Health & Safety Services

University of Reading

Safety Code of Practice 15

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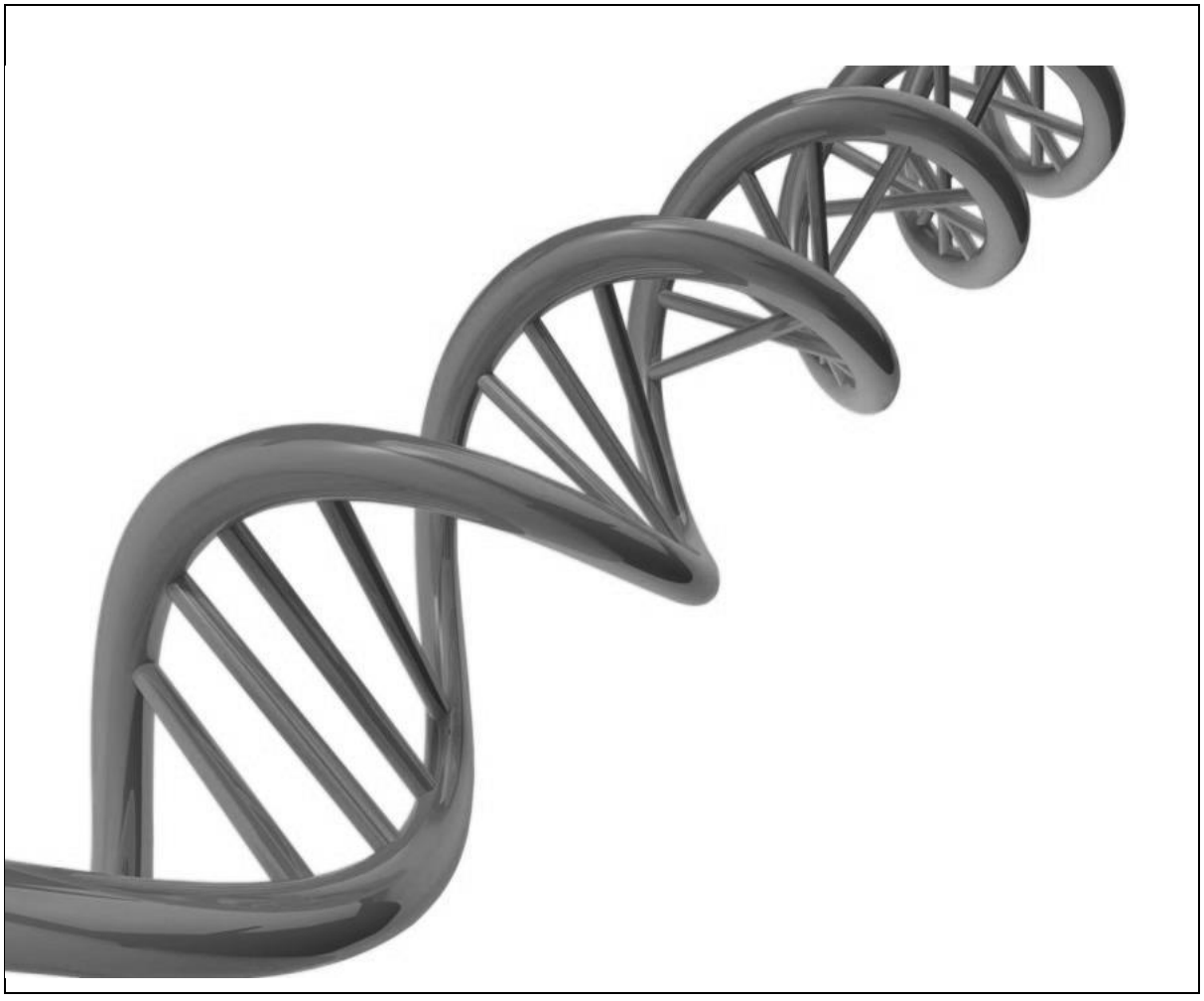
GENETIC MODIFICATION



Summary			
This CoP summarises the requirements for working with GMOs at University of Reading			
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Contents

1 INTRODUCTION

This Code of Practice sets out what managers, staff, students and tenants have to do when working with genetically modified organisms at the University of Reading, It is intended to ensure safe working and legal compliance with the Genetically Modified Organisms (Contained Use) Regulations 2014. This CoP is of particular importance to GM Project supervisors.

This Code of Practice should be read in conjunction with Safety Code of Practice 14 Part 1 *Biological Hazards in University Laboratories*. A complementary e-learning module is also available via UORLearn, titled *Biological and GM safety* .

