Genetically Modified Organism Risk Assessment

1. Introduction

This guidance is provided to help you carry out genetically modified organism (GM) 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 genetically modified organisms by doing risk assessments and providing effective containment and controls. The Health and Safety at Work Act (HSWA), Environmental Protection Act (EPA) and Genetically Modified Organisms (Contained Use) Regulations (GMOCU) require controls for work with genetically modified organisms to protect people and the environment. In addition there are related laws which are involved in the control of genetically modified organisms including the Control of Substances Hazardous to Health Regulations (COSHH), the Animal Health Act (AHA) and Specified Animal Pathogens Order (SAPO), Plant Health Act (PHA) and Plant Health Order (PHO). Guidance on the law and practice relating to work with genetically modified organisms, GM risk assessments, containment and controls is provided by the Health and Safety Executive (HSE). 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 genetically modified organisms.

3. Summary

Here is a brief summary of some of the key requirements to help you carry out your GM risk assessments and work safely with genetically modified organisms.

1. GM risk assessments are used to assess the potential risks to people or the environment arising from work involving genetically modified organisms 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 the potential risks of harm to people.
5. Assess the potential risks of damage to the environment.
6. Assess the nature and level of risks to people and the environment.
7. Decide on the activity class 1, 2, 3, non-harmful or harmful.
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 genetically modified organisms 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 class 2, 3 or harmful genetically modified organisms.
16. Specified animal pathogen licences are required for work with serious animal pathogens including when they are genetically modified organisms.
17. Plant health licences are required for work with serious plant pathogens and pests including when they are genetically modified organisms.
18. GM risk assessments and other relevant records must be kept by Schools and principal investigators.
19. GM 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, GM Safety Committees and regulators.

4. Genetic Modification Safety Committees and Safety Advisers

There are Genetic Modification Safety Committees (GMSC) and safety advisers to provide advice on GM 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. School Genetic Modification and Biological Safety Committees (GMBSC) provide advice on both biological safety and genetic modification safety. Schools which carry out work with genetically modified organisms must be covered by a GMBSC which operates on their behalf. A GMBSC may cover more than one School but it must be formally appointed by each of the Schools it represents and report to all the Heads of Schools and their School Safety Committees.

The GMBSC should be constituted to represent both management, staff and advisers. There should be enough members with sufficient knowledge and experience to understand and recognise the risks arising from the work activities and the types of controls which may be required. The GMBSC is chaired and

administered by a GM Biological Safety Officer (GMBSO) who provides local advice on genetic modification safety. The University Biological Safety Adviser (UBSA) is a member of all GMBSC within the University to provide professional advice on biological safety but does not provide management approval of genetic modification work or GM risk assessments. The following roles are examples of what might be appropriate representation on a School GMBSC.

- School GM Biological Safety Officer to chair and administer the GMSC and cover the specified units.
- School Deputy GM Biological Safety Officers as needed to cover different buildings or units.
- School Biological Safety Advisers
- School Safety Adviser to liaise with the School safety Committee.
- Management representatives.
- Academic research representatives to provide expertise where necessary on particular areas of research work.
- Staff representatives.
- Representatives of each school or unit undertaking genetic modification work.
- Specialists to provide advice where needed such as on high containment laboratories, animal facilities, plant facilities or occupational health.
- University Biological Safety Adviser.

The GMBSO and GMBSC may refer matters to other University colleagues where specialist advice is needed or if additional technical expertise is needed then members can be sought from other Schools. Details of all GMBSC and their GMBSO contacts are provided here on the website.

- GM Biological Safety Committees and Biological Safety Adviser Contacts

School GMBSC must operate a strict permission system for any work involving genetic modification or genetically modified organisms in the University. Genetically modified organisms must not be brought into the University or any genetic modification work conducted until a suitable and sufficient GM risk assessment has been carried out and approved by the GMBSC and for higher risk work by HSE. GM risk assessments must also be reviewed and approved by the GMBSC whenever there are proposed changes or when there is reason to believe the assessment is no longer valid.

School GMBSO and GMBSC provide local advice on genetic modification safety, GM risk assessments and control measures. However the Schools and principal investigators are directly responsible for ensuring that work involving genetically modified organisms is properly managed with GM risk assessments carried out, approved and appropriate controls in place so that the work is conducted safely. The University provides standard GM risk assessment forms and guidance to help you carry out your work safely. Please contact your School GM Biological Safety Officer if

you need advice on any aspect of genetic modification safety including work involving genetically modified organisms, GM risk assessments and control measures.

