Biological Agent Risk Assessment

1. Introduction

This guidance is provided to help you carry out biological agent (BA) risk assessments and control the risks of the work to protect humans, animals, plants and any other aspect of the environment.

2. Law

Health and safety, animal health, plant health and environmental laws require employers to protect people and the environment against risks to health, safety or the environment from work involving biological agents by doing risk assessments and providing effective containment and controls. The Health and Safety at Work Act (HSWA), Environmental Protection Act (EPA) and Control of Substances Hazardous to Health Regulations (COSHH) require controls for work with biological agents to protect people and the environment. The Animal Health Act (AHA) and Specified Animal Pathogens Order (SAPO) require controls for work with animal pathogens and other relevant materials to protect animal health and the environment. The Plant Health Act (PHA) and Plant Health Order (PHO) require controls for work with plant pathogens and pests and other relevant materials to protect plant health and the environment. Guidance on the law and practice relating to work with biological agents, BA risk assessment, containment and controls is provided by the Health and Safety Executive (HSE), Animal Health, Plant Health, Public Health and other agencies. The Health and Safety Executive is the primary regulator for health and safety and biological safety matters are dealt with by its specialist division the HSE Biological Agents Unit (BAU). The University is notified to HSE as a single centre (207) for work with biological agents.

3. Summary

Here is a brief summary of some of the key requirements to help you carry out your BA risk assessments and work safely with biological agents.

1. BA risk assessments are used to assess the potential risks to people or the environment arising from work involving biological agents and to determine what risk controls are required.
2. Risk assessments must be done by competent persons and before starting any work.
3. Risk assessments and controls must be proportionate to the risks.
4. Assess potential risks of harm to people.
5. Assess potential risks of damage to the environment.
6. Assess the nature and level of risks to people and the environment.
7. Decide on the hazard group 1, 2, 3.
8. Decide on the containment level 1, 2 or 3.

9. Decide which control measures are necessary to prevent or adequately control exposure and reduce the risks to people, animals, plants and the environment to an acceptable level.
10. Control measures are based on minimum legal requirements which must always be used plus any additional controls determined to be necessary in the risk assessment.
11. Control measures are needed to ensure that biological agents are safely handled, stored, transported, inactivated and disposed.
12. Control measures must be fully implemented, maintained and regularly monitored to check that they are effective.
13. Plans and procedures are required for incidents and emergencies.
14. All workers must be properly informed, trained and supervised to enable them to safely carry out their work.
15. HSE notification and consent is required for work with group 3 and some group 2 biological agents.
16. Specified animal pathogen licences are required for work with serious animal pathogens.
17. Plant health licences are required for work with serious plant pathogens and pests.
18. BA risk assessments and other relevant records must be kept by Schools and principal investigators.
19. BA risk assessments and control measures must be reviewed and revised where they are no longer valid or where there are significant changes to the scope or risks of the work.
20. Prior permissions where relevant must be obtained from Schools, Biological Safety Committees and regulators.

4. Biological Safety Committees and Safety Advisers

There are Biological Safety Committees (BSC) and safety advisers to provide advice on BA risk assessments and help ensure that proper and valid assessments have been made of the risks to human health and safety and to the environment, satisfactory decisions are made about appropriate containment and control measures and the risk assessment and controls are in accordance with the relevant regulations and guidance. Schools which carry out work involving biological agents must have a BSC which is part of the School Safety Committee or may be integrated into a GMBSC. School Genetic Modification and Biological Safety Committees (GMBSC) provide advice on both biological safety and genetic modification safety. Details of all GMBSC and their GMBSO contacts are provided here on the website.

- GM Biological Safety Committees and Biological Safety Adviser Contacts

School Biological Safety Advisers (BSA) provide advice on biological safety, BA risk assessments and control measures. School BSC must operate a strict permission system for any work involving biological agents which are notifiable, require a

licence, or are highly hazardous pathogens or pathogen infected materials in the University. All BA risk assessments for work which require HSE notification, an animal health licence or plant health licence must be reviewed and approved by the School BSC and advice obtained from the University Biological Safety Adviser (UBSA). Biological agents must not be brought into the University or any work conducted until a suitable and sufficient BA risk assessment has been carried out and for higher risk work it must be reviewed and approved by the BSC and where required by the regulator such as the HSE or other relevant licencing authorities. BA risk assessments for hazardous work must also be reviewed and approved by the BSC whenever there are proposed changes or when there is reason to believe the assessment is no longer valid.