2 SCOPE

This Code of Practice covers all work with genetically modified organisms (GMOs) in contained use facilities. Deliberate release of GMOs to the environment is contrary to UoR policy and anyone wishing to conduct such work a must first consult H&S Services.

This Code of Practice applies to all staff, students, contractors, and visitors carrying out, or planning to carry out, work activities that involve any form of genetic modification. It applies to both research and teaching activities. Relevant work includes genetically modified microorganisms, genetic modification work that involves plants (including plant-associated genetically modified microorganisms), genetic modification of animals and the use of genetically modified microorganisms in a clinical setting.

This COP applies to all work places under the direct control of the University of Reading, including laboratories, farm premises and temporary fieldwork premises.

3 DEFINITIONS

Genetic modification; any alteration of the genetic material (DNA or RNA) of an organism which does not occur naturally (by mating or natural recombination) and which has been achieved through one of the techniques listed in Part 1 of Schedule 2 of the Genetically Modified Organisms (Contained Use) Regulations 2014.

The listed techniques include:

- recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur, but in which they are capable of continued propagation;
- techniques involving the direct introduction into an organism of heritable genetic material prepared outside the organism, including micro-injection, macro-injection and micro-encapsulation;
- cell fusion or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

Some similar techniques are not considered to be genetic modification activities:

- *in vitro* fertilisation;
- natural processes, such as conjugation, transduction or transformation, and
- polyploidy induction.

By contrast, some techniques are specifically excluded from the Regulations:

- mutagenesis
- cell fusion of prokaryotic species that can naturally exchange genetic material;
- cell fusion of cells of any eukaryotic species, including hybridomas and plant cell fusions; and
- self-cloning (see info box below), where the resulting organism is unlikely to cause disease or harm to humans.

Guidance

Self-cloning – covers the removal of DNA or RNA from a cell of an organism, which may be followed by the reinsertion of all or part of it into the same species or into cells of phylogenetically closely related species which can exchange genetic material by homologous recombination.

Self-cloning may include the use of recombinant vectors, with an extended history of safe use in the particular organism, to manipulate and reinsert the nucleic acid sequences, but the vectors shall not consist of any genetic elements other than those designed for its construction, maintenance and replication.

In order to decide whether a project is covered by the self-cloning exemption, a risk assessment should be completed and H&S Services consulted.

Further guidance is available in the Scientific Advisory Committee on Genetic Modification (SACGM) compendium of guidance. GM project supervisors are recommended to read the relevant SACGM guidance for their specialist area of work, as follows;

Part 3: Containment and control of activities involving genetically modified microorganisms

Part 4: Containment and control of activities involving genetically modified plants (including plant associated genetically modified microorganisms),

Part 5 : Genetic modification of animals

Part 6: the use of genetically modified microorganisms in a clinical setting

The following definitions have been taken from the Guidance on the Regulations L29

<table>
<tr><td>Contained use</td><td>Is "an activity in which organisms are genetically modified, or in which genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which physical, chemical or biological barriers, or any combination of such barriers, are used to limit their contact with, and to provide a high level of protection for, humans and the environment."</td></tr>
<tr><td>Activity</td><td>A GM activity not only includes the generation of genetically modified organisms but also its culture, storage, disposal or any other use.</td></tr>
<tr><td>Barriers</td><td>Physical – a building, room, container, equipment, or physical process used to prevent escape or exposure to the GMO.

Chemical – use of chemicals to inactivate or destroy a GMO before waste disposal.

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.</td></tr>
<tr><td>Class</td><td>Contained uses of genetically modified microorganisms are classified into one of four classes, as described below, based on the risk that the contained use presents to human health and the environment.

<table><tr><td></td><td>Description</td></tr><tr><td>1</td><td>Contained use of no or negligible risk for which containment level 1 is appropriate to protect human health and the environment</td></tr><tr><td>2</td><td>Contained use of low risk for which containment level 2 is appropriate to protect human health and the environment</td></tr><tr><td>3</td><td>Contained use of moderate risk for which containment level 3 is appropriate to protect human health and the environment</td></tr><tr><td>4</td><td>Contained use of severe risk for which containment level 4 is appropriate to protect human health and the environment</td></tr></table></td></tr>
<tr><td>Containment level</td><td>Describes the standards of containment measures required to protect human health and the environment, includes requirements of facilities, equipment, systems of work, waste disposal and other measures.</td></tr>
<tr><td>Microorganism</td><td>Is "a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, and includes a virus, a viroid and an animal or plant cell in culture."</td></tr>
</table>

Genetically modified microorganism	Genetically modified microorganism (GMM) - a microorganism that has been genetically modified.
Genetically modified organism	Genetically modified organism (GMO) - an organism created through use of one of the techniques listed (defined) as "genetic modification."
Larger GMO	An organism which is genetically modified or is the subject of genetic modification which is not a microorganism. For the purpose of this guidance, larger GMOs can be separated into two classes, those which do not pose additional risk compared to the unmodified organism ("safe"), and those who do ("harmful").
Organism	Is "a biological entity capable of replication or of transferring genetic material and includes a microorganism, but does not include a human or a human embryo."

