co-operate with their employer in the proper use of the control measures, and it is an offence to interfere with or misuse such control equipment. (Regulation 8)

Regulation 9 imposes a duty on the University to ensure that all equipment supplied as "engineering control measures" is regularly serviced and thoroughly tested for proper functioning. For items of Local Exhaust Ventilation (LEV) plant/equipment, the maximum interval for thorough examination and test is a period of 14 months, but may be considerably less.

- For example, LEV includes equipment such as Microbiological Safety Cabinets. *(See Part 7 of this Guide)* The normal service/test interval is once a year, but this frequency may be increased to once every 6 months if the cabinet is used with hazard Group 3 agents.

- Autoclaves used for decontamination of waste prior to disposal are also examples of "engineering controls". Their performance should be monitored on a day-to-day basis to ensure that the conditions required for decontamination are met. In addition, they should be validated as part of the annual "examination and test" regime (under the Pressure Systems Regulations). Note that this validation test (which should be to BS EN285 (1995) was previously performed by the Insurance Inspector as part of the annual insurance check of pressure vessels in the University. A recent change in University Insurers meant that this test is no longer performed during the Insurance examination. Consequently, Schools that have autoclaves used for waste control must arrange to have the validation test performed on an annual basis. Records of both the day-to-day performance and the validation tests must be kept.

5.2 The use of Personal Protective Equipment (PPE)

Items of personal protective equipment must always be worn whenever work liable to cause exposure to biological agents is being undertaken. *See the Good Microbiological Practice Guide*, and also Part 6 of this Guide, *Principles of Good Occupational Safety and Hygiene*.

PPE includes items such as laboratory coats, protective gloves, etc., which must be supplied and used where exposure cannot be adequately controlled by other means. Items such as filtering respiratory protective equipment (RPE) are not certified for protection against biological agents, mainly because there are no agreed criteria for the degree of protection required to prevent infection following exposure to hazardous biological agents. The degree of protection required will depend upon the intrinsic hazard of the agent, and the potential for exposure.

5.3 Lists of exposed employees and Health surveillance

Where the intention is to work with biological agents in Hazard Category 3 or 4, the Regulations require that all those potentially exposed be identified, and details of the work (plus details of any exposures, accidents and incidents) be kept. This list should be kept for a year.
minimum of 40 years following the date of the last (potential) exposure. Note that this (the date of the last exposure) is regarded as the last occasion of work with the agent: because of the nature of the agents concerned, it must be assumed that any intentional work with a particular type of biological agent also carries the risk that an individual may be exposed to that agent. In addition to the list of exposed employees, where appropriate, health records should be kept for each individual named on the list – the health records should also be kept for 40 years.

**Within the University, all those who work with hazard category 3 organisms are required to be under health surveillance. This also applies to some hazard category 2 organisms that present an enhanced risk. Work with hazard category 4 organisms is not permitted. See also Safety Note 17: Work at Category 3.**

The majority of those who people who work with hazard group 2 organisms are not under routine health surveillance. (Please contact the BSO if further information is required regarding the need for surveillance.) In general, the application of the techniques of good microbiological practice and good occupational safety and hygiene should be adequate to prevent exposure to hazard category 2 organisms under the particular conditions of the work.

If any worker were to contract a disease because of their work with a biological agent (i.e., an occupationally acquired disease), this could be regarded as *de facto* evidence of the failure to adequately control exposure. This would be reportable under RIDDOR - the University Occupational Health service (UOHS) would inform the BSO of any such case of occupationally-acquired disease, so that the circumstances could be investigated.

- If a worker suspects that he/she may have contracted a disease as a result of their work, he/she should consult the UOHS as soon as possible. If an occupationally-acquired disease is medically confirmed, the circumstances would be investigated and reported as above.

- Where health surveillance is undertaken, the medical records of that surveillance must also be maintained for 40 years. Note that these records are not the same as the "list of exposed employees" described above, but complementary to it.

In most cases, surveillance is limited to a pre-assessment of suitability for the proposed work, based on the response to a health questionnaire, but at higher hazard levels it will include a medical interview. This may also involve requesting a sample of blood serum from a candidate worker. (Taking of blood samples is itself not without risk, and a risk/benefit assessment will be undertaken prior to a decision whether to actual sampling.)

5.4 **Information, instruction and training**

As a general principle, all persons must be given sufficient information on the hazards that they may encounter during their work. (This reference to "any person" means that non-employees such as students, visiting service engineers, and others who may be affected are included -see

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2 The organisms concerned are those HG2 organisms that are listed in Part V to Schedule 3 to the COSHH Regulations, i.e., *Neisseria meningitidis; Bordetella pertussis* and *Corynebacterium diphtheriae*. 
In most cases, this duty is devolved to the Laboratory Supervisor, or other person in charge of the work. He/she has the knowledge necessary to understand the risks involved in the work, and therefore is able to provide others with information on those risks. The overall responsibility for the safety of the employees and "other persons" however rests with the Head of the School where the work is undertaken.