School BSA and BSC provide local advice on biological safety, BA risk assessments and control measures. However the Schools and principal investigators are directly responsible for ensuring that work involving biological agents is properly managed with BA risk assessments carried out, approved and appropriate controls in place so that the work is conducted safely. The University provides a standard BA risk assessment form and guidance to help you carry out your work safely. Please contact your School Biological Safety Adviser if you need advice on any aspect of biological safety including work involving biological agents, BA risk assessments and control measures.

5. BA Risk Assessment Forms

Please use the BA risk assessment form to carry out your risk assessments for all work involving biological agents.

- BA risk assessment forms

6. BA Risk Assessment and Control

BA risk assessments are required to be done before any work commences or for any work involving the possession or use of biological agents or where there is a risk of exposure to biological agents involved in the work. A BA risk assessment is used to assess the potential risks to humans, animals, plants or other aspects of the environment arising from the work and determine what controls are required to protect humans and the environment. Managers and principal investigators are responsible for ensuring that risk assessment are carried out and the controls are fully implemented, regularly monitored and that the assessment and controls are regularly reviewed and revised where required. BA risk assessments must be carried out by competent persons and approved by the appropriate manager or principal investigator. The work must be categorised on the basis of risks taking into account the biological agents, the type of activity, hazard group, containment level and all the necessary controls required to ensure that the work can be done safely while protecting people and the environment. BA risk assessments must address all

aspects of the work including routine and non-routine work and what to do in emergencies if something goes wrong. The risk assessment and control measures must be suitable and sufficient and proportionate to the risks. All workers including staff, students and visitors must be provided with adequate information, instructions, training and supervision to enable them to safely and competently perform their work.

BA risk assessments should be a high standard in respect of clarity, justification of statements on hazards and risks and the selection of control measures. The risk assessment will enable valid decisions to be made about what needs to be done to prevent or control adequately exposure to biological agents. Risk assessments need to be sufficiently specific but should be understood by non-experts such as colleagues, safety advisers or HSE Inspectors. It is important that the risk assessment is clear and statements about risks and controls are properly justified. Avoid being unnecessarily restrictive and try to anticipate future changes and incorporate these into the risk assessment. The information should focus 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. Statements about risks should be explicitly justified based on evidence, relevant information and reasoned logical arguments. Statements about risks must be evaluated prior to the use of controls. Avoid meaningless circular arguments, such as statements that the risks are low because of the use of controls, since this tells you nothing about the risks or level of the risks if people were actually exposed to the biological agent or if there was a release of the biological agent into the environment. You want to be able to identify before the use of controls, the potential risks and evaluate the level of these risks if people were exposed or there was a release into the environment, to enable you to determine a proportionate level of controls which would be adequate to protect people and the environment. Bear in mind that the risks should always be low, after the use of controls, otherwise you need to do more to control the risks of the work. Statements may also be justified by citing appropriate references such as scientific publications, official guidance documents and commercial catalogues.

7. Guidance Sources for Work with Biological Agents

There is detailed regulatory guidance and information on safe working with biological agents and BA risk assessment, containment and control which is available from the Health and Safety Executive (HSE), Advisory Committee on Dangerous Pathogens (ACDP), Animal Health, Plant Health, Public Health and other agencies. Please see the links below to some important resources.

7.1 Guidance

- HSE ACDP Approved list of biological agents

- HSE ACDP Management and operation of microbiological containment laboratories
- HSE ACDP Infection risks to mothers and babies
- HSE Managing infection risks when handling the deceased
- HSE ACDP Working safely with research animals: Management of infection risks
- HSE Control of laboratory animal allergy
- HSE Containment and control of specified animal pathogens

7.2 Websites

- HSE Biological Safety
- HSE Biological Agents
- HSE Specified Animal Pathogens
- Animal Health (Scotland)
- Plant Health (Scotland)
- Animal and Plant Health Agency
- Public Health (Scotland)
- Public Health (UK Health Security Agency)
- World Health Organization
- World Health Organization Biological Safety
- World Organisation for Animal Health

8. Assessing Risks of Work with Biological Agents

Your BA risk assessment should start with the basic information about the project or activity and the principal investigator who is responsible for management of the work. The project title should state the biological agents involved and the broad nature of the work. Provide the name of the principal investigator or manager, School, date and the building or location where the work will be carried out.

