Northumbria University
NEWCASTLE

Genetically Modified Organisms (including cellular and animals) Code of Practice

Reviews and Revisions

Date	Reason	Reviewer	Next review date	Approved by
21/02/2017	New Document	L Rounds	21/02/2018	UHSMG
03/01/2018	Annual Review	Lynn Dover Anita Sampson	03/01/2019	Emrys Pritchard
15/01/2019	Annual Review	Lynn Dover Adam Swinburne	31/01/2020	Emrys Pritchard
14/08/2019	Format changed Names of individuals removed from the committee section	Adam Swinburne	14/08/2021	Emrys Pritchard

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Introduction

Work with genetically modified organisms is subject to the legislative requirements of the Genetically Modified Organisms (Contained Use) Regulations 2014 and the GMO (Contained Use) Regulations 2014 Approved Code of Practice and must be carried out in a way that prevents undue risk to human health or the environment.

Accordingly, Northumbria University is a registered GM Centre (Centre number GM 826). The registered locations for the contained use of genetically-modified organisms are the laboratories of the Faculty of Health & Life Sciences in Ellison Building. Use at other locations must be considered by the University Health, Safety and Wellbeing Management Group and approved before work commences.

General Principles

GMOs must not be ordered, received or used on site unless registered with the University GMO Officer. Work (including culture, manipulation, processing and destruction) will only be carried out after prior assessment of the associated hazards and ensuring that suitable facilities, local procedures and organisational arrangements are in place, which will reduce risk to low or effectively zero.

Work may only be carried out by trained competent workers with adequate supervision and may not commence without:

- A genetic modification (GM) risk assessment, which is required by law for the use or possession of any genetically-modified organisms.

- Where deemed necessary, the University GM Safety Committee has successfully notified or sought permission from the HSE.

Definitions

Genetic Modification

The legislation defines genetic modification (GM) as the altering of the genetic material in an organism in a way that does not occur naturally by mating or natural recombination, or both.

The genetic modification activity class directly relates to the appropriate containment level for the work activity based on both the nature of the recipient organisms and the nature of the modification.

Class	Description
1	Activities of no or negligible risk, for which containment level 1 is appropriate to protect human health and the environment.
2	Activities of low risk, for which containment level 2 is appropriate to protect human health and the environment.
3	Activities of moderate risk, for which containment level 3 is appropriate to protect human health and the environment.
4	Activities of high risk, for which containment level 4 is appropriate to protect human health and the environment.

Organism

This term covers all organisms, including multicellular organisms, such as animals, plants, insects, nematodes, i.e. larger GMOs, as well as micro-organisms (including those made synthetically). The definition does not include humans, human embryos and human admixed embryos, which are excluded from these regulations.

Micro-organism

This term covers bacteria, fungi and viruses, as well as cell and tissue cultures from plants, animals or humans. Naked nucleic acid, oligonucleotides, synthetic DNA, plasmids or liposomes are not considered to be micro-organisms. However, full-length copies of the genomes of viruses (whether recombinant or synthetically made) that have the potential to be infectious in their own right are considered to be micro-organisms (even when they are not encapsulated or enveloped). In the case of negative strand viruses, the notion of having the potential to be infectious should include situations where the infectivity of the genome is dependent on the presence of an exogenous source of polymerase. Plant pollen, animal ova and sperm are not considered to be micro-organisms. However, where they are from larger GMOs, the same controls apply for minimising dissemination of larger GMOs.

Contained Use

Any activity involving GMOs where barriers are used to limit contact with and protect humans and the environment. Barriers used must provide a high level of safety for humans and the environment. These barriers can be:

- **Physical**: This would normally take the form of a building, a room, a container, an obstruction, equipment or physical process (e.g. ventilation, UV irradiation) used to prevent escape or exposure to the GMO.

