Introduction

The university recognises its responsibility to comply with current legislation and appropriate guidelines in the management of hazardous biological agents. This document and the laboratory code of practise for biological agents form part of the University requirements to comply with the relevant areas of the Control of Substances Hazardous to Health Regulations (COSHH). In addition, The Specified Animal Pathogens (Wales) Order 2008 (SAPO), The Animal Health Act 1981 and The Schedule 5 to the Anti-terrorism, Crime and Security Act 2001 (Modification) Order 2007 (ATCSA) may apply to your work.

These management arrangements apply to all intentional work which involves the handling, storage, transport and waste disposal of biological agents at the University. Work placements in external health care facilities are not covered by this document. This also does not include contact with blood/bodily fluid through first aid/cleaning activities.

The use of Genetically Modified Organisms (GMOs) is not covered in detail in this document, please see G034 Guidance

Biological hazards that occur from means other than deliberate work such as food safety, Legionella control in water systems, or pandemic infections in the workplaces, are dealt directly with through other specific policies.

These arrangements are necessary in order to safeguard the health and safety of staff and students, the environment, and others that might be affected by activities involving biological material such as micro-organisms, cell cultures, parasites, human tissue (including blood, urine, and other body products), or any other material of a biological origin which could constitute a risk of infection, allergy, toxicity, or is potentially hazardous to health.

Appendix 1 provides direction to enable safe and effective planning and execution of undergraduate student research projects where exposure to biological agents and/or genetically modified organisms could reasonably be foreseen.

This is achieved through risk assessment and control, appropriate training, and the provision of suitable facilities in which to work with biological agents.

What is Biological Safety?

A biological agent is defined in COSHH as:

‘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.’

Most biological agents are microorganisms, i.e. bacteria, viruses, fungi, microscopic endoparasites such as the malarial parasite, amoebae and trypanosomes and the microscopic forms of the larger endoparasites such as the ova and larval forms of helminths. A microorganism is defined in COSHH as:

‘a microbiological entity, cellular or non-cellular, which is capable of replication or of transferring genetic material.’

Hazard groupings of biological agents

Biological agents are classified into four Hazard Groups, as published in the Approved List of Biological Agents based on their ability to infect healthy humans.

Information box: Hazard group definitions When classifying a biological agent, it should be assigned to one of the following groups according to its level of risk of infection to humans.	
Group 1	Unlikely to cause human disease
Group 2	Can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or treatment available.
Group 3	Can cause severe human disease and may be a serious hazard to employees; it may spread to the community, but there is usually effective prophylaxis or treatment available.
Group 4	Causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

Only agents in Hazard Groups (HG) 2, 3 and 4 are listed in this publication. Those not listed in these groups are not necessarily classified in Group 1. If there is no approved classification for an agent, the Principal Investigator must provisionally classify the agent according to its nature and properties (refer to Schedule 3 Part 1 of the COSHH Regulations: http://www.hse.gov.uk/pUbns/priced/l5.pdf). A risk assessment should be carried out to determine the containment level required for working with any organisms. The risks of allergenicity and toxicity should also be considered.

What are containment levels?

For laboratory areas, the ACDP publication Management and operation of microbiological containment laboratories describes the requirements for containment levels: Management and operation of microbiological containment laboratories.

When working with a biological agent in a particular hazard group, COSHH requires that the containment level selected matches the hazard group of the agent as a minimum:

- **Containment Level 1 (CL1)** is appropriate in secondary education and undergraduate teaching laboratories for work with well-defined and characterised strains of HG1 biological agents, which are unlikely to cause disease in healthy humans. If work at this level (or at any containment level) involves genetic modification, then other legislative controls, in addition to COSHH, will also apply. Toxic and allergenic risks should also be assessed and prevented or controlled as appropriate.
- **Containment Level 2 (CL2)** is a minimum for activities which involve working with a HG2 agent. CL2 must be used where there are any uncertainties about the presence of HG2 (and some HG3 agents if the intention is not to deliberately propagate and concentrate such agents). CL2 is the most used containment level and is suitable for a broad range of clinical, diagnostic and research work with biological agents which, although capable of causing disease, only present a low-to moderate risk to employees and are unlikely to spread to the community, with effective treatment or prophylaxis being

available. Examples of agents that must be handled at CL2 include common clinical isolates such as *Staphylococcus aureus*, human respiratory syncytial virus and *Toxoplasma gondii*.

- **Containment Level 3 (CL3)** is a minimum for activities which involve intentional working with a HG3 agent. CL3 or CL4 must be used, where appropriate, if the employers knows or suspects that such a containment level is necessary even if there is no intention to deliberately propagate and concentrate biological agents. CL3 must be used when it has not been possible to carry our conclusive risk assessment but where there is concern that the activity might involve a serious risk for employees. CL3 laboratories are the highest containment laboratories in common use in the UK. The type of work carried out at this level varies but containment measures must provide adequate protection to employees and others from laboratory work with biological agents which can cause severe disease and pose a serious hazard to employees (because of their infectivity and/or route of transmission). These agents may also spread within the community, but effective treatment or prophylaxis is usually available. An example of such an agent is *Mycobacterium tuberculosis*.

Aberystwyth University does not have facilities to work at CL4; therefore, research at these levels is not permitted under any circumstances.

Specified Animals Pathogens for laboratory areas, the publication, Guidance for licence holders on the containment and control of specified animal pathogens, describes the required standards.

Biological safety risk assessment

All work with biological agents (or material which may contain biological agents, such as human or animal tissues) must have an up-to-date risk assessment as part of their teaching or research documentation.

A template biological safety risk assessment has been created to support colleagues develop their arrangements.

All biological safety risk assessments will be approved by the Biological Safety and GM Safety Committee (BSGMSC), which can be submitted to biological-gm-committee@aber.ac.uk

Advice on risk assessments can be found in appendix 2, Biological Safety Risk Assessment Guidance and discussed with any colleague representative on the BSGMSC, details can be found Biological Safety Committee : Health, Safety & Environment , Aberystwyth University

Significant findings from biological risk assessments, including the controls required, will be communicated clearly to staff and students through the line management structure in order that responsibilities and the risk is understood, and the control measures identified and implemented.

Workers list

An up-to-date workers list must be kept for every teaching or research activities involving biological agents. This is maintained by the Principal Investigator and a copy provided to the BSGMSC.

Ethics Approval

All research with human participants and animals (including work with human tissue and bodily fluids) must follow the University ethics approval process: https://www.aber.ac.uk/en/rbi/support-services/ethics/ethical-research/. A valid risk assessment must accompany the ethics submission.

HSE Notification

The first use (i.e. deliberate work) of a biological agent in a hazard group at a premises must be notified to the HSE prior to the work commencing. This is carried out by the Health, Safety & Environment (HS&E) Team via the BSGMSC; therefore, they should be informed of all new scheme proposals and the revision of any existing schemes at CL2 before work commences. Allow at least 20 days for the assessment by the HSE before work starts.

There is also a requirement to notify subsequent use of any agents in Hazard Group 3, and specific agents listed in Part V of Schedule 3 of the COSHH Regulations, which can be found at this link: http://www.hse.gov.uk/pUbns/priced/l5.pdf.