8.1 Definition of Biological Agents

Biological agents is a broad general term which covers any pathogens, toxins, allergens, carcinogens or any biological materials which are harmful to people, animals, plants or any other aspect of the environment. But there are also under various laws more specific definitions of terms like biological agents, pathogens and pathogen infected materials.

Biological agents are defined under 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. 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, microscopic infectious forms of larger parasites, cell cultures and hazardous nucleic acids. Biological agents are defined under SAPO as animal pathogens which are capable of causing serious disease or damage to the environment or economy. Biological agents are defined under PHO as plant pathogens or pests which are capable of causing serious disease or damage to the environment or economy.

Biological agents may be encountered where you are intentionally or unintentionally working with them in research, teaching, fieldwork and travel. The term biological agent includes where relevant any biological materials which contain or may contain biological agents. These biological agents or materials may also be described using terms like biological hazards or infectious materials.

8.2 Classification of Biological Agents

Biological agents are classified according to the risks to human health and the environment. COSHH classifies human pathogens into four groups, SAPO classifies animal pathogens into four groups and PHO individually classifies plant pathogens and pests.

8.2.1 Classification of Human Pathogens

Human pathogens are classified by COSHH into four groups broadly 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 groups of human pathogens and the basis of their classification are as follows.

- **Group 1:** Biological agent that is unlikely to cause human disease.
- **Group 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.
- **Group 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.
- **Group 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 ACDP Approved List of Biological Agents list is not exhaustive so if a biological agent is not included, it does not automatically fall into 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 groups is the most appropriate then the agent must be assigned to the higher one. Biological agents that are classified as 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 group than that given for the agent on the list. This must only be done by consultation with and obtaining permission from HSE.

8.2.2 Classification of Animal Pathogens

Animal pathogens are classified by SAPO into four groups broadly 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 groups of animal pathogens and the basis of their classification are as follows.

- **Group 1:** Disease producing organisms which are enzootic (native in animals in this country) and do not produce notifiable disease.
- **Group 2:** Disease producing organisms which are either exotic or produce notifiable disease, but have a low risk of spread from the laboratory.
- **Group 3:** Disease producing organisms which are either exotic or produce notifiable disease and have a moderate risk of spread from the laboratory.
- **Group 4:** Disease producing organisms which are either exotic or produce notifiable disease and have a high risk of spread from the laboratory.

8.2.3 Classification of Plant Pathogens and Pests

Plant pathogens and pests are classified by the Plant Health Order (PHO) into individual groups depending on their role in disease in the UK.

8.2.4 Compliance with Classification Systems

The COSHH, SAPO, PHO 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, PHO and other relevant requirements then the higher requirements must be followed. Where an agent is listed by COSHH, SAPO or PHO then all sets of requirements for risk assessment and control must be satisfied. Where an agent is not controlled under these or other relevant laws then the assessor should still identify a suitable hazard group and follow the same broad process of BA risk assessment and control.

8.3 Basic Requirements for Work with Biological Agents

There are some basic university requirements for work with biological agents (BA) which are determined by the specific group of the biological agents involved in the work.

8.3.1 Group 1 BA

The possession or use of group 1 biological agents is subject to the following requirements.

1. **BA risk assessment:** A BA risk assessment is required for work involving the use of or exposure to group 1 biological agents. Please complete the BA risk assessment form.
2. **Monitoring:** The School and PI must monitor the work to ensure that the controls are used and effective.
3. **Review:** BA risk assessments must be reviewed and amended immediately where there are any changes to the activity or the risks.
4. **Records:** The School and PI must keep BA risk assessments including all revised versions and other relevant records.

8.3.2 Group 2 BA

The possession or use of group 2 biological agents is subject to the following requirements.

1. **BA risk assessment:** A BA risk assessment is required for work involving the use of or exposure to group 2 biological agents. Please complete the BA risk assessment form.
2. **Pathogen and toxin registration:** Group 2 biological agents must be registered with the School and University using the pathogen and toxin registration form

on the RETAIN system. The registration of pathogens and toxins must be done before any biological agents are brought into the university.

3. **Monitoring:** The School and PI must monitor the work to ensure that the controls are used and effective.
4. **Review:** BA risk assessments must be reviewed and amended immediately where there are any changes to the activity or the risks.
5. **Records:** The School and PI must keep BA risk assessments including all revised versions and other relevant records.