5. GM Risk Assessment Forms

Please use the following GM risk assessment forms to carry out your risk assessments for all work involving genetically modified organisms.

- GM risk assessment forms

6. GM Risk Assessment and Control

GM risk assessments are required to be done before any work commences for any work involving the possession or use of genetically modified organisms involved in the work. A GM 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. GM 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 hosts, vectors, genetic materials, genetically modified organisms, the type of activity, class, containment level and all the necessary controls required to ensure that the work can be done safely while protecting people and the environment. GM 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.

GM 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 genetically modified organisms. 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 genetically modified organisms or if there was a release of the genetically modified organisms 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 Genetically Modified Organisms

There is detailed regulatory guidance and information on safe working with genetically modified organisms and GM risk assessment, containment and control which is available from the Health and Safety Executive (HSE) and the Scientific Advisory Committee on Genetic Modification (SACGM). Please see the links below to some important resources.

7.1 Guidance

- HSE SACGM Compendium of guidance Parts 1-6

7.2 Websites

- HSE Genetically Modified Organisms
- HSE SACGM Compendium of guidance

8. Assessing Risks of Work with Genetically Modified Organisms

Your GM 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 genetically modified organisms 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 Genetically Modified Organisms

Genetically modified organisms can be microorganisms, animal or plants. GMOCU defines genetically modified organisms as organisms produced by genetic

modification. Genetic modification is defined as the altering of the genetic material (DNA or RNA) of an organism in a way that does not occur naturally by mating and or natural recombination or both. Genetically modified organisms can be derived from microorganisms, animals or plants. A microorganism is defined as a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, and includes a virus, a viroid, an animal or plant cell in culture, an artificially created cell into which it is intended genetic material will be introduced and a prion. Organism means any biological entity capable of replication or of transferring genetic material and includes a microorganism but does not include a human, human embryo or human admixed embryo. Contained Use activity is where genetically modified organisms are cultured, stored, transported, destroyed, disposed of, or used in any way, and for which physical, chemical or biological barriers, or any combination are used to limit contact with and provide a high level of protection for humans and environment.

Genetically modified organisms are produced from a combination of a host, vector and genetic material. Genetically modified organisms (GMO) include genetically modified microorganisms (GMM) and larger genetically modified organisms (LGMO) which includes genetically modified animals (GM animals) and genetically modified plants (GM plants). GMM also includes certain infectious nucleic acids (eg GM infectious virus DNA or RNA) or proteins (GM TSE). There are some exemptions to which the regulations do not apply providing they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms as recipient or parental organisms, such as radiation or chemical mutagenesis, humans and human embryos.

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

The four activity classes of genetically modified microorganisms (GMM) and the basis of their classification are as follows.

- **Class 1 GMM**: Contained use of no or negligible risk for which containment level 1 is appropriate to protect human health and the environment.
- **Class 2 GMM**: Contained use of low risk for which containment level 2 is appropriate to protect human health and the environment.
- **Class 3 GMM**: Contained use of moderate risk for which containment level 3 is appropriate to protect human health and the environment.
- **Class 4 GMM**: Contained use of high risk for which containment level 4 is appropriate to protect human health and the environment.

The two classes of larger genetically modified organisms (LGMO) which includes GM animals and GM plants and the basis of their classification are as follows.

- **Non-Harmful to Humans LGMO:** Unlikely to cause harm to human health.
- **Harmful to Humans LGMO:** May cause harm to human health.
- **Non-Harmful to Environment LGMO:** Unlikely to cause or damage to the environment.
- **Harmful to Environment LGMO:** May cause damage to the environment.

8.3 Basic Requirements for Work with Genetically Modified Organisms

There are some basic university requirements for work with genetically modified organisms which are determined by the specific class of the work.

8.3.1 Class 1 GMM

The possession or use of class 1 genetically modified microorganisms (GMM) is subject to the following requirements.