The formal acknowledgement letter from the HSE will be held by the HS&E Team and Biological Safety and GM Safety Committee.

Laboratory Infrastructure

All laboratory facilities must be maintained to an appropriate standard to maintain compliance with the https://www.hse.gov.uk/biosafety/assets/docs/management-containment-labs.pdf

All building defects must be reported to campushelp@aber.ac.uk or ring 01970 622999, enable maintenance requests, issues and faults to be rectified as quickly as possible.

All laboratory facilities will be subject to self-assessment of their facility once a term. A further inspection of laboratory facilities will be undertaken by members of the BSGMSC and the HS&E Team on an annual basis.

Biological Safety Training

All staff and students working with Biological Agents must undertake the Introduction to Biological Safety training before commencing their activities.

Training will be provided by the Biological Safety Advisor as required. Refresher training will be provided at a frequency determined by the Biological Safety and Genetically Modified Safety Committee.

Security

Access to laboratory facilities will be restricted, colour to be determined by the risk levels, displayed by signage on the door. Doors must always be secure. All staff must wear lanyards and identifiable badges in restricted areas. Staff are required to politely challenge anyone present in areas or tailgating, where they are not familiar and/or whose actions may arise concern. Immediately report any security concerns to Security on 01970 622649 or mobile 07889 596220.

Health Surveillance and Immunisation

Any health surveillance or immunisation must be identified through the risk assessment for all those working with the material, both staff and students. The University has a contract in place for occupational health advice. To access advice for health surveillance or immunisation, please contact hasstaff@aber.ac.uk or to arrange health surveillance or immunisation, please contact hr@aber.ac.uk

Incident Reporting

The laboratory code of practise will contain the specific details for dealing with spillages; immediate actions in the event of an accident, fire, flood or other emergency, especially where there is a risk of infection.

All incidents including near misses should be reported, recorded and investigated as detailed in the Incident Reporting : Health, Safety & Environment , Aberystwyth University.

Record Keeping

Records shall be kept and retained as follows:

- At least 10 years for annual reviews of relevant risk assessments.
- At least 5 years for inspection and testing of Microbiological Safety Cabinets and autoclaves.
- At least 40 years for health surveillance.
- At least 40 years for instruction and training given in relation to work with biological hazards

Monitor and Review

The Biological Safety and Genetically Modified Safety Committee. will review the activity log on at least a 12 monthly period. The review will ensure all biological agent activity has a recently reviewed biological safety risk assessment; biological safety training has been undertaken and had at least one infrastructure inspection during the same period.

A summary of biological safety performance measures will be shared with the Faculty of Sciences Executive Group; the Health, Safety and Environment Operational Group; the University Executive Board; Governance and Culture Committee and the University Council.

Appendix 1

Undergraduate student research projects using biological agents and genetically modified organisms

Scope: All undergraduate research projects where the use or exposure to biological agents and/or genetically modified organisms can be reasonably foreseen.

Purpose: To enable safe and effective planning and execution of student research projects where exposure to biological agents and/or genetically modified organisms could reasonably be foreseen.

Background: As a university with a strong track record of excellence in research-led teaching, we have the expectation of providing students with a high-quality training experience during credit-bearing research projects. This can entail exposure to cutting-edge research questions and methodologies as part of a well-formulated research project. In the case of many disciplines, primarily in the laboratory-based life sciences, this conceivably could entail deliberate or incidental exposure to known or adventitious biological agents and/or genetically modified organisms. Such activities are overseen within Aberystwyth University by the Biological Safety and Genetically Modification Safety Committee (BSGMSC) with the support of its advisors and the University Health, Safety and Environment team and is subject to regulations and legislation at the national level.

Principles

1. A constructive research training experience which offers exciting hands-on opportunities for students is one which is safe and appropriate in construction. Deviating from this approach undermines the skill development and experience of the student and could result in preventable accidents, incidents, litigation and/or reputational damage.
2. When developing project ideas, supervisors should be alert from the outset to the potential for exposure to biological agents and/or genetically modified organisms. As always, the supervisor's legal and contractual obligations to abide by HSE regulations applies.
3. Furthermore, it should be recognized that the training of students is in preparation for careers which may include exposure to hazards in the workplace, therefore best practice should be modelled and communicated at every opportunity.
4. In the UK, HSE sets out a hierarchy of risk controls, where elimination or substitution of a hazard precede other control measures in terms of effectiveness. That is, it is preferable to eliminate a biological hazard or substitute it for a safer agent rather than proceed with an activity which entails exposure to the hazard but relies upon engineering, administrative, or personal protective equipment controls. In this context, it means that where a project entailing deliberate or incidental exposure to biological hazards and genetically manipulated organisms can be foreseen, every attention should be given to refining the project to one which eliminates or substitutes the hazard. Consequently, projects which must entail exposure to such hazards must make a strong academic case why the exposure cannot be eliminated or substituted.
5. The relative inexperience of undergraduate and taught postgraduate students in laboratory settings must be considered carefully. Equally, the limited timelines of a BSc or MBiol project, as well as competing demands on student time should be borne in mind. Supervisors should therefore assess the scope and risk

appetite of a project conservatively and consider the resource implications of the additional training and supervision a project entailing exposure to biological hazards and/or genetically modified organisms will entail.

6. Where the control measures required to mitigate the risk are substantial, it should be recognised that these are likely to bear both resource implications and reduce the opportunity for the student to demonstrate ownership of the project. Both considerations mitigate against projects requiring substantial risk controls. Projects requiring resource-intensive controls e.g. health surveillance and/or direct supervision of the student throughout laboratory work by the academic supervisor require Head of Department approval.
7. Following the careful consideration of the above factors, should a project be planned where exposure to biological agents and/or genetically modified organisms could reasonably be foreseen, the advice of the Biological Safety Advisor and/or GM Advisor should be sought at the first available opportunity through emailing bio_gm@aber.ac.uk If following consultation the project is to proceed, a full risk assessment (Bio COSHH or GMRA as appropriate) should be prepared and submitted to the BSGMC before the 31st of May. This is to ensure that the assessment is scrutinised in a timely manner, and relevant practical steps (e.g. laboratory inspections, biosafety training) can be scheduled to enable a timely project commencement in October. Therefore, late submissions will not be accepted.
8. Where a student research project can be covered by an existing risk assessment, for example for a broader activity on-going within the same laboratory, this represents a revision to the risk assessment. If the risk assessment is approved for prior work including students at the same level, this represents a minor revision, considering the prior skill and experience level of the new student(s). If the prior risk assessment does not include students at the same level, then this represents a major revision. In both cases, the revision should be prepared and submitted to the BSGMC before the 31st of May.
9. Where potential hazards are identified within projects where such exposure is not foreseen, the project must be halted by the supervisor immediately upon the identification of hazard(s) and the Committee and University HSE team notified.