- **Chemical:** This can be interpreted as the use of chemicals to inactivate/ destroy a GMO before waste disposal, or the use of chemicals to prevent escape of larger GMOs (e.g. a chemical moat used to contain GM insects).

- **Biological:** Where a GMO has inherent or engineered characteristics that mean it is attenuated, disabled or rendered unable to survive outside of a specialised environment, this is considered to provide a biological barrier. Where such barriers are included in the risk assessment, these characteristics should be well understood and robust, e.g. be stable, unable to be complemented and the result of multiple mutations.

GM Safety Committee

Composition of the Committee

Chair –Assistant Director, Health and Safety and Sustainability
University GMO Officer
Health and Life Sciences GMO Officer
Health and Life Sciences Faculty Technical Manager

Objectives

- To provide the forum for the exchange of information, ideas and concerns about biological safety issues between the University and faculty staff involved with GMO's, in order to maintain the highest standard of safety awareness and practice in accordance with current legislation.
- To stimulate interest in GMO safety issues and to provide a channel by which ideas and issues can be brought to the attention of University management for consideration.
- To fulfill the legislative requirements, to assess and control work with GMO's.
- To advise on the accuracy and adequacy of the risks assessments undertaken.
- To audit the application of risk assessments.
- To ensure the correct notifications are made to the HSE.

Function of the Chairperson

- To organise a minimum of four meetings per year.
- To ensure minutes of the meeting are kept and published within 1 week of the meetings.
- To ensure any matters arising at the meeting are referred to the Assistant Director – Health, Safety & Sustainability and responses fed back to the committee.

Functions of the Committee

- To investigate potential GMO safety matters within their faculty.
- To identify and control potential GMO hazards in their faculty.
- To carry out, when required, audits of GMO activities.
- To ensure departmental records involving GMOs are kept.
- To ensure compliance in their faculty to this document.

Responsibilities

A risk assessment is required before starting any work involving GM. The GM risk assessment supersedes a COSHH risk assessment. If you do not already have a COSHH assessment for the GM project, you do not need to complete one.

The Principal Investigator (PI) is required to conduct a risk assessment prior to using any GMO. The risk assessment must:

- Identify any hazards to humans or the environment resulting from the recipient, insert, vector and final GMO.
- Identify any potentially harmful effects; (e.g. harmful properties of recipient and donor micro-organisms, vectors or inserted material, consulting the ACDP Approved List of Biological Agents) and assigning a provisional level of risk associated with the GMM.
- Characterise the proposed activity.
- Describe the severity of any potentially harmful effects.
- Consider of how and where the contained use will be undertaken (including any non-standard procedures or higher risk environments) and adjusting the provisional level of risk accordingly.
- Select the appropriate containment measures based on the provisional (i.e. the unmitigated) level of risk and assign the contained use to the appropriate containment level and classify the activity according to that level.
- Define disposal of waste and effluent.
- Review and reconsider the classification in light of the completed assessment.
- Classify the GMO into class 1,2,3 or 4 (see below).
- Be approved by the Faculty GMO Officer.

Once the risk assessment is approved, the PI must communicate the risk assessment to those involved and ensure all safety measures are followed.

The Faculty GMO Officer is required to:

- Assess the risk assessment and discuss any changes required with the PI and the GM Safety Committee.

- Approve the ordering of the GMO.
- Update the GMO register.
- Keep a register of all GMO activities.

The University GMO Officer is required to:

- Ensure the notification to the HSE is approved for the correct containment level.
- Audit the risk assessment regularly.
- Audit the GMO Register.

Approvals Process (new/modification or cessation)

The University does not have facilities to handle Class 3 and 4 materials. Some GMOs based on ACDP Hazard Group 3 organisms might be used as per Class 2 GMOs with appropriate exemptions agreed with HSE relating principally to respiratory protection.