With particular reference to risks from biological agents:

- The employer must provide written instructions (and, if appropriate, display notices) on the procedures to be followed in the case of an accident or incident which has (or may have) resulted in the release of an agent responsible for severe human disease. (i.e., Hazard Group 3 or higher - see Safety Note 17). In practice, this duty is delegated to the laboratory Supervisor, who should ensure that the appropriate information is incorporated into the Local Rules. (see Part 5).

There should also be written instructions for dealing with all accidents or incidents involving biological agents.

- Employees must report "to the employer" (via the Laboratory Supervisor to the BSO) any accident or incident that involves the (potential) release of Hazard Group 3 agents.

The Biological Safety Officer has specific responsibilities for investigating any such accident or incident, and details should be reported to him as soon as possible. (Note that any accident or incident involving the release of a hazard group 2 agent should be reported in the first instance to the laboratory supervisor, who should supervise the decontamination activities required for the clean-up. Details should be reported to the BSO as a matter of course, but advice on decontamination may be obtained at any time.)

The employer is required to inform employees or their representatives forthwith of:

- any accident or incident involving the possible release of a Group 3 agent; and (as soon as practicable thereafter)
- of the causes of the accident/incident; and
- the measures (to be) taken to rectify the situation.

The duties relating to “information, instruction and training” for employees who work with biological agents may be satisfied in part by the provision and enforcement of Local Rules (Part 1: University Procedures).

It is essential that the Local Rules for each laboratory take proper account of:

- the organisms to be used;
- the procedures to be adopted;
- the experience of the workers concerned, and
- the amounts / physical form of the materials to be used in the work to be done in that laboratory.

The requirement for “information, instruction and training” is also relevant to service
engineers who may come into the laboratory to service and maintain equipment. They must be informed of the nature of any risks to which they may be exposed. However, the prime requirement of the COSHH Regulations is that risks be prevented (so far as is reasonably practicable). As there is no intention for them to work with the agents, it is considered reasonably practicable to prevent exposure. This means that equipment they are requested to service must be rendered microbiologically safe (by decontamination) before they start work. The engineer must be informed that this has been done, and he/she must be informed of any other relevant information on potentially hazardous conditions that may affect them.

In some cases (as for servicing equipment used at Containment level 3), a "permit to work" system should be operated to control the work of the service engineer. See Safety Note 17, "Procedures for work at Containment Level 3".

5.5 Summary of the COSHH key-points
For the system of risk assessment and control to be deemed "suitable and sufficient", it must:

- identify all hazards, and those individuals at risk from those hazards;
- determine the potential for exposure to hazards (this depends on the specific operations undertaken during work activities);
- identify (and put in place) all control measures required to prevent or minimise exposure.

The assessment must be recorded and reviewed at regular intervals, or if circumstances change significantly.

Once control measures are put in place, employees must co-operate with the employer by:

- using those control measures in a proper manner; and
- reporting any defects in those control measures to their employer.

The employer must ensure that:

- control measures are regularly maintained, examined and tested;
- employees are properly informed of any hazards, and
- employees are instructed and trained in the proper use of any control measures etc.

6 OTHER RELEVANT LEGAL REQUIREMENTS

Part 7 of the Act (Ref. 4) requires that any occupier of premises must notify the Secretary of State (the Home Office) before specified "dangerous substances" may be kept or used on those premises. The specified substances include:

- specified pathogenic microorganisms (as listed in Schedule 5 to the Act.) The term microorganism includes nucleic acid sequences associated with pathogenicity of the listed microorganisms, and genetically modified organism containing such a sequence.
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Certain listed toxins. The term "toxin" includes nucleic acid sequences coding for the
toxin, and genetically modified organisms containing such a nucleic acid sequence.
Where a toxin is composed of several subunits, all such subunits are included, even if
the subunit is not toxic in isolation.

This notification procedure will alert the local Police Force, and allows them to request details of:

- the material being held, and
- the names of people with regular access to the areas of the facility where such material
  is held.

The Act also authorises the access of the Police to the facility (following due notification of an intention to visit). Visits would be undertaken to conduct security checks; following such a visit, the organisation must comply with any reasonable recommendation in respect of security measures.

Finally, the Act gives the Secretary of State (the Home Secretary) the power to direct that specific (named) persons be excluded from such areas of the facility. If such an Order is made, the person responsible for the laboratory must ensure compliance.

Most of the listed organisms are Hazard Category 4, but some Category 3 and Category 2 organisms are included. Details of the listed organisms and toxins are held at the Health & Safety Services office by the BSO.

6.2 The Genetically Modified Organisms (Contained Use) Regulations (2000).

Users of genetically modified organisms must comply with the appropriate legislation. For laboratory work, the “Contained Use Regulations” (Ref. 5) will apply, although the COSHH Regulations may also apply. A risk assessment made under the GMO (Contained Use) Regulations will suffice as a COSHH risk assessment. See Safety Guide 15 - The contained use of Genetically Modified Organisms.

Safety guide 15 also deals with the use of hazardous nucleic acids (for example, oncogenes). Although such materials are “hazardous substances of biological origin”, they are so closely related to GMOs that it is convenient to include reference to them in that Guide.

Note that separate legislation applies where there is an intention to release genetically modified organisms to the environment: anyone proposing to undertake work of this nature is advised to consult the Biological Safety Officer at the earliest opportunity.

7 REFERENCES