1. **GM risk assessment:** A GM risk assessment is required for class 1 genetically modified microorganisms. Complete the appropriate GM risk assessment form.
2. **GM Safety Committee advice and permission:** Class 1 GM risk assessments require permission from the GM Safety Committee (GMSC) before bringing any genetically modified microorganisms into the University or starting work. The principal investigator (PI) must complete and send the GM risk assessment to the GMBSO for submission to the GMSC. The GMSC will review and advise the PI on the GM risk assessment and may request amendments. The GMSC will approve satisfactory GM risk assessments. The PI may then commence the work once all controls are in place.
3. **Monitoring:** The School and PI must monitor the work to ensure that the controls are used and effective.
4. **Review:** GM risk assessments must be reviewed and revised where there are any changes to the activity or the risks of the work. There are various aspects of the GM risk assessment which may require amendment including changes to the project, hosts, vectors, gene material or genetically modified microorganisms, personnel working on the project, location with details of the building and room numbers and closing date. The GMSC will approve satisfactory revised GM risk assessments. The PI may then commence the work once all controls are in place.
5. **Records:** The School and PI must keep all GM risk assessments including all revised versions and other relevant records.

8.3.2 Class 2 GMM

The possession or use of class 2 genetically modified microorganisms (GMM) is subject to the following requirements.

1. **GM risk assessment:** A GM risk assessment is required for class 2 genetically modified microorganisms. Complete the appropriate GM risk assessment form.
2. **GM Safety Committee advice and permission:** Class 2 GM risk assessments require permission from the GM Safety Committee (GMSC) and Health and Safety Executive (HSE) before bringing any genetically modified microorganisms into the University or starting work. The principal investigator (PI) must complete and send the GM risk assessment to the GMBSO for submission to the GMSC. The GMSC will review and advise the PI on the GM risk assessment and may request amendments. The GMSC will provisionally approve satisfactory GM risk assessments. GMSC approval for work to commence will only be issued once HSE permission has been obtained.
3. **HSE notification:** Class 2 GM risk assessments must be notified to the HSE using an HSE CU2 notification form. There is a fee that must be paid by the PI to HSE for this type of notification. The UBSA will advise the GMBSO and PI on completion of the CU2 form and do the HSE notification by sending the completed CU2 form and GM risk assessments to HSE. The PI must then pay the fee to HSE by BACS or by cheque. HSE may request further information about the work or request changes to the risk assessment. The UBSA will inform the GMBSO and PI of all HSE requests and advice and issue the HSE permission once received. The PI may then commence the work once all controls are in place.
4. **Monitoring:** The School and PI must monitor the work to ensure that the controls are used and effective.
5. **Review:** GM risk assessments must be reviewed and revised where there are any changes to the activity or the risks of the work. There are various aspects of the GM risk assessment which may require amendment including changes to the project, hosts, vectors, gene material or genetically modified microorganisms, personnel working on the project, location with details of the building and room numbers and closing date. The GMSC will provisionally approve satisfactory revised GM risk assessments. The UBSA will notify any significant changes to the project or risks to HSE. The UBSA will inform the GMBSO and PI of all HSE requests and advice and issue the HSE permission once received. The PI may then commence the work once all controls are in place.
6. **Records:** The School and PI must keep all GM risk assessments including all revised versions and other relevant records.

8.3.3 Class 3 GMM

The possession or use of class 3 genetically modified microorganisms (GMM) is subject to the following requirements.

1. **GM risk assessment:** A GM risk assessment is required for class 3 genetically modified microorganisms. Complete the appropriate GM risk assessment form.
2. **GM Safety Committee advice and permission:** Class 3 GM risk assessments require permission from the GM Safety Committee (GMSC) and Health and Safety Executive (HSE) before bringing any genetically modified microorganisms into the University or starting work. The principal investigator (PI) must complete and email the GM risk assessment to the GMBSO for submission to the GMSC. The GMSC will review and advise the PI on the GM risk assessment and may request amendments. The GMSC will provisionally approve satisfactory GM risk assessments. GMSC approval for work to commence will only be issued once HSE consent has been obtained.
3. **HSE notification and consent:** Class 3 GM risk assessments must be notified to the HSE using an HSE CU2 notification form. There is a fee that must be paid by the PI to HSE for this type of notification. The UBSA will advise the GMBSO and PI on completion of the CU2 form and do the HSE notification by sending the completed CU2 form and GM risk assessments to HSE. The PI must then pay the fee to HSE by BACS or by cheque. HSE may request further information about the work or request changes to the risk assessment. The UBSA will inform the GMBSO 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. **Monitoring:** The School and PI must monitor the work to ensure that the controls are used and effective.
5. **Review:** GM risk assessments must be reviewed and revised where there are any changes to the activity or the risks of the work. There are various aspects of the GM risk assessment which may require amendment including changes to the project, hosts, vectors, gene material or genetically modified microorganisms, personnel working on the project, location with details of the building and room numbers and closing date. The GMSC will provisionally approve satisfactory revised GM risk assessments. The UBSA will notify any significant changes to the project or risks to HSE. The UBSA will inform the GMBSO 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.
6. **Records:** The School and PI must keep all GM risk assessments including all revised versions and other relevant records.