Practical considerations

1. Projects entailing deliberate or incidental exposure solely to biological agents in ACDP Hazard Group 1 and/or Class I GM activities may proceed following approval of the risk assessment.
2. Projects entailing incidental exposure to biological agents in ACDP Hazard Group 2 or 3 which may be present in blood or other body fluids, or environmental substrates may be difficult to eliminate or substitute and are likely to represent most projects requiring consideration.
3. Projects entailing the concentration or propagation of biological agents where ACDP Hazard Group 2 or 3 agents are likely to be enriched (e.g. through centrifugation, filtration, or cultivation) require careful consideration. This evidently includes activities where the object of the activity is the enrichment of a biological agent in ACDP Hazard Group 2 or 3, but also activities where the enrichment of adventitious agents could occur. Additional risk controls will be required. These include selection of conditions biasing against enrichment of the hazard, handling of enriched agents by suitably experienced and qualified personnel rather than the student and disposal of sealed, unopened culture vessels following propagation.
4. Student work at Containment Level 3 is not feasible within the scope of an undergraduate project.
5. Prior to the commencement of laboratory work within the scope of this policy, students and their supervisors should attend either/both introductory biosafety awareness or GM training as appropriate.

Appendix 2 – Biological Agents and Materials Risk Assessment Guidance

There is detailed guidance on work with biological hazards which must be followed that is available from a range of enforcing bodies in the links below. You need to read the relevant guidance if you are working with biological hazards and to understand biological COSHH risk assessment and control.

HSE HSE Biological Safety	Welsh Government Animal Health Welsh Government Plant Health
DEFRA DEFRA Animal Health DEFRA Plant Health	Natural Resources Wales
Health Protection Wales United Kingdom Health Security Agency	World Health Organisation safeguarding biosafety and biosecurity in laboratories World Organisation for Animal Health

There is extensive guidance for work with biological hazards, biological risk assessment and controls for protection of people and the environment. Please read the guidance below since they will help you understand how to best do your risk assessments and safely carry out the work.

- HSE Approved list of biological agents
- HSE Control of Substances Hazardous to Health Regulations ACOP
- HSE Safe working and prevention of infection in clinical laboratories and similar facilities
- HSE Management and operation of microbiological containment laboratories
- HSE Fumigation
- HSE Bloodborne viruses in the workplace
- HSE Working safely with research animals: Management of infection risks
- HSE Control of laboratory animal allergy
- HSE SACGM Compendium of guidance
- HSE Containment and control of specified animal pathogens
- Transport of infectious substances

Essentials of Biological Risk Assessments

Biological risk assessments are required before work commences for all work involving the possession or use of biological agents and hazards or where there is a risk of exposure to biological agents or hazards. Principal Investigators are responsible for ensuring that the risk assessment and controls are carried out, adequate for the work, regularly monitored and that the assessment and controls are reviewed and revised.

To help you carry out your biological risk assessments here are some of the essential steps which you need to follow to protect humans, animals, plants and the environment from risks associated with biological agents and hazards.

1. Consider the biological hazards and the work activity.
2. Decide who or what might be harmed and how.
3. Assess risks relating to biological agents and hazards.
4. Decide on the hazard group (1 - 3).
5. Decide on the containment level (1 - 3).
6. Decide what control measures are necessary to prevent or adequately control exposure and minimise the risks.
7. Control measures must be implemented, monitored, and maintained.
8. Decide whether health surveillance and monitoring of exposure is required.
9. Ensure biological agents and hazards are safely handled, stored, transported, inactivated, and disposed.
10. Ensure there are plans and procedures to deal with emergencies.
11. Ensure workers are properly informed, trained and supervised to enable them to perform the work safely and competently.
12. HSE notification and consent is required for hazard group 3 and several hazard group 2 biological agents.
13. Animal Health licences and Plant Health licences are required for work with certain animal pathogens and plant pathogens and pests.
14. Biological risk assessments and other relevant records must be kept by the relevant managers and principal investigators.
15. Biological risk assessments must be reviewed and revised where they are no longer valid or where there are significant changes to the activity or risks.

Biological risk assessments need to be sufficiently specific but should be understood by non-experts such as colleagues, workers, safety advisers or HSE inspectors.

It is important that the risk assessment is clear and statements about risks and controls are properly justified. Probably the easiest way to justify most statements is to either cite an appropriate reference or provide sufficient information and explanation. Appropriate references can include

scientific publications, official guidance documents which are very useful but please specify section and paragraph numbers and commercial catalogues.

Avoid being unnecessarily restrictive and try to anticipate future changes and incorporate these into the risk assessment. The information should be kept as brief as possible and focused on what is needed to understand the risk assessment.

Remember that you are writing a risk assessment not a grant application so you do not have to justify doing the work only that it will be done safely.

Assessing Risks of Work with Biological Agents and Hazards

Using the F020 Biological Agents and Material Risk Assessment Template, complete each section.

Section 1 – Basic Details

Requires factual practical information, such as the project title and detailed locations of the work.

Section 2 - Project

Provides basic information about the project or activity, the biological agents and hazards involved and nature of the work.

Section 3 – Risk Assessment

3.1-3.9 Definition of Biological Agents and Hazards

Biological agents can be pathogens, toxins, allergens or carcinogens. Biological hazards include biological agents, any material which contains biological agents or any other biological substances which are not classified as biological agents.

COSHH defines biological agent as 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. A microorganism is defined as a microbiological entity, cellular or non-cellular, which is capable of replication or of transferring genetic material, and a cell culture is defined as the *in-vitro* growth of cells derived from multicellular organisms.

The definition of biological agents includes microorganisms, parasites, the microscopic infectious forms of larger parasites, cell cultures and nucleic acids.

Animal and plant health laws define animal pathogens and pests and plant pathogens and pests as harmful to the environment or economy.

Classification of Biological Agents

Biological agents are classified according to the risks to human health, animals, plants and the environment. COSHH classifies human pathogens into four hazard groups while SAPO classifies animal pathogens into four hazard groups and various plant health laws classifies plant pathogens and pests into multiple groups.

Classification of Human Pathogens

Human pathogens are classified by COSHH into four hazard groups (HG 1 - 4) according to these criteria.

- Ability to cause infection.
- Severity of the disease that may result.
- Risk that infection will spread to the population.
- Availability of vaccines and effective treatment.

The four hazard groups of human pathogens and the basis of their classification are as follows.

- **Hazard group 1** (HG 1): Biological agent that is unlikely to cause human disease.
- **Hazard group 2** (HG 2): Biological agent that can cause human disease and may be a hazard to employees but is unlikely to spread to the community and there is usually effective prophylaxis or treatment available.
- **Hazard group 3** (HG 3): Biological agent that can cause severe human disease and may be a serious hazard to employees and it may spread to the community but there is usually effective prophylaxis or treatment available.
- **Hazard group 4** (HG 4): Biological agent that causes severe human disease and is a serious hazard to employees and it is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

The HSE Approved List of Biological Agents list is not exhaustive so if a biological agent is not included it does not automatically fall into hazard group 1 and it should be classified according to its level of risk using the definitions given in COSHH. If there is any doubt as to which of two alternative hazard groups is the most appropriate, then the agent must be assigned to the higher one. Biological agents that are classified as hazard group 1 are not necessarily safe since they may cause harm under specific circumstances. The list also provides the following additional information on pathogens.

- A: Known to have allergenic effects.
- T: Toxin production.
- V: An effective vaccine is available.

In some cases, such as for attenuated strains of pathogenic microorganisms it is possible to reclassify a biological agent to a lower hazard group than that given for the agent on the list. This must only be done by consultation with and obtaining permission from HSE.

