Introduction

Genetic modification is the modification of genetic material of an organism (either DNA or RNA) using a method that does not occur in nature and where the modification can be replicated and/or transferred to other cells or organisms.

Gene editing is the alteration of the genetic material of a living organism by inserting, replacing, or deleting a DNA sequence, typically with the aim of improving some characteristic of a crop or farm animal or correcting a genetic disorder.

This guidance provides the arrangements for working with genetically modified organisms (GMOs) this includes genetically modified micro-organisms (GMMs), animals or plants, you must assess the risks to human health and the environment.

Before commencing or bidding for grant/research funding to work with GMO's on behalf of the University, approval must be received from the Genetically Modified Safety Committee (GMSC), Chaired by Associate Dean Research, Knowledge Exchange and Innovation, Faculty of Earth and Life Sciences.

What are GMOs?

Cells and DNA

Living things are made of building blocks called cells – this helps to understand genetic modification (GM). Higher animals are made up of hundreds of thousands of cells (many of which are specialised, such as muscle cells and nerve cells) while bacteria consist of a single cell. At the centre of each cell are long chains of a complex chemical, known as DNA (deoxyribonucleic acid). These DNA chains form the genetic material of the cell. The information encoded on DNA is sub-divided into blocks known as genes.

GMOs

All living organisms – animals, plants and micro–organisms (such as bacteria or fungi) – carry copies of all their genes in their cells. Those genes hold the information that determines the organism's particular form and function. Specific characteristics of an organism may be linked to particular genes or combinations of genes. Genetically modified organisms (GMOs), therefore, are organisms whose genes have been artificially altered to modify their characteristics in some way or another. For example, medicinal products such as insulin, blood factor VIII and human growth hormone were formerly produced from humans and animals and some carried a slight risk of transmitting disease. Now, with the use of GM technology, pure and safe equivalents can be produced using GMOs and industrial scale quantities are possible by growing such modified bacteria on a large scale in fermenters.

Genetic modification

GM is the process of altering the genetic material of an organism by use of a method that does not occur in nature. Often GM involves isolating and removing the DNA encoding a single gene from one organism, manipulating it outside the cell (in a laboratory) and reinserting it into the same organism or into the genetic material of another organism. The aim of GM is often to introduce a new or altered characteristic to the target organism.

GMOs may be plants, animals or (most commonly) micro-organisms (including bacteria, viruses' parasites and fungi). Where the GMO is a micro-organism it is typically referred to as a genetically modified micro-organism (GMM). An important point to note about GMOs is that in the case of humans, even if they have undergone genetic modification as a result of, for example, gene therapy, they are not regarded as GMOs in HSE's legislation. A GMO that is a plant or an animal can be referred to as a larger GMO (LGMO).

What is 'contained use'?

Contained use is any activity in which GMOs are cultured, stored, transported, destroyed, disposed of or used in any other way and for which physical, chemical or biological barriers are used to limit contact with humans or the environment to ensure a high degree of safety.

- Activity class 1 - Activities of no or negligible risk, for which Containment Level 1 is appropriate to protect human health and the environment
- Activity class 2 - Activities of low risk, for which Containment Level 2 is appropriate to protect human health and the environment
- Activity class 3 - Activities of moderate risk for which Containment Level 3 is appropriate to protect human health and the environment
- Activity class 4 - Activities of high risk for which Containment Level 4 is appropriate to protect human health and the environment

Typical contained use facilities would be microbiology laboratories, animal houses, plant growth rooms and glasshouses, industrial fermenters used for large scale production of enzymes or therapeutics, and facilities to contain genetically modified farm animals.

GMOs that are deliberately introduced into the environment for experimental purposes, or placed on the market, for example, as food or for medicinal purposes, are obviously not contained. They are outside the scope of the Regulations on contained use and regulated under other legislation.

The vast majority of work with GMOs in contained use is inherently safe. This is because most work involves the insertion of genes into micro-organisms that have been deliberately 'crippled' with disabling mutations so that they will not grow outside of the controlled environment of a laboratory test tube. Safety is thus built into the experimental design. However, a small number of activities involve GMMs that are not disabled and still capable of growth outside of the laboratory. It is, therefore, very important to assess the risks of all activities and make sure that any necessary controls are put in place to protect people and the environment.

Risk assessments for such work must be submitted to the regulatory authorities for approval before work can commence. The regulatory authorities are thus in a position to ensure that the work is carried out in facilities and equipment that contain the infectious materials during the work activities. The assignment of these containment measures tends to be done on a precautionary basis to allow some margin of safety, where there is any uncertainty over the risks. Gradually, as knowledge increases, some precautionary safeguards are being removed, where there is clear evidence that they are not necessary, and efforts are being focused on ensuring the safety of those projects where there are tangible hazards. The safety record in this industry is extremely good.