4 RESPONSIBILITIES

4.1 Sub-Committee for Biological Safety

The Sub-Committee for Biological Safety (SCBS) acts as the University's Genetic Modification Safety Committee, as required by Regulation 8 of the Genetically Modified Organisms (Contained Use) Regulations 2014. The SCBS is responsible for the approval (or refusal) of all GM project submissions, whether contained or deliberate release.

The SCBS has the authority to stop work or require changes to be made to projects or facilities where there may be a breach of health & safety legislation or it is deemed dangerous to people or the environment.

The SCBS is formally a sub-committee of the University Health, Safety & Wellbeing Committee.

4.1.1 Scientific Safety Advisor

The Scientific Safety Advisor is responsible for:

- Developing policies, standards and providing advice on local rules and systems of work with genetically modified organisms;
- Advising on and approving risk assessments (class 1 or "safe" larger GMOs)*;
- Advising the Sub-Committee for Biological Safety on risk assessments for class 2 and 3 and "harmful" larger GMOs;
- Liaising with the relevant regulatory authorities, including carrying out any notifications required under the regulations;
- Maintaining a register of all genetic modification projects;
- Retaining copies of all risk assessments, including risk assessments for closed projects;

- Maintaining a register of all genetic modification workers;
- Advising on the referral of staff and students to the University's Occupational Health provider for health surveillance when necessary;
- Monitoring and auditing health and safety performance;
- Investigating accidents and incidents involving genetically modified organisms and the provision of advice on remedial actions;
- Advising Schools and Estates & Facilities on the suitability of containment level facilities;
- Assisting in the provision of suitable training for those involved in activities using genetic modification;
- Supporting the Chair of the Sub-Committee for Biological Safety in ensuring effective operation of the sub-committee and reporting on their behalf to the University Health, Safety & Wellbeing Committee

The SSA has the authority to stop biological activities where the containment measures are considered insufficient to control the risks. The project should then be referred to the Sub-Committee for Biological Safety.

4.1.2 Heads of School

Heads of School are responsible for establishing arrangements to ensure that where their School is undertaking biological research or teaching, or where their School is facilitating a third party to use UoR facilities for biological work, that work complies with the requirements of this Code of Practice. This includes ensuring any third party research facilitated by the School and hosted on the University farms also complies with this Code of Practice.

Heads of School are responsible for ensuring adequate resources and appropriate measures are in place for the protection of all persons working with genetically modified organisms as part of their School's research, teaching or fieldwork.

Heads of School are responsible for having arrangements in place to ensure:

- the requirements of this Code of Practice are implemented;
- risk assessments are carried out;
- laboratory facilities are fit for purpose;
- a good standard of housekeeping maintained;
- appropriate waste disposal procedures are in place and are followed;
- emergency plans are drawn up and practiced if required;
- microbiological safety cabinets and autoclaves are tested at least annually (see Safety Code of Practice 14 parts 6 and 7) and that all equipment is in good repair;
- staff and students receive adequate training and supervision;
- accidents and spillages are reported to H&S Services for investigation allocation
- laboratories are inspected regularly and remedial action is taken where working practices, housekeeping and maintenance are found to not meet an acceptable standard;
- recommendations of School and University inspections are implemented.

4.1.3 GM Project Supervisors

GM project supervisors are responsible for ensuring that all their genetic modification activities meet the requirements of this Code of Practice, including:

- a suitable and sufficient risk assessment is carried out for all activities involving genetic modification, using the appropriate assessment template;
- that this assessment includes emergency arrangements and documents spills procedures, taking into account the concentration, volume, location and biological/chemical hazard(s) of the spillage. It must also document what to do in the event of sharps injury, if this is identified as a hazard by the risk assessment.
- that this assessment is approved by the Sub-Committee for Biological Safety (or for low risk activities the Scientific Safety Advisor) ***before*** any work starts or genetically modified organisms are acquired;
- paying of the appropriate notification or significant change fee (for class 2/3 or "harmful" larger GMO projects only);
- risk assessments are reviewed when changes to work are planned and that the appropriate University approval is obtained ***before*** the new work starts, risk assessments should also be reviewed at least every year to ensure that they remain relevant and up-to-date;
- keeping records of risk assessment reviews and keep electronic copies of all project assessments and approvals;
- that only appropriate containment level laboratory facilities are used for the work and that a good standard of housekeeping maintained;
- all persons working under their supervision have received appropriate training and information, including awareness of risks, appropriate control measures to apply, waste and emergency procedures;
- they provide or organise appropriate supervision to assess and monitor competence of persons under their control to work safely;
- all accidents and spillages are reported to H&S Services;
- appropriate licenses are in place for the non-GM aspects of their work, such as licences to work with plant or animal pathogens.

Please note additional responsibilities will apply to Project Supervisors of Class 3 GM activities, Consult H&S Services for further information before planning any Class 3 work.

4.1.4 Occupational Health Service

The Occupational Health Advisor/Physician is responsible for:

- Advising on the need for vaccination prior to work commencing;
- Maintaining a record of immunisation;
- Reporting (to H&S Services) any occurrences where a GM worker has been diagnosed with a disease which may be related to the GMO they work with;
- Advising where additional measures may be required to protect the health of individuals working with genetically modified organisms;

- Carry out health surveillance and clearance in line with the occupational health policy and procedures.

4.1.5 Estates

Estates are responsible for the general maintenance of all containment laboratories. Maintenance personnel and contractors are responsible for obtaining permits before accessing and working in University laboratories.

4.1.6 Individuals working with Genetically Modified Organisms

All those working with GM organisms are responsible for ensuring they:

- are familiar with, and understand the risk assessments that apply to their work, and ensure that they stay within the project boundary;
- adopt safe practices in activities involving genetically modified organisms, including the principles of good occupational hygiene;
- wear the appropriate protective equipment and clothing;
- dispose of waste in the manner specified by the approved risk assessment;
- follow the requirements of relevant local rules and standard operating procedures;
- report any incident, accident or defect in equipment relating to the handling of genetically modified organisms;
- co-operate with their supervisors, School and H&S Services to monitor safety in the School;
- where appropriate, as determined by risk assessment, comply with the requirement for occupational health surveillance.

Under 16 year olds are not permitted to work with any genetically modified organisms unless part of an approved outreach programme and then only with class 1 or "safe" larger GMOs.

Young persons (16-18 year olds) may work with class 1 or "safe" larger GMOs as part of an undergraduate taught practical session. They may also work with these GMOs in research facilities as part of a work-experience or summer studentship programmes subject to an appropriate level of supervision and no work with sharps and GMOs will be permitted. .

Persons aged below 18 years old are not permitted to work with class 2 genetically modified organisms.

4.1.7 Property Services

The landlord function of the University is responsible for ensuring any commercial tenants undertaking biological work on University premises are aware of this Code of Practice and the requirements it places on them.

4.1.8 Tenants

Any tenant working with genetic modification within University premises must:

- Obtain competent advice

- Establish their own GM committee
- Carry out all notifications to the competent authority, including notifications of premises and activities
- Where space is shared with University staff and students, tenants must inform H&SS and share information on their genetic modification activities with the University e.g. HSE centre number; details of any higher risk GM projects (class 2 genetically modified; microorganisms or activities involving "harmful" larger GMOs;
- Comply with all relevant policies and codes of practice issued by the University

5 REQUIREMENTS

5.1.1 Compliance with the GM regulations

The major requirements of the Genetically Modified Organisms (Contained Use) Regulations 2014 are set out below:

Risk assessments are carried out before any contained use involving microorganisms (reg. 5) and larger GMOs (reg. 6);
That genetic modification safety committees, or for very low risk work, a competent person* advise on risk assessments (reg. 8);
That risk assessments are reviewed regularly, and when there is reason to suspect that it is no longer valid (reg. 7);
Premises where GM activities are carried out are notified to the HSE (reg. 9);
Activities involving class 2, class 3 or 4 genetically modified microorganisms or larger GMOs which present more of a risk than the unmodified organisms are notified to the HSE (regs. 10, 11, 12 and 13);
That changes in the circumstances of, or significant changes in risk of notified projects are notified to the HSE (regs. 14 and 15);
Should HSE request further information with respect to notified projects, a duty to cease the activity until HSE approval is given (reg. 16);
That the principles of occupational and environmental safety should be applied to reduce risk as low as reasonably practicable (reg. 18);
That the specified containment and control measures are applied for the activity classification (regs. 19 and 20); and

HSE are notified, where appropriate of incidents which represent a significant hazard to human health or to the environment (reg. 22).