Classification of Animal Pathogens

Animal pathogens are classified by SAPO into four hazard groups (HG 1 - 4) according to these criteria.

- Ability to cause infection.
- Severity of the disease that may result.
- Risk that infection will spread to the population.
- Risk of damage to the environment or economic loss.
- Availability of vaccines and effective treatment.

The four hazard groups and several special groups of animal pathogens and the basis of their classification are as follows.

- **Hazard group 1** (HG 1): Disease producing organisms which are enzootic and do not produce notifiable disease.
- **Hazard group 2** (HG 2): Disease producing organisms which are either exotic or produce notifiable disease but have a low risk of spread from the laboratory.
- **Hazard group 3** (HG 3): Disease producing organisms which are either exotic or produce notifiable disease and have a moderate risk of spread from the laboratory.
- **Hazard group 4** (HG 4): Disease producing organisms which are either exotic or produce notifiable disease and have a high risk of spread from the laboratory.
- **Foot and Mouth Disease**: There is special classification for foot and mouth disease virus.
- **Rabies**: There is special classification for rabies and rabies related viruses.
- **Arthropods**: There is special classification for vectors and parasites.

Classification of Plant Pathogens and Pests

Plant pathogens are classified by plant health laws into multiple groups depending on their role in disease in the UK.

The COSHH, SAPO and other relevant classifications are not complementary, and the requirements are very different for the classification, containment and control of human pathogens, animal pathogens, plant pathogens and pests. Compliance with one does not absolve you and your workers from responsibilities under the other and in all cases where there is any discrepancy between COSHH, SAPO and other relevant requirements then the higher requirements must be followed. Where an

agent is listed by COSHH, SAPO and other relevant then all sets of requirements for risk assessment and control must be satisfied.

Biological Agents and Hazards

You should describe the exact nature of the work and the biological agents and hazards which will be used or to which people or the environment could be exposed in the work. There may be intentional or unintentional exposure to bacteria, viruses, fungi, parasites or infectious materials in the work. Biological agents and hazards might include hazard group 1 pathogens, hazard group 2 pathogens, hazard group 3 pathogens, toxins, carcinogens, allergens, human primary or continuous cell cultures, animal primary or continuous cell cultures, human cells or tissues, animal cells or tissues, human blood, patient contact, animals, plants, soils and environmental materials. Your work may involve potential exposure to biological agents and hazards such as teaching, research, laboratory work, fieldwork, travel, people, microorganisms, animals, plants, estate, facility, construction, maintenance, cleaning, visitors or contractors. Give details of how often the biological agents and hazards will be used, the activity carried out, or how often people will be exposed to the biological agents and hazards. You should briefly describe the specific methods involved the scale or volumes of materials in use and their presentation, e.g. cultures of less than 25ml of plant material. You should provide details of the maximum amount or concentration of the biological agents and hazards used or to which people could be exposed. Fieldwork in the UK or overseas may lead to exposure to various local or exotic biological agents and hazards.

Pathogens, Toxins, Allergens and Carcinogens

Pathogens are microorganisms such as bacteria, viruses, fungi and parasites which can colonise humans and cause infection and harm to health. You should provide details of whether they are pathogenic, toxic, allergenic, carcinogenic or environmental hazards. Microorganisms may be obligate opportunist pathogens, zoonotic pathogens capable of infecting humans and animals, or environmental pathogens. Pathogens vary greatly in their ability to cause infection and may be weakly or highly infectious. Infectious doses will vary enormously depending on the pathogen, strain and physical condition of the organism, exposure route and host resistance. In some cases, it is not the microorganism which is harmful but microbial products. Some microorganisms produce powerful toxins which are harmful to humans. Toxigenic microorganisms can be transmitted by many routes although they do necessarily not need to be viable for their toxins to cause harm since the microbial toxins can be hazardous. Inhalation, ingestion or injection of toxigenic microorganisms or toxins can cause infection or toxigenicity. Many biological agents or hazards including animals, plants, microorganisms or their products can be allergenic and cause mild or severe hypersensitivity reactions such as occupational asthma, dermatitis or anaphylaxis. Once sensitized then very low

concentrations of allergens may elicit allergic hypersensitivity reactions. Sometimes the consequences of an exposure may be sufficiently severe for the person to be unable to safely continue working in areas where they might be exposed to the agents or hazards. Some biological agents are carcinogens and can cause cancer. Some biological hazards such as humans and animal tissues, cancer cells and cell lines may contain cancer-associated viruses.

Host and Tissue Specificity

Some microorganisms and pathogens infect a broad range of host species while others infect very few or are species specific. Some pathogens have complex life cycles involving more than one host species and some stages but not others may be hazardous. Humans, animals or plants may be end hosts and not normally transmit infections. Some pathogens may infect a variety of tissues while others are tissue specific. Remember that microorganisms can evolve and adapt so they may infect different host species or tissues to those expected.

Pathogenicity

Pathogenicity or virulence is the measure of the harm that may be caused by a pathogen such as human, animal or plant disease or environmental damage. Some pathogens have highly virulent strains and avirulent or attenuated strains (eg vaccine strains). Attenuated strains may act as opportunist pathogens or revert to virulence. Attenuated strains may still be harmful and there have been many laboratory infections involving vaccine strains.

Humans, Animals, Plants and the Environment

Human and animal bodies, organs, tissues, cells, samples, blood, body fluids or waste materials may contain biological agents. Clinical samples could include samples from patients, volunteers or postmortem specimens. Human and animal tissues and cell cultures including primary or continuous cell lines and cancer cell lines are potentially hazardous because they may contain biological agents. Plant tissues and cell cultures may contain pathogens, toxins, carcinogens or allergens. Animals may carry zoonotic pathogens which are harmful to humans. Experimental animals from laboratory suppliers may be screened for several common specific pathogens but the risks are much greater in wild animals or experimental animals that have been in contact with wild animals. Cages, excreta, bedding and equipment used to trap or handle animals may be contaminated with biological agents and hazards. Plants, plant pathogens and pests, plant toxins and allergens may be hazardous to humans or the environment. Environmental samples can contain pathogenic organisms which may be

unintentionally concentrated or propagated in the laboratory. Microorganisms isolated from the environment should be treated as potentially pathogenic until shown to be otherwise.

Routes of Exposure or Release

You should provide details of the potential routes of exposure to or release of the biological agents or hazards. The potential for biological agents or hazards to cause harm will depend upon the exposure route and nature of any disease or damage. Biological agents or hazards may be harmful to people by one or more of the following exposure routes of inhalation, ingestion, injection or absorption. Working with agents in a laboratory setting can cause atypical routes of exposure which may lead to unusual symptoms or misdiagnosis by medical practitioners. There are multiple routes of exposure through air, land or water to animals, plants or release to the environment. Routes of exposure may be unknown and may be different from the natural route in the laboratory. You should provide details of any hazardous aerosols which might cause airborne exposure that could be produced by the work. You must carefully consider the risks of harmful exposure or release if things go wrong such as the absence or failure of control measures or in a serious incident.