8.3.4 Class 4 GMM

The possession or use of class 4 genetically modified microorganisms (GMM) is prohibited in the University.

8.3.5 Non-Harmful to Humans LGMO

The possession or use of larger genetically modified organisms (LGMO) which are not harmful to human health is subject to the following requirements.

1. **GM risk assessment:** A GM risk assessment is required for larger genetically modified organisms non-harmful to humans. Complete the appropriate GM risk assessment form.
2. **GM Safety Committee advice and permission:** Non-harmful to humans GM risk assessments require permission from the GM Safety Committee (GMSC) before bringing any larger genetically modified organisms into the University or starting work. The principal investigator (PI) must complete and send the GM risk assessment to the GMBSO for submission to the GMSC. The GMSC will review and advise the PI on the GM risk assessment and may request amendments. The GMSC will approve satisfactory GM risk assessments. The PI may then commence the work once all controls are in place.
3. **Monitoring:** The School and PI must monitor the work to ensure that the controls are used and effective.
4. **Review:** GM risk assessments must be reviewed and revised where there are any changes to the activity or the risks of the work. There are various aspects of the GM risk assessment which may require amendment including changes to the project, hosts, vectors, gene material or larger genetically modified organisms, personnel working on the project, location with details of the building and room numbers and closing date. The GMSC will approve satisfactory revised GM risk assessments. The PI may then commence the work once all controls are in place.
5. **Records:** The School and PI must keep all GM risk assessments including all revised versions and other relevant records.

8.3.6 Harmful to Humans LGMO

The possession or use of larger genetically modified organisms (LGMO) which are harmful to human health is subject to the following requirements.

1. **GM risk assessment:** A GM risk assessment is required for larger genetically modified organisms harmful to humans. Complete the appropriate GM risk assessment form.
2. **GM Safety Committee advice and permission:** Harmful to humans GM risk assessments require permission from the GM Safety Committee (GMSC) and Health and Safety Executive (HSE) before bringing any larger genetically modified organisms into the University or starting work. The principal investigator (PI) must complete and send the GM risk assessment to the GMBSO for submission to the GMSC. The GMSC will review and advise the PI on the GM risk assessment and may request amendments. The GMSC will provisionally approve satisfactory GM risk assessments. GMSC approval for work to commence will only be issued once HSE permission has been obtained.

3. **HSE notification:** Harmful to humans GM risk assessments must be notified to the HSE using an HSE CU2 notification form. There is a fee that must be paid by the PI to HSE for this type of notification. The UBSA will advise the GMBSO and PI on completion of the CU2 form and do the HSE notification by sending the completed CU2 form and GM risk assessments to HSE. The PI must then pay the fee to HSE by BACS or by cheque. HSE may request further information about the work or request changes to the risk assessment. The UBSA will inform the GMBSO and PI of all HSE requests and advice and issue the HSE permission once received. The PI may then commence the work once all controls are in place.
4. **Monitoring:** The School and PI must monitor the work to ensure that the controls are used and effective.
5. **Review:** GM risk assessments must be reviewed and revised where there are any changes to the activity or the risks of the work. There are various aspects of the GM risk assessment which may require amendment including changes to the project, hosts, vectors, gene material or larger genetically modified organisms, personnel working on the project, location with details of the building and room numbers and closing date. The GMSC will provisionally approve satisfactory revised GM risk assessments. The UBSA will notify any significant changes to the project or risks to HSE. The UBSA will inform the GMBSO and PI of all HSE requests and advice and issue the HSE permission once received. The PI may then commence the work once all controls are in place.
6. **Records:** The School and PI must keep all GM risk assessments including all revised versions and other relevant records.

8.3.7 Non-Harmful to Environment LGMO

The possession or use of larger genetically modified organisms (LGMO) which are not harmful to the environment is subject to the following requirements.