Further information on these requirements can be found in the appropriate sections of this code, and a summary, including details of how the University complies with the regulations, and responsibilities for compliance can be found in Appendix 1.

5.1.2 Risk assessments

Before any work with genetic modification is commenced, the project supervisor must ensure that a suitable and sufficient assessment of the risks to human health and the environment is carried out. These risk assessments must be submitted to, reviewed and approved by the Sub-Committee for Biological Safety or, for low risk work GM Class 1, the Scientific Safety Advisor.

The GM project proposal and risk assessment form has been designed to address the key aspects of what to consider when carrying out a risk assessment as laid out in the GM regulations. The amount of detail in the risk assessment should be proportionate to the level of risk, providing sufficient detail to assess, and for the committee to review, the hazards, the means by which harm could be realised, the likelihood of this occurring and the control measures required.

Project supervisors should pay due notice to the risk assessment guidance laid out in the SACGM Compendium of Guidance relevant to their particular type of activities.

All GM risk assessments must be reviewed annually and the review date recorded. For GM class 2 work the risk assessment must be re-submitted to the SCBS on a three yearly basis or if changes are made to the working practices.

Please see the guidance on completion of GM risk assessments on the GM web page.

5.1.3 Approval of work

All activities with genetically modified organisms must be approved in advance by the Sub-Committee for Biological Safety (SCBS), or for low risk work (Class 1 GM), the Scientific Safety Advisor (SSA). A full GM risk assessment, using the appropriate GM form, must be conducted and submitted for approval. This GM risk assessment should be carried out with initial discussion and agreement with the school HSC and then approved by Head of School.

5.1.4 Approval Process

Project proposals and risk assessments should be submitted to H&S Services by email to safety@reading.ac.uk. The GM Project Proposal and Risk Assessment form (available on H&S Services website) is designed to ensure that the initial proposal has considered the necessary details and provides the necessary information for an approval decision to be made by the SCBS or SSA. All proposals will be initially triaged by the Scientific Safety Advisor.

NEW CLASS 1 OR "SAFE" LARGER GMOS PROJECT SUBMISSIONS

Risk assessments for projects that clearly fall within class 1 or "safe" larger GMOs, will be reviewed by the SSA (acting as "competent person") who may approve, approve subject to

changes, or refer the project to the next SCBS meeting. Work may start as soon as approval has been granted.

Normally, approvals by this route take about four weeks from the date of submission.

All projects operating under SSA approval will be submitted to the first available meeting of SCBS for ratification. At that meeting, a summary of the project will be presented to the committee, during their consideration of the project, SCBS may require changes to be made, or impose additional conditions.

EXTENSIONS/MODIFICATIONS TO CLASS 1 / "SAFE" LARGER GMO PROJECTS

Updated risk assessments should be submitted as above, with the changes clearly highlighted. The risk assessment will be reviewed as for class 1 projects

Unless otherwise agreed by the SCBS at the time of approval, Class 1 projects will not require resubmission. The approval remains valid until changes are made. Upon making changes to the original GM project proposal and risk assessment, resubmission will be necessary, to confirm that the project is still within scope of the approval.

CLASS 2 OR 3 GENETICALLY MODIFIED MICROORGANISMS OR "HARMFUL" LARGER GMOS

Risk assessments for these projects should be submitted at least three weeks before a SCBS meeting. They will be initially reviewed by the SSA, who may suggest changes or ask for clarification, and then submit the project to the next SCBS committee meeting.

The project risk assessment will be reviewed by the SCBS, which includes technical specialists, where necessary additional specialists will be requested to advise on the project. Project proposers will be invited to attend the SCBS committee meeting to explain their project in further detail.

The SCBS will decide on the final classification of the project, and may require modifications to the risk assessment, request further information, or that the application should be revised and resubmitted to the next committee meeting.

Once approved by the SCBS, the SSA will notify the HSE accordingly. Work cannot commence until a written letter of approval has been received from the SCBS, which will be issued once the appropriate notification conditions have been met;

For class 2 projects

A letter acknowledging receipt by the HSE has been received by the University (usually within 10 working days).

If, following the notification, additional information relating to a notification is requested by the HSE, any active work on the project must stop and, unless otherwise notified by the HSE, the only contained use activity permitted would be the storage or destruction of the material.

HSE will acknowledge receipt of the additional information within 10 working days, but work cannot restart until the HSE has given written approval to do so.