8.3.3 Group 3 BA

The possession or use of group 3 biological agents which contain group 3 biological agents and also the group 2 agents Bordetella pertussis, Corynebacterium diphtheriae and Neisseria meningitidis is subject to the following requirements.

1. **BA risk assessment:** A BA risk assessment is required for work involving the use of or exposure to group 3 biological agents and also the group 2 biological agents Bordetella pertussis, Corynebacterium diphtheriae and Neisseria meningitidis. Please complete a BA risk assessment form.
2. **Biological Safety Committee advice and permission:** Group 3 biological agents and the group 2 agents Bordetella pertussis, Corynebacterium diphtheriae and Neisseria meningitidis BA risk assessments require permission from your School Biological Safety Committee (BSC) and Health and Safety Executive (HSE) before bringing any biological agents into the University or starting work. The principal investigator (PI) must complete and email the BA risk assessment form to the School Biological Safety Adviser (BSA) for submission to the School BSC. The School BSA must contact the University Biological Safety Adviser (UBSA) for advice on all notifiable BA risk assessments. The BSC will review and advise on the BA risk assessment and may request amendments. The BSC will provisionally approve satisfactory BA risk assessments. Approval by the BSC will only be issued once HSE consent has been obtained.
3. **HSE notification and consent:** Group 3 biological agents and the group 2 agents Bordetella pertussis, Corynebacterium diphtheriae and Neisseria meningitidis BA risk assessments must be notified to the HSE using an HSE CBA1 notification form. There is no HSE fee required for this type of notification. The UBSA will advise the School BSA and PI on completion of the CBA1 form and do the HSE notification by sending the completed CBA1 form and BA risk assessments to HSE. HSE may request further information about the work or request changes to the risk assessment or controls. The UBSA will inform the School BSA and PI of all HSE requests and advice and issue the HSE consent once received. The PI may then commence the work once all controls are in place.
4. **Pathogen and toxin registration:** Biological agents must be registered with the School and University using the pathogen and toxin registration form on the RETAIN system. The registration of pathogens and toxins must be done before

any biological agents are brought into the university and they must not be acquired until the School BSA and PI has obtained HSE permission.

5. **Monitoring:** The School and PI must monitor the work to ensure that the controls are used and effective.
6. **Review:** BA risk assessments must be reviewed and revised where there are any changes to the activity or the risks of the work. The University BSA should be contacted by the School BSA for advice on revision of all notifiable BA risk assessments. The BSC will approve satisfactory revised BA risk assessments. The BSC will notify any significant changes to the project or risks to the UBSA to notify to HSE. There is no HSE fee required for this type of notification. The UBSA will inform the BSA and PI of all HSE requests and advice and issue the HSE consent once received. The PI may then commence the work once all controls are in place.
7. **Records:** The School and PI must keep BA risk assessments including all revised versions and other relevant records.

8.3.4 Group 4 BA

The possession or use of group 4 biological agents is prohibited in the University.

8.3.5 Biological Materials

The possession or use of other biological materials (eg human or animal cells and tissues, allergens, animals, plants, soils, organisms, toxins and biological products) is subject to the following requirements. Please note that you must follow the specific requirements for the relevant group for those biological materials which contain or are likely to contain a biological agent in that group.

1. **BA risk assessment:** A BA risk assessment is required for other biological materials. Complete a BA risk assessment form.
2. **Pathogen and toxin registration:** Relevant biological materials must be registered with the School and University using the pathogen and toxin registration form on the RETAIN system. The registration of pathogens and toxins must be done before any biological agents are brought into the university.
3. **Monitoring**: The School and PI must monitor the work to ensure that the controls are used and effective.
4. **Review:** BA risk assessments must be reviewed and revised where there are any changes to the activity or the risks of the work.
5. **Records:** The School and PI must keep all BA risk assessments including all revised versions and other relevant records.

8.4 Biological Agents

You should describe the exact nature of the work and the biological agents 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 might include non-hazardous microorganisms, group 1 pathogens, group 2 pathogens, 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 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 will be used, the activity carried out, or how often people will be exposed to the biological agents. You should briefly describe the specific methods involved and whether it will be small, medium or large scale work. You should provide details of the maximum amount or concentration of the biological agents 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.