1. **GM risk assessment:** A GM risk assessment is required for larger genetically modified organisms non-harmful to environment. Complete the appropriate GM risk assessment form.
2. **GM Safety Committee advice and permission:** Non-harmful to environment GM risk assessments require permission from the GM Safety Committee (GMSC) before bringing any larger genetically modified organisms into the University or starting work. The principal investigator (PI) must complete and send the GM risk assessment to the GMBSO for submission to the GMSC. The GMSC will review and advise the PI on the GM risk assessment and may request amendments. The GMSC will approve satisfactory GM risk assessments. The PI may then commence the work once all controls are in place.
3. **Monitoring:** The School and PI must monitor the work to ensure that the controls are used and effective.

4. **Review:** GM risk assessments must be reviewed and revised where there are any changes to the activity or the risks of the work. There are various aspects of the GM risk assessment which may require amendment including changes to the project, hosts, vectors, gene material or larger genetically modified organisms, personnel working on the project, location with details of the building and room numbers and closing date. The GMSC will approve satisfactory revised GM risk assessments. The PI may then commence the work once all controls are in place.
5. **Records:** The School and PI must keep all GM risk assessments including all revised versions and other relevant records.

8.3.8 Harmful to Environment LGMO

The possession or use of larger genetically modified organisms (LGMO) which are harmful to the environment is subject to the following requirements.

1. **GM risk assessment:** A GM risk assessment is required for larger genetically modified organisms harmful to environment. Complete the appropriate GM risk assessment form.
2. **GM Safety Committee advice and permission:** Harmful to environment GM risk assessments require permission from the GM Safety Committee (GMSC) before bringing any larger genetically modified organisms into the University or starting work. The principal investigator (PI) must complete and send the GM risk assessment to the GMBSO for submission to the GMSC. The GMSC will review and advise the PI on the GM risk assessment and may request amendments. The GMSC will approve satisfactory GM risk assessments. The PI may then commence the work once all controls are in place.
3. **HSE notification:** Harmful to environment GM risk assessments are not required be notified to the HSE.
4. **Monitoring:** The School and PI must monitor the work to ensure that the controls are used and effective.
5. **Review:** GM risk assessments must be reviewed and revised where there are any changes to the activity or the risks of the work. There are various aspects of the GM risk assessment which may require amendment including changes to the project, hosts, vectors, gene material or larger genetically modified organisms, personnel working on the project, location with details of the building and room numbers and closing date. The GMSC will approve satisfactory revised GM risk assessments. The PI may then commence the work once all controls are in place.
6. **Records:** The School and PI must keep all GM risk assessments including all revised versions and other relevant records.

8.4 Description of the Activity

You should provide a sufficiently detailed description of the work to enable workers, other people and non-experts to understand the nature of the work. You need to

describe the genetically modified organisms which will be used and to which people or the environment could be exposed in the work and the specific methods involved in the work. You should consider all of the relevant characteristics including the pathogenic, toxic, allergenic, carcinogenic and environmental properties of the hosts, vectors, genetic material and genetically modified organisms.

8.5 Host Organisms

You should provide details of the host organisms that you intend to use in this project. Host organisms include microorganisms, animals and plants. State the scientific names, strains and provide relevant references.

8.6 Vectors

You should provide details of the vector systems that you intend to use on this project. State the names of the vectors and provide relevant references.

8.7 Genetic Materials

You should provide details of the origins, nature of modifications and intended function of the genetic materials that you intend to use on this project. Genetic material includes nucleic acid sequences of any kind whether coding or non-coding, whole or part of gene sequences. You should define the types of gene sequences that you intend to use including the designations of specific genes or classes of genes, cDNA, genomic sequences or gene libraries. You should state the intended function of the gene including whether or not you intend to carry out genes expression. It is important to specify whether based on evidence the gene sequences are expected to be harmless genes, harmful genes and undefined genes to humans or the environment. Your work may include one or more potential types of genetic material. It is important to provide relevant references to support statements made about the nature of genetic material.

8.8 Genetically Modified Organisms

You need to describe the final genetically modified organisms which are derived from the combination of hosts, vectors and genetic material. You must consider the ways by which harm could be caused to people or the environment from exposure to the genetically modified organisms. The risk assessment and classification procedures required by the GMOCU are complicated and difficult to summarise but depend on the type of activity. You should read and follow the detailed guidance on risk assessments and controls which are given in the HSE SACGM Compendium of guidance. Basically the risk assessment starts with the description of the risks relating to the hosts, vectors, genetic material and then to the final genetically modified organisms. The risks of the genetically modified organisms to human health and the environment are then determined and the activity class assigned. The containment level and

control measures which are necessary to protect human health and the environment from exposure to genetically modified organisms must then be established for the work. Different types of GM risk assessments must be carried out for genetically modified microorganisms (GMM) and larger genetically modified organisms (LGOM) which includes genetically modified animals (GM animals) and genetically modified plants (GM plants). Bear in mind that genetic modification work may also involve a combination of different types of genetically modified organisms which all need to be properly assessed and adequately controlled. For example GMM may be used to infect or introduced into LGMO (GM animals or plants) in which case the risks of the GMM and the LGMO have to be assessed in their own right and then the combined risks of the GMM and LGMO have to be assessed and then properly controlled.