For class 3 projects

Work must not commence until the HSE has given its consent.

For a "first use" of Class 3 activities, HSE must inform the University whether or not consent has been issued within 90 days of acknowledging receipt of the notification, for subsequent Class 3 activities, the period is 45 days.

If, during the course of the assessment procedure, HSE decide that they need additional information to evaluate the proposal, the time between making the request and the supply of the requested information is not counted as part of the specified period.

Work with "harmful" larger GMOs

Unless otherwise advised in writing by the HSE, work may only commence 45 days after the HSE letter of acknowledgement of notification has been received.

EXTENSIONS/MODIFICATIONS TO NOTIFIED PROJECTS

If you wish to modify or extend the scope of a previously approved (and HSE notified) GM project it is essential that the project is reassessed by the SCBS before the additional work is commenced. Updated GM risk assessments should be submitted to the SCBS, with the changes clearly highlighted.

For Class 2 (and above) GM projects there is a requirement to resubmit an updated GM project risk assessment to the SCBS at an interval of not more than 3 years from the original approval, even if the project remains unchanged. This is in order to demonstrate that the project is still operating within the scope of the original approval. This additional control measure is on top of the regular review of the risk assessments by the project supervisor. Any changes to the project should be declared before these changes are implemented. If changes require further notification to the HSE , this will be done by the SSA following a review by the SCBS.

5.1.5 Transportation

On site

Transport of Genetically Modified Organisms (GMOs) and Genetically Modified Micro-Organisms (GMMs) between university labs or buildings (not requiring use of off-campus/public roads) must be carried out in a way to ensure containment of the samples if dropped. Material should be in sealed vessels (tubes or plates) placed in (at least) a secondary sealed container with sufficient absorbent material (e.g. paper towel) to absorb a spill. Boxes should be labelled with name of the person responsible and their contact details and should never be left unattended. For larger GMOs that may require special arrangements, contact H&S Services before transporting.

Off site

Transportation of hazardous biological material by public transport e.g. tube, bus or passenger rail is prohibited.

Transport of GMOs and GMMs off-site that meet the definition of an infectious substance shall be classified as either Category A, UN 2814 - Infectious substance, affecting humans

Category A, UN 2900 - Infectious substance, affecting animals (only)

Or Category B, UN 3373 – Biological substance

(for the purpose of diagnostics or investigation)

GMMs that do not meet the definition of an infectious substance but are capable of altering animals, plants or microbes in a way not normally the result of natural reproduction are classified in Class 9 - 'Miscellaneous Dangerous Goods' and consigned as 'UN 3245 Genetically Modified Micro-organisms'

Due to the complexity of the regulatory requirements that cover transport of dangerous goods, dependant on if road, rail, air or sea or a combination of any of the 4 are used, it is recommended you contact H&S Services for further guidance before you intend to ship GMOs or GM material.

5.1.6 Information

Staff, students, and visitors must be provided with relevant information relating to the risks associated with their work and any relevant control measures. The safety information for laboratory workers should generally be written and would include:

- local rules
- standard operating procedures (SOPs) and
- risk assessments

Typical content of local rules
Organisms in use in the area
Lab rules, such as prohibitions, mandatory PPE requirements
Disinfectant policy (types of disinfectant in use vs efficacy on organisms), concentration and shelf-life
Waste arrangements for disposal of contaminated solid and liquid waste
Emergency procedures such as spillage or first aid

5.1.7 Use of Genetically modified organisms during teaching practicals

It is permissible to use class 1 or "safe" genetically modified organisms as part of undergraduate or taught postgraduate practical class so long as:

- their use is justified (i.e. the same teaching objective cannot be met using less this material is used)
- the activities are risk assessed and approved by the Sub-Committee for Biological Safety for use in teaching practicals
- activities are adequate supervised and appropriate containment facilities are used.

5.1.8 Containment measures and systems of work

The University requires all GM work to be carried out in strict accordance with the regulations. The regulatory requirements for the containment measures and systems of work are clearly set out in the SACGM guidance documents. Legal requirements will be stated clearly as such, with the use of the words 'regulatory requirement', 'required' or 'must'.