8.5 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 the biological agents 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 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 viruses.

8.6 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.

8.7 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.

8.8 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 post mortem 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. 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.

8.9 Routes of Exposure or Release

You should provide details of the potential routes of exposure to or release of the biological agents. The potential for biological agents to cause harm will depend upon the exposure route and nature of any disease or damage. Biological agents may be harmful to people by one or more of the following exposure routes of inhalation, ingestion, injection or absorption. Atypical routes of exposure 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 in the laboratory may be different from the natural route. 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.

8.10 Harm or Damage Caused by Biological Agents

You should provide details of any human, animal or plant diseases or environmental damage associated with exposure to or release of the biological agents. 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 may lead to asymptomatic, subclinical, acute, chronic, persistent or fatal infections or other diseases or damage. Some biological agents 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 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 instead adopt the precautionary principle that until proven otherwise they are harmful.

8.11 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 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 employees who may be more susceptible to some illnesses because of their individual health status. Immunocompromised people may be very susceptible to infection. 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 risks to these people also needs to be evaluated and controlled.

8.12 Risk Evaluation

You have considered the ways by which harm could be caused from exposure to the biological agents 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 in the work.

8.12.1 Assessment of Risk to Human Health

You need to decide on the level of risk to human health from exposure to biological agents 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 of the work to human health.

8.12.2 Assessment of Risk to Environment

You need to decide on the level of risk to the environment from exposure to biological agents 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 of the work to the environment.

8.12.3 Estimating the Risk Level

The risk of the activity is determined by evaluating both the biological agents 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.

- **Risk** = **Likelihood** x **Consequences** = Effectively Zero, Low, Medium / Low, Medium or High. In practice an estimate of the level of risk can be calculated using a risk estimation matrix.

Consequences of Hazard	**Likelihood of Hazard**			
	High	**Medium**	**Low**	**Negligible**
Severe	High	High	Medium	Effectively Zero
Modest	High	Medium	Medium / Low	Effectively Zero
Minor	Medium / Low	Low	Low	Effectively Zero
Negligible	Effectively Zero	Effectively Zero	Effectively Zero	Effectively Zero

9. Controlling Risks of Work with Biological Agents

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 in the work. COSHH requires that the risks of exposure to biological agents is prevented or where this is not reasonably practicable then adequately controlled to reduce the risk of exposure to an acceptable level. SAPO, PHO and other environmental laws require similar specific control measures for animal pathogens or plant pathogens and pests. The purpose of the BA 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. 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.

9.1 Containment Levels

Specific control measures and containment levels are required for activities with biological agents under COSHH, SAPO, PHO and other relevant laws and these are described in the HSE, Animal Health, Plant Health guidance or licences. You must select the appropriate containment level for your work which is derived from the 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 activities which involve work with group 1 biological agents.
- **Containment level 2 (CL 2)** for activities which involve work with group 2 biological agents.
- **Containment level 3 (CL 3)** for activities which involve work with group 3 biological agents.
- **Containment level 4 (CL 4)** for activities which involve work with group 4 biological agents.
- **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 group 3 or group 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 group 3 or group 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 guidance as well as SAPO and PHO licences. Biological containment laboratories, animal facilities and plant facilities must therefore be classified into one of the three containment levels (CL 1 - 3). Basically, containment level 1 is for no to low risk work, containment level 2 is for low to medium risk work, and containment level 3 is for medium to high risk work. The containment level and all the necessary controls required for the activity must be specified in detail in the BA risk assessment and implemented. In some cases depending on the nature of the biological agents or the activity it may be necessary to use additional control measures. In some other cases there are provisions on the basis of the risk assessment or by obtaining permission for derogation from HSE to apply less than the minimum containment and control measures normally required for that containment level. Requests for derogations must be made to the HSE and must be fully justified on the basis of risk assessment and may only be applied on receipt of written agreement from the HSE.

9.2 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 on the basis of the specific requirements of the legislation which are detailed in relevant HSE guidance. Remember also that any associated SAPO or PHO licences will require additional controls. 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. If 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. Control measures must be selected in this order of priority according to the level of risk identified in the BA 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. 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 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, sharps control, 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 partial enclosure (eg class I or II safety cabinets or cage cleaning cabinets), total enclosure (eg class III safety cabinets, isolators, anaerobic 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 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 annually. 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. Personal protective equipment (PPE) used to protect workers should be stored, checked and cleaned in such ways as to prevent the equipment being a contaminated by biological agents. 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.