8.9 Risk Evaluation

You have considered the ways by which harm could be caused from exposure to the genetically modified organisms 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 genetically modified organisms in the work.

8.9.1 Assessment of Risk to Human Health

You need to decide on the level of risk to human health from exposure to genetically modified organisms 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.

8.9.2 Assessment of Risk to Environment

You need to decide on the level of risk to the environment from exposure to genetically modified organisms 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.

8.9.3 Estimating the Risk Level

The risk of the activity is determined by evaluating both the genetically modified organisms 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 Genetically Modified Organisms

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 genetically modified organisms in the work. GMOCU requires that the risks of exposure to genetically modified organisms is prevented or where this is not reasonably practicable then adequately controlled to reduce the risk of exposure to an acceptable level. The purpose of the GM risk assessment process is to enable you to select the most suitable controls or combination of controls that are proportionate to the risk. Control measures are systems and actions used to reduce the risks of exposure to genetically modified organisms. 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 genetically modified organisms under GMOCU and these are described in the HSE SACGM Compendium of guidance. The appropriate containment level is derived from the activity classification of the genetically modified organisms. GMOCU specifies minimum containment levels required for the following types of work.

- **Containment level 1 (CL 1)** is required as a minimum for work with class 1 genetically modified microorganisms.

- **Containment level 2 (CL 2)** is required as a minimum for work with class 2 genetically modified microorganisms.
- **Containment level 3 (CL 3)** is required as a minimum for work with class 3 genetically modified microorganisms.
- **Containment level 4 (CL 4)** is required as a minimum for work with class 4 genetically modified microorganisms.
- **Containment level 1 (CL 1)** is required as a minimum for work with non-harmful larger genetically modified microorganisms.
- **Containment level 2 (CL 2) or 3 (CL 3)** is required as a minimum for work with harmful larger genetically modified organisms.

There are minimum and recommended control measures which are required for work at each containment level and these are specified in the HSE SACGM Compendium of guidance. 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 GM risk assessment and implemented. In some cases depending on the nature of the genetically modified organisms 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 GM 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 genetically modified organisms. 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 genetically modified organisms 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 genetically modified organisms, 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 total enclosure (eg glove box, anaerobic cabinets, flexible film isolators or class III safety cabinets), partial enclosure (eg class I or II 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 genetically modified organisms at work.

Control measures which are used to prevent or control exposure to genetically modified organisms 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 genetically modified organisms. 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 genetically modified organisms. 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 genetically modified organisms 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 genetically modified organisms 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 genetically modified organisms 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 genetically modified organisms 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 genetically modified organisms. You should consider the potential routes of exposure to the genetically modified organisms 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. The type of RPE used must be suitable to adequately protect against the specific genetically modified organisms. Simple disposable dust masks do not provide protection against genetically modified organisms 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 Genetically Modified Organisms

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

9.8 Inactivation of Genetically Modified Organisms

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

9.8.1 Disinfection

Disinfectants must be appropriate for the relevant genetically modified organisms used in the work. The effectiveness of many disinfectants can vary considerable depending on the genetically modified organisms, concentration, exposure time, pH and presence of organic matter, liquids or solids. Disinfectants may be used for inactivating genetically modified organisms 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 genetically modified organisms 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 genetically modified organisms contaminated waste including all liquid waste and waste destined for incineration be autoclaved unless there is a very good reason to use another method. Genetically modified organisms 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 genetically modified organisms 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 genetically modified organisms but may be required for certain occupational diseases or adverse health effects to check that people exposed to genetically modified organisms 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 genetically modified organisms 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 genetically modified organisms. 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 genetically modified organisms 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 genetically modified organisms or an accidental release of genetically modified organisms. 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 genetically modified organisms 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 genetically modified organisms 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 genetically modified organisms 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 genetically modified organisms involved to the medical staff.