Disease or Damage Caused by the Biological Agents and Hazards

You should provide details of any human, animal or plant diseases or environmental damage associated with exposure to or release of the biological agents or hazards. Infection and disease are complex processes affected by multiple host, agent and environmental factors (eg agent genotype, host genotype, virulence, host immunity). Humans, animals or plants have many physical, chemical and biological and immunological defence mechanisms. Exposure to biological agents or hazards may lead to asymptomatic, subclinical, acute, chronic, persistent or fatal infections or other diseases or damage. Some biological agents or hazards may be hazardous only to an exposed person, animal or plant while others may be hazardous to other people, close contacts, community or the environment. The effects of exposure to some pathogens may be delayed. You should use relevant sources of information to find out as much as you can about any diseases or damage associated with the biological agents and hazards in your work. Do not assume that a biological agent is safe if there is any uncertainty especially if you are dealing with novel agents or isolates but adopt the precautionary principle that until proven otherwise, they are harmful.

3.10 Who Might be at Risk

You should provide details of who will be doing the work and if any other people will be affected by the work. Specify which persons might be directly or indirectly at risk of exposure to the biological agents and hazards in the work including staff, students and other persons. Consider whether any particular groups of people might be at increased risk or adversely affected by the work and might not be able to do the work. These include new or expectant mothers, young persons under 18, disabled workers, those allergic to particular biological agents and hazards, and employees who may be more susceptible to some illnesses because of their individual health status. Immunocompromised people may be very susceptible to infection, which must be identified through the risk assessment. Occupational Health will be able to offer advice, should it be required. There may be aspects where other people who are not members of your department or team such as collaborators, visitors, cleaners and porters may be affected by the work and the risk to these people also needs to be evaluated and controlled.

3.11 – 3.12 Risk Evaluation

You have considered the ways by which harm could be caused from exposure to the biological agents and hazards in your work. You will then need to make an assessment of the overall level of risk of harm to human health and the environment from exposure to biological agents and hazards in the work.

Assessment of Risk to Human Health

You need to decide on the level of risk to human health from exposure to biological agents and hazards in this work. Please note that this is the level of risk prior to the use of controls. You will then select the necessary control measures which are required to reduce the level of exposure to the lowest level that is reasonably practicable and in any case to a level which is adequate to protect human health. To help you estimate the level of risk you should use the information below and the risk estimation matrix. This will give you an estimate of the potential risks to human health of the work.

Assessment of Risk to Environment

You need to decide on the level of risk to the animals, plants and other aspects of the environment from exposure to biological agents and hazards in this work. Please note that this is the level of risk prior to the use of controls. You will then select the necessary control measures which are required to reduce the level of exposure to the lowest level that is reasonably practicable and in any case to a

level which is adequate to protect the environment. To help you estimate the level of risk you should use the information below and the risk estimation matrix. This will give you an estimate of the potential risks to human health of the work.

Estimating the Risk Level

The risk of the activity is determined by evaluating both the biological agents and hazards and the potential for exposure to them and how they are used in the work. The level of risk of exposure to the hazard is calculated from a combination of the likelihood and consequences of the hazard in the given circumstances.

In practice an estimate of the level of risk can be calculated using a risk estimation matrix.

		Probability				
		1	2	3	4	5
Severity	1	1	2	3	4	5
	2	2	4	6	8	10
	3	3	6	9	12	15
	4	4	8	12	16	20
	5	5	10	15	20	25

	Probability	Severity
1	**Rare** - Could happen, but probably never will	**Insignificant** - No treatment or first aid only. No measurable physical effects.
2	**Unlikely** - Incident foreseeable, but not likely to occur under normal operation or circumstances	**Minor** - Injuries or illness requiring medical treatment beyond first aid. Temporary impairment.
3	**Possible** - May occur at some time under normal operation or circumstances	**Moderate** - Temporary impairment causing lost time or job restriction. May result in hospital admission.
4	**Likely** - Expected to occur at some time under normal operation or circumstances	**Major** - Permanent / prolonged impairment
5	**Almost certain** - Expected to occur regularly under normal operation or circumstances	**Catastrophic** - Fatalities or life-long impairment. Adverse reproductive effects.

Section 4 Controlling Risks of Work with Biological Agents and Hazards

You need to describe the control measures which will be used to protect people, animals, plants and other aspects of the environment from exposure to biological agents and hazards in the work. COSHH requires that the risks of exposure to biological agents and hazards is prevented or where this is not reasonably practicable then adequately controlled to reduce the risk of exposure to an acceptable level. SAPO and other environmental laws require similar specific control measures for biological hazards. The purpose of the biological risk assessment process is to enable you to select the most suitable controls or combination of controls that are proportionate to the risks. Control measures are systems and actions used to reduce the risks of exposure to biological agents and hazards. These include engineering controls such as containment laboratories and microbiological safety cabinets, management controls such as safe operating procedures, training, supervision, and personal protective equipment like lab coats, gloves and spectacles.

4.2 Containment Levels

Specific control measures and containment levels are required for activities with biological agents and hazards under COSHH, SAPO and other relevant laws and these are described in the HSE, Welsh Government and DEFRA guidance. You must select the appropriate containment level for your work which is derived from the hazard group classification of the biological agent or what is suspected about the possible presence of a biological agent in the hazard. COSHH specifies minimum containment levels required for the following types of work.

- **Containment level 1** (CL 1) for work with a **hazard group 1** (HG 1) biological agent.
- **Containment level 2** (CL 2) for work with a **hazard group 2** (HG 2) biological agent.
- **Containment level 3** (CL 3) for work with a **hazard group 3** (HG 3) biological agent.
- **Containment level 4** (CL 4) for work with a **hazard group 4** (HG 4) biological agent.
- **Containment level 2** (CL 2) for laboratories which do not intentionally propagate, concentrate or otherwise increase the risk of exposure to a biological agent but work with materials in respect of which it is unlikely that a **hazard group 3** (HG 3) or **hazard group 4** (HG 4) biological agent is present.
- **Containment level 3** (CL 3) or 4 (CL 4), where appropriate, for laboratories which do not intentionally propagate, concentrate or otherwise increase the risk of exposure to a **hazard group 3** (HG 3) or **hazard group 4** (HG 4) biological agent but where the employer knows, or it is likely, that such a containment level is necessary.
- **Containment level 3** (CL 3) for activities where it has not been possible to carry out a conclusive assessment but where there is concern that the activity might involve a serious health risk for employees.

There are minimum and recommended control measures which are required for work at each containment level, and these are specified in the relevant HSE, Welsh Government and DEFRA guidance.

Biological containment laboratories, animal facilities and plant facilities must therefore be classified into one of the three containment levels (CL 1 - 3). Containment level 1 is for low-risk work, containment level 2 is for medium risk work, and containment level 3 is for high-risk work. The containment level and all the necessary controls required for the activity must be specified in detail in the biological risk assessment and implemented. In some cases, depending on the nature of the biological agents or hazards or the activity it may be necessary to use additional control measures. In some other cases there are provisions to obtain permission for derogation from HSE to apply less than the minimum containment and control measures normally required for the containment level. Requests for derogations must be made to the HSE and must be fully justified based on risk assessment and may only be applied on receipt of written agreement from the HSE. However, there is permission for general derogations for certain types of work which are detailed in the relevant HSE guidance and subject to the risk assessment do not require specific request to HSE.