Approval Stage	Activity Class 1	Activity Classes 2 and 3
GM Risk Assessment	PI completes the appropriate GM risk assessment form, taking advice as necessary.	
GM Safety Committee (GMSC)	Before bringing any genetically modified organisms into the University or starting work, GM risk assessments require permission from: • University GM Safety Committee (GMSC)	Before bringing any genetically modified organisms into the University or starting work, GM risk assessments require approval from: • University GM Safety Committee (GMSC) • Health and Safety Executive (HSE)
	On completion of a GM risk assessment form: • PI emails GM risk assessment to GMSC. • GMSC reviews and may advise PI and request amendments (if so - return to top of stage). • GMSC EITHER approves satisfactory GM risk assessments and e-mails satisfactory OR rejects back to PI. • If approved, Faculty GM Officer records details of the project and emails approval to PI. • PI may then commence work.	On completion of a GM risk assessment form: • PI emails GM risk assessment to GMSC. • GMSC reviews and advises PI and may request amendments (if so return to top of stage). • GMSC approves satisfactory GM risk assessments or rejects pending modifications. • GMSC emails satisfactory GM risk assessments • GMSC provisionally approves project. • Approval will only be issued once HSE permission has been obtained (second approval stage below).

Approval Stage	Activity Class 1	Activity Classes 2 and 3
HSE notification and second GMSC approval	University has approval for the laboratories of Applied Sciences (within the faculty of Health & Life Sciences) to be used as a premises for contained use. No further notifications are required for use at these sites.	**GM risk assessments to be notified to HSE with fee paid by PI:** • GMSC emails PI an HSE CU2 notification form along with BACS payment details. • PI completes CU2 and returns to GMSC. • GMSC sends completed CU2 and approved GM risk assessment to HSE. • PI pays the fee to HSE by BACS. • HSE may request further information about the work or request changes to the risk assessment. • GMSC emails any HSE advice and requests to PI. **If HSE required amendments:** • PI emails amended form to GMSC • GMSC reviews and if satisfactory emails to HSE. • GMSC emails any HSE advice and requests to the PI. **If HSE are satisfied:** • HSE notifies GMSC in writing. • GMSC approves GM risk assessments. • GMSC emails approval certificate and copy of HSE approval letter to PI. A copy is also stored in the Share Point GM Risk Assessment Library. • PI may then commence work.
Monitoring	• PI must monitor the work to ensure controls are effective and all workers comply with controls identified in GM risk assessments.	
Records	• PI must keep all GM risk assessments and other relevant records in the appropriate laboratories. • Keep electronic versions of all records.	

Modifications to an approved project

Minor modifications to an approved project should be submitted to your GM Officer. The GMSC will review these and will issue the approval certificate.

Significant changes require a review and replacement of the original risk assessment. Certain changes to Activity Class 2 and 3 projects are notifiable to HSE. Significant changes to notified activities that have consequences for the risks arising from the activity incur a fee (approximately £1000). Therefore, it is recommended that new Activity Class 2 and 3 risk assessments cover all foreseeable avenues of research to avoid subsequent additional fees.

Cessation or transfer of an approved project

Inform Faculty GM Officer when:

- Your GM project has finished and all associated GM materials have been destroyed.
- Your GM project has finished and all associated GM materials have been donated to someone else.
- You move to another University or company and take your samples with you.

This is important because:

- An amendment to the GM Register is required.
- HSE must be notified if Activity Class 2 or 3 projects have ceased (there is no fee for this).
- HSE must be notified if an Activity Class 2 or 3 project is transferred to another University or company (there is no fee for this).
- Samples may be classed as dangerous goods for transportation, and require special transport arrangements.
- If you have finished working on a GM project but you are keeping GM materials in storage, a valid risk assessment is still required.

Training

The GMSC will maintain a register of staff, students and visitors who work with GMOs. This will record the training needs of the individual and how they have been met. Training needs can be discussed with the Faculty GMO Officer.

Forms

Risk assessment forms can be accessed here.

Related Documents

Supporting HSE documentation can be found here.