9.3 Local Exhaust Ventilation and Microbiological Safety Cabinets

Local exhaust ventilation (LEV) 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. There are three basic types of MSC which offer different types of protection to the operator, work and environment.

- Class I (Operator and environment protection).
- Class II (Operator, material and environmental protection).
- Class III (Operator, material and environmental protection).
- Class I/III hybrid (Operator and environmental protection only, or operator, material and environmental 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 British 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.

9.4 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 taken into account. Priority should be given to the elimination or substitution of the carcinogenic biological agents 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 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.

9.5 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. You should consider the potential routes of exposure to the biological agents 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.

9.6 Respiratory Protective Equipment

You should provide details of any respiratory protective equipment (RPE) such as respirators or breathing apparatus which will be required. RPE should only be used where other more effective control measures cannot be used and generally only as an only additional control. RPE may be useful for work with animals or plants or fieldwork. The type of RPE used must be suitable to adequately protect against the specific biological agents. Simple disposable dust masks do not provide protection against biological agents and should not be used. All RPE must be carefully selected to be appropriate, properly maintained and cleaned. Workers should be fully trained in its use and limitations. RPE which relies on a tight-fit to the face for protection such as disposable filtering 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.

9.7 Storage and Transport of Biological agents

You should consider at this stage the quantity you need and the facilities required to store the biological agents. Special conditions may also be required such as ventilation and security. You should provide details of how you will safely transport the biological agents. For example what special packaging and multiple containment will be required for internal and external transport of the biological agents. Special controls may also be required such as, hazard signage, carrying spillage kits and PPE.

9.8 Inactivation of Biological agents

You should provide details of how you will destroy the biological agents used in the work since effective inactivation and disposal of waste is an important part of work. Biological agents must be inactivated by validated methods. There are chemical and physical methods of inactivating biological agents and validation of effectiveness is required to prove that the inactivation method works. Biological agents and contaminated waste must be inactivated by either autoclaving or disinfection or both unless other methods are specified in the BA risk assessment and approved by the BSC. There are situations where autoclaving is not possible such as where there are biological agents and radioactively contaminated waste. Records must be kept.

9.8.1 Disinfection

Disinfectants must be appropriate for the relevant biological agents, 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 in solid and liquid materials and also 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 although 100% kill is normally required. The % kill to be achieved must be defined and appropriate methods of validation and monitoring that demonstrate this is achieved need to be specified and employed.

9.8.2 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 contaminated waste including all liquid waste

and waste destined for incineration be autoclaved unless there is a very good reason to use another method. Biological agents can be inactivated by autoclaving typically at 121ºC or 134ºC. Inactivation is defined as achieving a sufficient % kill commensurate with the risks although 100% kill is normally required. The % kill to be achieved must be defined and appropriate methods of validation and monitoring that demonstrate this is achieved need to be specified and employed. 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 the printout recording 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 log book that records the results of each run. Most commercially available indicators including standard autoclave tapes are not adequate for monitoring inactivation of waste, because they change colour either at temperatures considerably lower than 121ºC, or within minutes of reaching 121ºC, or in the absence of steam penetration, and therefore do not confirm that the appropriate conditions have been maintained for a sufficient time. A suitable indicator is Browne TST (Time, Steam, and Temperature) test strips. Note that there are several versions of these and you need to ensure you are using the appropriate strips for the temperature and time (eg 121ºC for 20 min or 134ºC for 5 min). These indicators can be obtained from commercial laboratory suppliers.

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. For autoclaving you should use one or both of the following standard statements.

- ‘All contaminated materials, including waste destined for incineration will be inactivated by autoclaving (100% kill) prior to disposal of waste or cleaning and recycling of reusable laboratory equipment. Autoclaves will be validated by

annual thermocouple mapping and each run will be monitored by continuous chart or digital recording of the temperature/time profile.'

- 'All contaminated materials including waste destined for incineration will be inactivated by autoclaving (100% kill) prior to disposal of waste or cleaning and recycling of reusable laboratory equipment. Autoclaves will be validated by annual thermocouple mapping and each run will be monitored using Browne TST (Time, Steam, and Temperature) test strips (TST indicator 121ºC for 20 min or 134ºC for 5 min).'