Control Measures

Control measures will predominantly reflect the risks, activity and potential routes of exposure of people, animals or plants or release to the environment. Control measures must be selected based on the specific requirements of the legislation which are detailed in relevant HSE, Welsh Government and DEFRA guidance. Broadly, the control of risks involves a systematic approach which requires the application of the most effective control measures which are reasonably practicable, and the selection of risks control measures should be done using a hierarchical approach.

The most effective control measures must be used in preference to the least effective ones starting with elimination, followed by substitution, engineering controls, administrative controls and lastly personal protective equipment. Once you have decided that you cannot eliminate hazardous activities or substitute less hazardous activities, you should implement control measures that prevent or minimise exposure to risk. The control measures must be selected in this order of priority. Control measures must be selected in this order of priority according to the level of risk identified in the biological risk assessment to ensure that they are effective.

When deciding on the sort of control measures that you intend to use the most important requirement is that control of exposure should be achieved by the most effective means, and this must not be only by the use of personal protective equipment where more effective measures can be used. In practice a combination of control measures are generally used to reduce the risks of exposure to the biological agents and hazards. In some cases depending on the activity additional

control measures may also be necessary or in other cases less stringent control measures may be applied. Once you have decided on the appropriate controls then they must be implemented and used. The controls must be used to reduce the level of exposure to the lowest level that is reasonably practicable and at least to a level which is adequate to protect human health, animals, plants and other aspects of the environment.

You should provide details of where the work will be done and how the biological agents and hazards will be properly contained. Consider if the work will be done in a containment laboratory, animal facility, plant facility or will specialised facilities be required.

General control measures should include systems and procedures for safe use, handling, storage and transport of biological agents and hazards, sharps, maintenance of equipment, reducing numbers of exposed persons, duration of exposure and quantities to the minimum, controlling the working environment, appropriate disinfection and decontamination, safe collection, storage and disposal of contaminated waste, displaying hazard warning signs and using appropriate hygiene measures.

Consider if the work will require total enclosure (eg glove box, anaerobic cabinets, flexible film isolators or class 3 safety cabinets), partial enclosure (eg class 1 or 2 safety cabinets or cage cleaning cabinets), local exhaust ventilation (eg exhaust ducting for laboratory equipment) or general ventilation (eg containment laboratories, animal or plant facilities).

You should also consider whether you will need to control access to the area where the work will be done by limiting it to authorised persons only. Where an effective vaccine is available the workers may need to be offered immunisations to individuals who may be exposed to biological agents at work.

Control measures which are used to prevent or control exposure to biological agents and hazards are properly maintained, examined and tested to ensure that they are working efficiently. The control measures subject to detailed examination and testing include engineering controls, local exhaust ventilation (LEV), which includes microbiological safety cabinets and extract ventilation for equipment, and respiratory protective equipment (RPE).

The precise nature of the maintenance, examination and test and degree of competence of the tester will vary depending on the nature of the equipment. Controls must be visually inspected periodically and maintained according to the manufacturer's instructions. LEV must be regularly maintained and thoroughly examined and tested at least once every 14 months. Reuseable respiratory protective equipment must be thoroughly examined and tested at suitable intervals. People and contractors carrying out examinations and tests must be competent.

Where equipment is simple, and its operation easily checked a local examination might be sufficient. However, where more complex systems are in use an examination by an external specialist contractor is likely to be required. This is generally undertaken by the institution where such systems form an integral part of a buildings fabric such as the air handling systems in containment laboratories and microbiological safety cabinets which are externally ducted to the roof of a building.

There must be an effective fault reporting system established. The requirement to inspect and test extends to administrative controls where it may be work practices that ensure adequate control and in these circumstances such systems should be subject to regular monitoring and inspection. Suitable records of any testing and examination of controls must be kept.

4.3 Local Exhaust Ventilation and Microbiological Safety Cabinets

Local exhaust ventilation is equipment used to control airborne contaminants by containing and capturing hazardous solids, liquids, or gases. There are many types of LEV such as fume cupboards (FC) and microbiological safety cabinets (MSC). You should provide details of the LEV which will be required to control aerosols of biological agents or hazards. There are three basic types of MSC which offer different types of protection to the operator, work and environment.

- Class 1 (Operator and environment protection).
- Class 2 (Operator, work and environment protection).
- Class 3 (Operator, work and environment protection).
- Class 1/3 hybrid (Operator and environment protection only, or operator, work and environment protection).

Microbiological safety cabinets function by using airflows to capture hazardous aerosols generated by work, transferring microorganisms away from the operator before trapping them in a high efficiency particulate air (HEPA) filter. Selection requires an assessment of the work and operator protection requirements but also the proposed location as draughts or physical obstacles may compromise cabinet performance. MSC must be tested after installation to ensure they provide operator and environment protection. Commissioning tests need to be repeated whenever an MSC is moved or there is a major change to the local environment. LEV and MSC must be selected, installed and maintained according to the relevant Standards. Note that fume cupboards and clean cabinets have different functions from MSC and must not be used instead of MSC for work with biological hazards. Clean cabinets are not LEV or safety cabinets but are designed solely to provide a clean working area so they do not protect people or the environment and must not be used for work with biological hazards.

4.5 Special Controls

You should provide details of any special control measures that you intend to use for your work. For example, work with toxic or carcinogenic hazards requires a high level of control. When selecting the appropriate measures for controlling the risks of carcinogens or toxins, the potential for long term and possibly fatal effects must be considered. Priority should be given to the elimination or substitution of the carcinogenic biological agents or hazards in question with a non-carcinogen. If alternatives are not reasonably practicable then this must be stated with explicit reasons in the risk assessment. If no suitable alternative to the carcinogen is available, exposure to the carcinogenic biological agents or hazards must be prevented by the best practicable means and following the hierarchy of control measures. Because of the nature of the risks posed by carcinogens, it is particularly important to select the most effective measures possible. Strict control measures should be adopted including for example, totally enclosed process and handling, extensive cleaning and disinfection procedures, safe storage, and disposal and prohibition of eating and drinking. The storage, use and disposal of carcinogenic substances require careful control. Carcinogenic substances used in the workplace should be kept to the minimum needed for the process. Clearly identify the areas in which exposure to carcinogens may occur and take measures to prevent the spread of contamination within and beyond these areas. The number of people likely to be exposed to carcinogenic agents and the duration of their exposure must be kept to the minimum necessary for the work. Non-essential personnel must be excluded.

Where appropriate, store and transport them on site in closed containers, clearly labelled and with clearly visible warning and hazard signs. Clearly label and securely store carcinogenic waste products until they are removed according to the proper procedures for removal of hazardous waste.

4.6 Personal Protective Equipment

You should provide details of the personal protective equipment (PPE) which will be required to protect the body, hands, eyes, face etc such as laboratory coats, gowns, gloves or spectacles, goggles and face shields.

The risk assessment may specify that PPE is required to control exposure to a biological agent or hazard when it is not possible to achieve adequate control over exposure by any other means and then it should be used only in addition to other appropriate controls. The PPE must be suitable to adequately protect against specific biological agents or hazards. You should consider the potential routes of exposure to the biological agents and hazards when deciding on appropriate PPE.

All PPE must be carefully selected and properly maintained, serviced and cleaned. Workers should be fully trained in its use and limitations.