9.12 Emergency Planning

GMOCU requires the production of a suitable emergency plan where the GM risk assessment indicates that the result of any foreseeable accident could seriously affect the health and safety of people outside the premises where the activity takes place or seriously damage the environment. Plans should be reviewed and revised at appropriate intervals and emergency services must be informed. Emergency plans are unlikely to be necessary for most activities involving genetically modified organisms.

9.13 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 genetically modified organisms involved. The information and

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

9.14 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 GM 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 GM risk assessments require advice and approval from your GMBSO and GMSC.

11. Notification and Licencing of Work with Genetically Modified Organisms

11.1 HSE Notifications

GMOCU 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 genetically modified organisms. Class 2 and 3 GMM and harmful to human health LGMO activities have to be notified in advance to the HSE on an individual basis and specific consent obtained to carry out the work. Harmful to environment LGMO do not require any notification. HSE produces a CU2 notification form to provide the information and request consent for the activity. A copy of the GM risk assessment for the work has to be provided as part of the notification. A single notification may be made under of a connected programme of work at one site or a single activity carried out by the same person at more than one site. 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 activity class 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. Note that HSE charges fees for processing GMOCU notifications. Work may not start until HSE has given written acknowledgement or consent depending on the activity.

HSE must be notified of any subsequent significant changes to the scope or risks of the work covered by a GM 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 would need to review and revise the risks of the project and make the appropriate changes to the GM 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 GMSC 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 GMSC and HSE. This will require making changes to the GM risk assessment and sending the modified risk assessment and an updated CU2 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 GMSC and HSE. This will require a separate new GM risk assessment, GMSC approval and CU2 notification to HSE.

HSE must be notified when the project has ceased and all of the genetically modified organisms 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.

GMOCU requires all GMO activities including all GM risk assessments, controls, notifications and all changes to be advised on and approved by the School GM Safety Committee. The GMBSO chairs the GMSC and is the point of contact for all principal investigators on all matters relating to work with genetically modified organisms, GM risk assessments and controls. The GMSC must be informed of all proposed GM risk assessments for all classes and will advise the principal investigator and issue approval for the work. The GMSC must be informed of all proposed changes to approved GM risk assessments and HSE notified projects and will decide whether these are significant and will communicate with the BSU. The GMSC and BSU will advise principal investigators and will deal with all notifications to HSE, provide feedback and issue the relevant approvals and consents.

11.2 SAPO and PHO Licenses

Serious animal pathogens and plant pathogens and pests are covered by specific animal health or plant health laws and require licences for possession, use, consignment, importation and exportation. The SAPO or PHO licences specify specific containment and control conditions. The COSHH, SAPO and PHO 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 GMOCU, COSHH, SAPO 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.

11.3 Lists of Exposed Workers

Managers and principal investigators must keep a list of workers using class 3 or 4 genetically modified organisms, including details of the type of work involved, the genetically modified organisms to which they have been exposed and records of exposures, accidents or incidents. The list must be kept for at least 40 years from the last known exposure.

11.4 HSE Incident Reports

HSE must be notified of any accident involving a significant and unintended release of genetically modified organisms 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 genetically modified organisms 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. HSE Notification Fees

The University of Edinburgh has made notification to the Health and Safety Executive as a single centre GM 207 for genetic modification activities involving classes 1, 2 and 3 genetically modified microorganisms (GMM) and larger genetically modified organisms (LGMO). Class 1 activities do not require payment of any fees. Class 2 and 3 GMM activities and hazardous LGMO activities require the payment of fees to the HSE. The full schedule of fees for GM activity notifications is available on HSE website.

- HSE Fees

13. Monitoring of Work with Genetically Modified Organisms

The principal investigator must carefully monitor the work. If your GM 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 GM 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 GM 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 GM Risk Assessments and Controls

GM 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 the risks of the work. When reviewing the risk assessment the effectiveness of the preventative or control measures should be carefully re-examined. GM 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 GM risk assessment then the project can be closed. However please note that a GM risk assessment project can legally only be closed if you destroy all genetically modified organisms or transfer the genetically modified organisms to

another appropriate approved GM risk assessment. Notified GM risk assessment projects can only be closed by notifying the GMSC and HSE. The principal investigator must keep the GM risk assessments, training records, maintenance and testing records and any other relevant records. The GM 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 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**
V1.1	**Minor updates to text and links**	**January 2024 PW**

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