Further guidance is available in the Scientific Advisory Committee on Genetic Modification (SACGM) compendium of guidance. GM project supervisors are recommended to read the relevant SACGM guidance for their specialist area of work, as follows;

Part 3: Containment and control of activities involving genetically modified microorganisms

Part 4: Containment and control of activities involving genetically modified plants (including plant associated genetically modified microorganisms),

Part 5 : Genetic modification of animals

Part 6: the use of genetically modified microorganisms in a clinical setting

5.1.9 Facilities & equipment

The GM regulations require that the level of containment to be used is numerically equal to the classification of the GM activity. The containment measures are designed to limit the exposure of workers to the agent, and to prevent or minimise the dispersal of the agent from the laboratory. The containment measures for GM activities are, on the whole, consistent with the standards required for work with biological agents in the Control of Substances Hazardous to Health. The containment measures required for different levels are laid out in The SACGM Compendium of guidance. Links to these important guidance documents are provided in the box above. Readers of this code of practice should read section 15 of Safety Code of Practice 14 part 1 for further information on laboratory standards.

In order to ensure compliance of laboratories with biological safety regulations, all works in containment level 2 or 3 laboratories involving changes to fixtures or fittings must be carried out by, or in agreement with Estates & Facilities and H&S Services.

6 EMERGENCY ARRANGEMENTS/EMERGENCY PREPAREDNESS

6.1 Emergency planning

Although the Contained Use Regulations require emergency plans to be prepared, they are only necessary if risk assessment indicates that the health and safety of people outside premises, or the wider environment, may be affected.

Plans to deal with foreseeable incidents should be in place;

When drawing up emergency plans a number of different factors will need to be considered to determine the most appropriate course of action, these include:

- Type of genetically modified organism, route of transmission, infectious dose (if known) and the stability in the environment.
- Severity of accident - amount and concentration of material that could potentially be released and its form, for example, is aerosol formation likely?
- Location within the laboratory - an accident in the open laboratory may require evacuation, as compared to a more 'contained' accident in a microbiological safety cabinet.

6.2 Spillages (of GMOs)

Spillage procedures for GMOs should be detailed in the relevant GM Project Proposal and Risk Assessment (3A.7 for GMM) BEFORE any work is started. The maximum volume of a spill can be determined by identifying the largest volume used of any organism in the process which is being risk assessed. The concentration of viable organisms is also relevant to this calculation. It is essential that any modifications to the process or changes in the volumes being generated/used are documented in an updated risk assessment which sets out how to deal with the spillage of the defined volume of any GMO.

6.3 Needlestick injuries and first aid

The expectation is that a protocol for action in the event of a sharps injury should be specified before the incident, be available on the wall of the lab and then be complied with.

For any accident involving broken skin, bleeding should be encouraged and the area washed with soap and water. A First Aider should be called. Where the wound may have been contaminated with a genetically modified microorganism, medical assessment (for example in A&E or a walk-in clinic) is required, and post-exposure prophylaxis may be prescribed by a medical professional. Occupational Health and H&S Services must also be informed of any such incident by the next working day.

6.4 Reporting of accidents and incidents

All incidents involving genetically modified organisms should be reported to H&S Services using the on-line incident reporting form. Where an incident involves a significant and unintended release and which presents an immediate or delayed risk to human health or environment this should be reported immediately to H&S Services by telephoning 8888, H&SS will investigate and where necessary notify the HSE of the incident.

Examples would include:

- Release of any GMO outside of the laboratory environment;
- Significant spillage of a class 2 genetically modified microorganism;
- Any inoculation injury with a GMO;
- Failure to decontaminate a GMO prior to disposal.

If a worker suspects that they may have contracted a disease as a result of their work, they should consult Occupational Health as soon as possible. The University Occupational Health service should inform H&S Services of any such case of occupationally-acquired disease, so that the circumstances could be investigated. H&S Services are responsible for reporting the disease to the HSE.

7 COMPETENCE/LEARNING REQUIREMENTS/TRAINING

7.1 Training

Before commencing work unsupervised with any GMO, all staff and students must;

- have received the relevant laboratory induction

- read the relevant local rules and risk assessments,
- have received appropriate training in safe handling of the materials they are working with, and have demonstrated to their supervisor that they are competent to perform the tasks which they will be carrying out. It is expected that at containment level 2, records are kept of training against SOPs and risk assessments.

Where equipment is used as a control measure, e.g. a microbiological safety cabinet, its proper use must be demonstrated and the worker advised of any routine checks to be undertaken that indicate normal function. e.g visual check that inflow readings are within the "safe" range before work in commenced. Records of this training must be kept locally and be available upon request during a biological and GM safety audit.

7.2 Supervision

The degree of ongoing supervision required will depend on the individual(s) being supervised and the tasks being carried out.

Undergraduates are not permitted to work unsupervised in research laboratories. A competent person who understands the risks in the area must be available at all times to intervene if safe working practices are not followed, or in an unexpected event happens, such a fire, spillage of hazardous material, or equipment malfunction.