4.7 Respiratory Protective Equipment

You should provide details of the respiratory protective equipment (RPE) which will be required to protect the respiration such as disposable masks, respirators or breathing apparatus. RPE should only be used where other more effective control measures cannot be used and generally only as an only additional control. The RPE must be suitable to adequately protect against the specific biological agents and hazards. Simple disposable dust masks do not provide protection against biological agents and hazards and should not be used. You need to consider the potential routes of exposure to the hazardous substances when deciding on appropriate RPE. Disposable respirators or filtering face piece (FFP) masks are available in three classes P1, P2 and P3 providing differing protection factors. For protection against biological agents and hazards reusable half or full-face respirators must be fitted with filters suitable to protect against the particular hazard present in the work. Detailed advice on this should be sought from the respirator manufacturer.

All RPE must be carefully selected to be appropriate, properly maintained, serviced and cleaned. Workers should be fully trained in its use and limitations. Reusable RPE must be thoroughly examined and tested at suitable intervals. RPE which relies on a tight-fit to the face for protection such as disposable filtering dust mask, reusable half face and full-face masks, and breathing apparatus must be face-fit tested for each individual wearer. Testing must be carried out by trained competent persons. Once face fit tested to a specific type of RPE then a certificate of test must be obtained and recorded. The worker must only wear the type of RPE on which they were tested, and they may need to be retested where required. Face fitting RPE does not work equally well for all individuals or situations and an alternative option is a powered respirator hood which supplies filtered air at positive pressure to the breathing zone of the wearer by a soft or hard top hood that encompasses the head.

4.8 Storage of Biological Agents and Hazards

You should consider at this stage the quantity you need, and the facilities required to store the biological agents and hazards. Special conditions may also be required such as ventilation and security.

4.9 Transport of Biological Agents and Hazards

The transport, import and export of dangerous goods has to be conducted in compliance with national and international regulations. Biological materials which are dangerous goods must be safely transported from the sender to the receiver to prevent exposure or release to protect workers, the public and the environment. Biological materials which are not dangerous goods still have to be properly transported so they do not leak in transit and trigger safety or security alerts or cause

unnecessary concern. The controls required for transport of dangerous goods is similar for the different modes of transport although materials sent by air generally have the most stringent standards. Remember that it is common for carriers to ship dangerous goods using multiple modes of transport like road and air in a journey. The transport of dangerous goods may involve additional restrictions imposed by operators and these are listed as operator variations in the various transport regulations. There are in addition many biological materials which require regulatory licences for their import or export.

The main responsibilities of shippers are classifying the biological materials or infectious substances, identifying the proper shipping name and UN number, correctly packaging, marking and labelling the packages, documenting the shipments for transport and customs requirements, arranging transport with carrier and notifying the receiver of shipments. The risks of improper packaging and shipping include incidents, potential exposure to infectious substances, failed or delayed package delivery, shipments stopped at customs and prosecution. The benefits of proper transport include no incidents, protection of people and the environment, timely package delivery and compliance with national and international regulations.

4.10 Destruction or Inactivation of Biological Agents and Hazards

You should provide details of how you will destroy the biological agents and hazards used in the work. The appropriate inactivation and disposal of waste is very important part of work. There are chemical and physical methods of inactivating biological agents and hazards. Monitoring of effectiveness is required to prove that inactivation method works, this can be achieved by regularly reviewing manufacturers information on the disinfectant or equipment being used. The effort involved in effective monitoring depends on the risks and inactivation method used. Records must be kept.

Disinfection

Disinfectants must be appropriate for the relevant biological agents or hazards, animals or plants used in the work. The effectiveness of many disinfectants can vary considerable depending on the biological agent, concentration, exposure time, pH and presence of organic matter, liquids, or solids. Disinfectants may be used for inactivating biological agents and hazards in solid and liquid materials and on contaminated surfaces and equipment. The effectiveness of some disinfectants rapidly diminishes after dilution to working concentrations. Validation procedures are generally more difficult to achieve for disinfectants than for autoclaving. Information on the efficacy of a disinfectant can be obtained from the manufacturer's instructions, published data or in house testing. In many cases disinfectants are used just as an additional control measure rather than the sole means of

inactivating biological agents such as where disinfectants are used prior to autoclaving. Inactivation is defined as achieving a sufficient kill commensurate with the risks.

Autoclaving

Autoclaving is the most effective inactivation method and by far the easiest and least time consuming to both validate and monitor. For these reasons it is strongly recommended that all biological agent or hazard contaminated waste including all liquid waste and waste destined for incineration be autoclaved unless there is a very good reason to use another method. It is generally accepted that any biological agent (except TSEs which are a special case) will be inactivated by autoclaving under conditions that maintain 121^{o}C for at least 15 min with full steam penetration. Note, the minimum 15 min excludes the time required to reach 121^{o}C, and the above conditions must be maintained even in the most inaccessible positions of the load. Inactivation is defined as achieving a sufficient kill commensurate with the risks. Records must be kept.

Validation of autoclaving should be carried out using thermocouple mapping. This involves placing multiple independent thermocouples at various sites, including the most inaccessible, within a typical load and recording output during a standard run to determine if all sites maintain the required temperature for the required time. This is usually done by a maintenance engineer as part of the annual maintenance contract and a recording of the output from each thermocouple will be provided and should be kept as a record. Because steam penetration varies it is important that validation be conducted using a load that represents the most difficult encountered in normal use.

Monitoring of autoclaving should be carried out on each run to confirm that both the correct temperature and time has been employed. This is very easy if your autoclave includes a built-in thermocouple linked to a chart or digital recorder which monitors each run and provides a printout, or you can download the information electronically that can be kept as a record. If your autoclave lacks this then you have two options. Install a suitable digital recorder linked to a thermocouple that can be fitted to many but not all older or small autoclaves but make sure you choose one that provides a continuous printout, recording the temperature throughout the run. Alternatively, you could place a suitable commercially available autoclave indicator in each load and keep a logbook that records the results of each run. Most commercially available indicators (including standard autoclave tapes) alone are not adequate for monitoring inactivation of waste, because they change colour either at temperatures considerably lower than 121^{o}C, or within minutes of reaching 121^{o}C, or in the absence of steam penetration, and therefore do not confirm that the appropriate conditions have been maintained for a sufficient time.

You should provide a brief statement in this section about the disinfection or autoclaving methods including and validation and monitoring which will be used in your work.

4.11 Waste Management and Disposal

All aspects of waste management need to be safely carried out including labelling, safe handling, storage, transport, and disposal. Waste containing biological agents and hazards should be properly inactivated using a validated means before disposal. You should describe what waste containers will be used such as waste bags, bins or sharps bins. You should also briefly describe how your waste will be disposed such as whether it will be hazardous or non-hazardous waste, biological, chemical, or radioactive waste.

4.12 Health Surveillance, Monitoring Exposure and Immunisation

Health surveillance may be required for certain occupational diseases or adverse health effects such as infection, cancer, and hypersensitivity, to check that people exposed to biological agents and hazards are not harmed during their work. This is usually where there is an identifiable disease or adverse health condition related to work, valid techniques are available for detecting indications of the disease or condition, there is a reasonable likelihood that the disease or condition will occur under the work, and where surveillance is likely to further the protection of health of workers. Health surveillance may involve preliminary and ongoing surveillance, questionnaires, interviews, examination, tests, monitoring and referrals. Health surveillance may be required for workers exposed to hazardous biological agents or certain animals and animal allergens. Monitoring exposure may be required for certain activities such as work involving laboratory animal allergens.