9.9 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 must 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.

9.10 Health Surveillance and Immunisation

Health surveillance is not usually required for most work with biological agents but may be required for certain occupational diseases or adverse health effects to check that people exposed to biological agents are not harmed during their work. It may be useful 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 particular 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 also be required for certain activities such as work involving laboratory animal allergens (LAA). Immunisation may be useful as a control measure to protect people against infection by certain biological agents. Vaccines must not be considered as a primary defence against infection but only as an additional control measure. Please see the Occupational Health Unit website and contacts for information and advice on health surveillance and immunisation.

9.11 Emergency Procedures

You need to describe the control measures and emergency procedures which will be used to protect people and the environment from exposure to the biological agents in the work in an emergency. You should provide details of the control measures that will be required to deal with incidents and emergencies that could cause people or the environment to be exposed to biological agents or an accidental release of

biological agents. 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 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 where needed.

The primary objective of the emergency procedures is the containment of the biological agents 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 standard operating procedures and spillage kits will be required. It is necessary to provide important emergency procedures as clear written instructions on display. For example 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. If an emergency occurs, procedures must be put into effect as soon as possible to minimise harm and return the situation back to normal as quickly as possible. Incidents and emergencies must be reported immediately or as soon as practicable to supervisors, safety advisers and managers and using the incident reporting form on the Health and Safety Department website.

You should provide details of the first aid procedures which would be needed to deal with the specific biological agents in this work in case of an accident or emergency. Training must be provided in all the relevant emergency first aid procedures. You should consider all of the relevant factors to establish effective emergency first aid procedures. This may include removing contaminated clothing as quickly as possible, removing contamination from skin, eyes and mouth by thorough washing with water, dealing with minor cuts and small puncture wounds, washing wounds with soap and water and dressing wounds. Use PPE if required when helping injured persons. Seek help promptly where required from first aiders, minor injuries unit or hospital. Emergencies should be referred to hospital and call ambulance if necessary. Explain the incident and biological agents involved to the medical staff.

9.12 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 coordinators 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 involved. The information and contact details of managers, safety advisers and coordinators, security, and emergency services are provided separately for example in emergency arrangements posters and websites.

9.13 Information, Instruction, Training and Supervision

You should provide details of the information, instruction, training, and supervision required for the work. 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. Standard operating procedures are required for every aspect of the work relating to high containment laboratories. It is important that information, instructions and training is appropriate to the level of risk and in a form which will be understood by those involved in the work. Information should be kept up to date taking into account any significant changes in the work. 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. 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.

10.Approval of BA Risk Assessments

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. Please note that all notifiable BA risk assessments require advice and approval from your BSA and BSC.

11. Notification and Licensing of Work with Biological Agents

COSHH requires HSE to be notified of premises and certain higher risk activities in advance of commencement of the work. The University of Edinburgh is notified to HSE as a single premises (207) for the purposes of work with biological agents. Group 3 and 4 biological agents and the group 2 agents and hazards Bordetella pertussis, Corynebacterium diphtheriae and Neisseria meningitidis activities have to be notified in advance to the HSE on an individual basis and specific consent obtained to carry out the work. HSE produces a CBA1 notification form to provide the information and request consent for the activity. A copy of the BA risk assessment for the work has to be provided as part of the notification. HSE will send acknowledgement of the notification and there are then various notification periods before work can start depending on the particular activity and whether that group of work has been done at the premises previously. HSE examines notifications and may request additional information, impose conditions and time limits to consents and revoke or vary them. HSE does not charge any fees for processing COSHH notifications. Work may not start until HSE has given written consent.

HSE must be notified of any subsequent significant changes to the scope or risks of the work covered by a BA risk assessment which has been notified under COSHH which may have a bearing on the risk assessment or controls. 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 would need to review and revise the risks of the project and make the appropriate changes to the BA risk assessment. If the changes are 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 BSC approval and no further action is required. If the changes are 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 BSC and HSE. This will require making changes to the BA risk assessment and sending the modified risk assessment and an updated CBA1 notification to the HSE. Note that you cannot change the scope of the original notified project. If the changes are 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 BSC and HSE. This will require a separate new BA risk assessment, BSC approval and CBA1 notification to HSE.