Gaining approval for GMO activities

All GMO activities undertaken on University premises or on behalf of the University at another location, must be approved and recorded on the GMO activity log, held by the Genetically Modified Safety Committee.

The GMO risk assessment process is in three parts:

- Part A – Initial request and base assessment
- Part B – Risk assessment

- Part C – review

Part A – Initial request and base assessment

The template document is to be completed in full by the Principal Investigator or Delegated Researcher, detailed on the form as the proposer. On completion, the initial request and base assessment should be emailed to GMSC Secretary sian.porter@aber.ac.uk.

On receipt of the GM Risk assessment template, the document will be uploaded to the GMSC Microsoft Teams site and allocated a Genetically Modified Risk Assessment (GMRA) number.

It will be reviewed in three stages:

1. Infrastructure – the initial request and base assessment will be reviewed by Senior Research Officer, Department of Life Sciences. This will confirm the proposed location for the work has capacity, is suitably equipped and has no outstanding significant infrastructure defects.
2. Management system – this stage will be completed by the AU HS&E Team and will check the risk assessment process; relevant GM training has been received; health surveillance requirements identified, if needed; changes to AU Public Register for Centre Number; HSE Notification requirements.
3. Technical Peer Review – this stage is completed by the GMRA panel - Identify any additional risk control measures; any additional technical improvements identified; confirm agreement with the risk category. At least 3 peer reviews will be obtained.

On completion and agreement of the three stages, the GMSC will be notified of the initial request and base assessment via email. The group will be offered 7 days in which to provide any reason for the request not to progressed to the GMSC Secretary.

The new activity will be placed on the GMO activity log to be monitored by the GMSC.

Part B – Risk Assessment

Where required for low, medium or high risk category as defined by the Contained Use Regulations 2014, colleagues will continue with the GMO risk assessment process. On completion of part B, risk assessment it should be emailed to the GMSC secretary sian.porter@aber.ac.uk

On receipt of the GM Risk assessment template, the document will be uploaded to the GMSC Microsoft Teams site and allocated a Genetically Modified Risk Assessment (GMRA) number.

The workflow will follow part A, with all stage parties' review the information in part A and part B for the approval method.

It is aimed to process Part A and B requests within 20 working days of receiving the email application. Should colleagues wish to discuss the progress of their GMRA, please contact GMSC Secretary Sian.porter@aber.ac.uk in the first instance.

HSE Notification

In the case of work that requires prior notification to the Health and Safety Executive (HSE) (Class 2 and above), you will need to:

- Completed the GMRA and obtain approval from the GMSC, as detailed above.
- Complete the HSE form (CU2); use the word form as it already contains relevant administrative information.

- Pay a fee to HSE - Current HSE fees by raising a purchase order number through your financial accounts.
- Submit to hasstaff@aber.ac.uk , the completed CU2 form, a PDF version of the approved GMRA and the PO number.

On notification to the HSE, an invoice will be requested to pay the fee which will be sent to the finance email system for payment to be made.

The HS&E Team member will advise the GMSC of the progress and approval of the HSE notification for GMO activity for work to commence.

Part C – Review GM Risk Assessments

All GMO activities will review their risk assessments on at least a 12 monthly period, completing part C of the GMO risk assessment form. The Completed part C of the form should be emailed to the GMSC Secretary sian.porter@aber.ac.uk

GMO Infrastructure

All GMO facilities must be maintained to an appropriate standard to maintain compliance with the Contained Use Regulations 2014.

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

All GMO facilities will be subject to at least one inspection per annum, which will be undertaken by the Senior Research Officer, Department of Life Sciences and a member of the HS&E Team.

GMO Training

All staff and students working with GMO must undertake the University's GMO training before commencing their activities.

Training will be provided by the GMO Technical Advisory Team as required. Refresher training will be provided at a frequency determined by the GMSC.

Security

Access to GM facilities will be restricted (orange). Doors must be secure at all times. All staff must wearing of lanyards and identifiable badges in restricted areas. Politely challenging anyone present in areas or tailgating, where they are not familiar and/or whose actions may arose concern.

Monitor and Review

The GMSC will review the activity log on at least a 12 monthly period. The review will ensure all GMO activity has a recently reviewed GM risk assessment, GMO training has been undertaken and had at least one infrastructure inspection during the same period.

A summary of GMO performance measures will be shared with the Faculty of Earth and Life Sciences Executive Group; the Health, Safety and Environment Operational Group; the University Executive Board; Governance and Compliance Committee and the University Council.