Immunisation may be useful as a control measure to protect people against infection by certain biological agents. For example, hepatitis B vaccine can offer valuable protection against infection for those people who work with human blood and tetanus vaccine is important for protecting against the risks of tetanus in the environment. Vaccines must not be considered as a primary defence against infection but only as an additional control measure. Please see the Occupational Health Service website and contacts for information and advice on health surveillance and immunisation.

4.13 Information, Instruction, Training, and Supervision

The control measures will not be effective if those involved in the work do not know their purpose, how to use them properly or the importance of reporting faults. Codes of practise are required for every aspect of the work relating to high containment laboratories. All workers and visitors must be provided with adequate information, instructions, training, and supervision to enable them to carry out their work safely. This should include local rules, safe working practices and standard operating procedures on the hazards, risks and effective application of control measures and emergency procedures.

Records of information, instruction and training should be kept. All workers and visitors must be adequately supervised. The principal investigator or manager must decide on the level of supervision required to do the work and this should be proportionate to the risks of the work, the containment level and competence of workers. Some work may not be carried out without direct personal supervision or not be started without the advice and approval of supervisor, while other work can be carried out without direct supervision. Some work may require more than one person to carry it out safely.

4.14 -4.17 Enforcement notifications and Licenses

COSHH requires that HSE be notified of premises and certain higher risk activities in advance of commencement of the work. Hazard group 3 and 4 biological agents and hazards, and the hazard group 2 agents and hazards *Bordetella pertussis*, *Corynebacterium diphtheriae,* and *Neisseria meningitidis* activities, must be notified in advance to the HSE on an individual basis and specific consent obtained to carry out the work. Work may not start until HSE has given written consent. HSE must also be notified of any subsequent significant changes in activities or new information which may have a bearing on the biological risk assessment.

HSE must be informed of any changes to processes, procedures or agents that are of importance to health and safety, and which render the original notification invalid.

You can modify a biological risk assessment which has been notified under COSHH, but you must first reassess the risks of the project and make the appropriate changes to the biological risk assessment. If the modification is within the scope of the original notified project and there is no significant increase in the risks of the work, then you only need to make the changes to the risk assessment and obtain the relevant approval and no further action is required. If the modification is within the scope of the original notified project but will significantly increase the risks of the work, then you must not carry out the work until consent for these changes has been obtained from the HSE.

This will require making changes to the biological risk assessment and sending the modified risk assessment and an updated form to the HSE. Note that you cannot change the scope of the original notified project. If the modification is outside the scope of the original notified project, whether or not it changes the risks, then you must not carry out the work until consent has been obtained from the HSE. Notifications do not have to be made if the activity has already been notified under the Genetically Modified Organisms (Contained Use) Regulations.

Many animal and plant pathogens and pests are covered by specific animal and plant health and environmental laws and in certain cases require licences from the Welsh Government, DEFRA, or related agencies for possession, use, consignment, importation and exportation. The Welsh

Government and DEFRA specify specific containment and control conditions for licensed pathogens and pests. COSHH, SAPO, and other relevant animal or plant health or environmental classifications are not complementary, and the requirements are very different for the containment and control of human and animal pathogens, plant pathogens and pests. Compliance with one does not absolve managers, principal investigators and their workers from responsibilities under the other and in all cases where there is any discrepancy between COSHH, SAPO or other relevant requirements then you must comply with all the requirements for containment and control although the higher control requirements must be the minimum standard which must be followed.

HSE is the licencing authority and regulator for the Specified Animal Pathogens Order (SAPO). Work with SAPO controlled pathogens requires a licence which is obtained from HSE and this will involve completion of a licence application and submission of a biological risk assessment and or GM risk assessment as part of the application process. HSE may carry out inspections as part of the application process depending on the pathogens and nature of the work. HSE will approve suitable licence applications.

Section 5 Emergency Procedures

The manager, principal investigator and workers are responsible for ensuring that incidents and emergencies are properly dealt with since these are the experts in the biological agents and hazards and the work. You need to assess the potential for accidental exposure and implementing emergency procedures for your work. Emergency plans and procedures must be prepared in advance.

The primary objective of the emergency procedures is the containment of the biological agents and hazards and the minimisation of risks to people and the environment. You should consider all of the relevant factors which may include assessing situations, instructions, informing others of accidents, isolation of area, evacuation, seeking assistance, PPE, RPE, preventing spread of contamination or spills, decontamination of work area or laboratory, safe waste disposal, first aid treatment and medical treatment if required. Anyone not concerned with the emergency action should be excluded from the area. Only people essential for dealing with the emergency of carrying out repairs and other essential work may be permitted in the affected area. They must be provided with appropriate personal protective equipment and any necessary equipment.

Emergency and spillage procedures should be specified in code of practise and spillage kits will be required, where identified. A spillage procedure can be provided on a laminated instruction sheet which can be placed where the hazardous work is done on the wall above a bench or on a piece of equipment. Appropriate training must be provided in all accident and emergency procedures.

All workers must understand and be able to implement the emergency procedures, including a first aid response. This can be achieved through regular practise for staff, which will enable you to review your procedures as you practise.

Emergency Contacts

You should provide the names and contact details of people to contact in case of an accident or emergency. This must include the name of the principal investigator or manager who is in charge of and understands the work together with details of other relevant persons including the workers doing the work and colleagues involved in the work.

Your emergency contacts should not normally include the names of safety advisers or co-ordinators since they are not responsible for the work or for implementing your emergency procedures and are unlikely to know about the specific work or biological agents and hazards involved.

The information and contact details of managers, safety advisers and coordinators, security, and emergency services etc are provided separately, and should be on access restriction code signage for the laboratory.

Section 6 Emergency Planning

This section should consider what arrangements need to be in place for unusual, rare situations such as a loss of utilities such as loss of water, electrical. You should consider what controls should be put in place to present an accidental release and protect the teaching or research activity or equipment.

Section 7 Final Risk Rating

Review section 3.11-3.12 to consider the level of risk to human health, animals, plants and other aspects of the environment from exposure to the biological agents and hazards in this work, following your control measures.

Section 8 Approval

The assessor and principal investigator or manager must sign and date the form to state that they have assessed the risks and reviewed and approved the risk assessment. The principal investigator or manager may delegate the work of preparing a risk assessment to any competent member of the team but the principal investigator or manager retains the responsibility for approval and ensuring that the assessment is adequate for the work. The assessment must be carried out correctly and to a suitable and sufficient standard identifying the hazards, risks, who or what might be at risk and the

selection of appropriate controls for the work. You should consult with other people who might be adversely affected by the work where it is necessary including other groups and workers.

Section 9 Review

This section requires the assessor and the Principal Investigator to review their assessment and work arrangements at least annually and immediately if there are any significant changes to the work, which includes following an incident.

This is documented on the front page of the risk assessment, to ensure any changes are clearly identifiable for those undertaking the activity.