HSE must be notified when any notified project has ceased and all of the biological agents have been destroyed. Information submitted to HSE as part of a notification is placed on the public register on the HSE website. However in certain circumstances it is possible to claim confidentiality and exemption from public disclosure for some information but any claim has to be fully justified against stringent criteria and is subject to agreement by HSE. COSHH notifications do not have to be made if the activity has already been notified under the Genetically Modified Organisms (Contained Use) Regulations.

Serious animal pathogens and plant pathogens and pests are covered by specific animal health, plant health and environmental laws and may require licences from HSE on behalf of Animal Health or SASA on behalf of Plant Health or related agencies for possession, use, consignment, importation and exportation. Plant Health SASA specifies containment and control conditions for licensed pathogens and pests. The COSHH, SAPO, PHO 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, PHO or other relevant requirements then you must comply with all of the requirements for containment and control although the higher control requirements must be the minimum standard which must be followed.

Managers and principal investigators must keep a list of workers exposed to group 3 or 4 agents, including details of the type of work involved, the agents to which they have been exposed and records of exposures, accidents or incidents. There is an exemption to this requirement if the risk assessment indicates the activity does not involve a deliberate intention to work with or use the agent or that there is no significant health risk to exposed workers. The list must be kept for at least 40 years from the last known exposure or work. HSE must be notified of any accident involving a significant and unintended release of biological agents which present an immediate or delayed hazard to either human health and safety or the environment. This requirement is in addition to any notification requirements under Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR). The HSE notification must provide information on the circumstances of the incident, identity and quantity of biological agents concerned, any information necessary to assess the risks and the actions taken to deal with the accident. Note that all incident reports should be made to the Health and Safety Department and Biosafety Unit which make RIDDOR and other reports to HSE.

12. Registration of Pathogens and Toxins

You must register any group 2, 3 or 4 biological agents and any animal pathogens and plant pathogens or pests licence. You also need to register any pathogen or toxin on Schedule 5 list of the Anti-Terrorism, Crime and Security Act. You also need to register any species, strains or isolates not appearing in any of the above lists when there are reasonable grounds for suspecting it might be a previously unrecognised human, animal pathogen or plant pathogen or pest. The principal investigator must register their materials using the pathogen and toxins registration form using the RETAIN system. Principal Investigators must keep details of strains, origin, or other identification of the biological agents and of all individuals who have access to the materials. These records must be kept readily available for inspection and use in an emergency.

13. Monitoring of Work with Biological Agents

The principal investigator or manager must carefully monitor the work. If your BA risk assessment is suitable and sufficient for the work then each identified control measure is necessary to prevent or control exposure to risk of people, animals, plants and other aspects of the environment. Active monitoring is necessary to ensure that the control measures identified in the BA risk assessment are appropriate, effective and properly implemented. The review process will provide a point of reference to decide if the risk assessment remains valid but regular monitoring can identify problems at any stage. You should regularly check what people are doing and the activities to ensure that the work is done safely. The type of monitoring needed is proportional to the risks with higher risk work requiring a higher level of monitoring than lower risk work. Where problems are identified such as with the BA risk assessment, controls or the need for additional training or supervision then action must be taken and the necessary changes or improvements must be to the risk assessment, controls, instructions, training and supervision.

14. Records and Review of BA Risk Assessments and Controls

BA risk assessments and controls must be reviewed regularly and immediately if they are no longer valid such as if there has been a significant change to the scope or risks of the work. When reviewing the risk assessment the effectiveness of the preventative or control measures should be carefully re-examined. BA risk assessments should in any case be periodically reviewed at least annually. If review of the risk assessment concludes that changes are required then those changes must be made while following the correct process. When you have finished the work relating to a notified BA risk assessment then the project can be closed. However please note that a notified BA risk assessment project can legally only be closed if you destroy all biological agents or transfer the biological agents to another appropriate notified and approved BA risk assessment. Notified BA risk assessment projects can only be closed by notifying the BSC and HSE. The principal investigator or manager must keep the BA risk assessments, training records, maintenance and testing records and any other relevant records. The BA risk assessment should be completed by computer so that you will have electronic records, people can read it easily and the risk assessment can be easily reviewed and communicated. The records must be available for examination at any reasonable time by the managers, safety advisers, safety representatives and HSE inspectors.

Document version

Version number	Summary of change	Date and by whom
V1.0	**New template**	**June 2023 HE**
V.1.1	**Minor updates to text and links.**	**January 2024 PW**

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