8 FURTHER INFORMATION/GUIDANCE

H&S Services website on Genetic Modification contains links to relevant forms, classification lists and guidance documents.

The Biological Safety website contains links to additional guidance for working with microorganisms including:

- Control of Substances Hazardous to Health Regulations 2002 (as amended)
- The Approved List of biological agents. Advisory Committee on Dangerous Pathogens (ACDP).
- The Management, design and operation of microbiological containment laboratories. Advisory Committee on Dangerous Pathogens [ACDP]. HSE Books, Sudbury, 2001.
- List of Specified Animal Pathogens and notifiable pathogens and toxins under the Anti-terrorism, crime and security Act 2002 (Code of Practice 50)

Confidentiality issues;

Project supervisors should be aware that all the information (with the exception of personal information) contained in a notification to HSE is disclosable to the public and will be entered in the Contained Use Public Register.

The areas for which disclosure may have the most serious implications are those of intellectual property rights (patent applications, etc.), or where the proposal is being conducted in conjunction with a company that claims commercial-in-confidence status for some of the materials or information used. Other grounds for withholding information from the Public Register include the possibility of compromising personal or national security, or public order.

If a project supervisor wishes to claim confidential status for any of the information contained in the University project application form, they must tick the appropriate box on the form, and indicate the areas of the form for which that claim is made.

If HSE decide that the claims are not to be granted, the project details will be entered onto the Register 14 days after that decision is communicated to the applicant. This delay gives the applicant time to withdraw the application if they so wish.

9 REVIEW, AUDIT AND MONITORING

Projects that are GM Class II and above will require resubmission to the SCBS on a 3 yearly cycle, unless a derogation of this requirement was agreed at the time of the original submission by the Chair of the SCBS.

Inspections will be carried out annually by the GM project Supervisor (or a delegate) to ensure that GM samples (of any type) are stored securely and their type, location, quantity and project number is accurately recorded. The generally condition of the containment facilities will be inspected annually by the GM Project Supervisor (or a delegate), lab manager or HSC to ensure that it meets the standards required for the designated containment level set out in the SACGM compendium of guidance.

H&SS shall conduct audits and inspections in line with their ongoing audit programme, to provide information on whether the GM management system: a) conforms to: — the UORs own requirements for its GM management system, and — the requirements of the 2014 regulations; b) is effectively implemented and maintained.

10 RECORDS & RETENTION REQUIREMENTS

H&S Services will keep copies of all approved risk assessments, including risk assessments for closed GM projects, for at least 10 years after closure.

11 RELEVANT LEGISLATION

The Genetically Modified Organisms (Contained Use) Regulations 2014

12 REFERENCES

https://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/

https://www.hse.gov.uk/biosafety/gmo/acgm/index.htm

13 APPENDICES

Appendix 1: Summary of the Genetically modified organisms (contained use) regulations 2014 and procedures for how the university will meet the requirements.

Regulation			Procedures at the University to comply with the regulations
5	Risk assessments of contained use involving microorganisms	Before any contained use involving microorganisms is commenced a person responsible for the contained use must ensure that a suitable and sufficient assessment of the risks to human health and the environment created by the contained use is carried out. The regulations specify the factors that must be taken into account as part of this risk assessment.	Project supervisors must ensure risk assessments (on the specified forms) are completed and approved by the Scientific Safety Advisor (SSA) (class 1 or "safe" Larger GMO) or the Sub-Committee for Biological Safety (SCBS) before work begins or new work is added. *See sections 4.1.3 Responsibilities of GM project supervisors, 5.1.2 Risk assessment, and 5.1.3 Approval of work.* GM risk assessment forms have been design to take into account the specified factors.
6	Risk assessments of contained use involving larger GMOs	Before any contained use involving larger GMOs is commenced, a person responsible for the contained use must ensure that a suitable and sufficient assessment of the risk to human health created by the contained use is carried out. Environmental risks are technically covered by the Environmental Protection Order. The regulations specify the factors that must be taken into account as part of this risk assessment.	
7	Review and recording of risk assessments	A person responsible for contained use must ensure that the risk assessment is reviewed immediately where there is reason to suspect that the risk assessment is no longer valid or there has been a significant change in the contained use to which the risk assessment related.	Project supervisors must review risk assessment, at least annually. Project supervisors must keep electronic records of risk assessments, reviews and University approvals. *See Section 4.1.3 Responsibilities of GM project supervisors.* If the project risk assessment needs to be updated, then the project supervisor must submit the revised form to SCBS for approval (*see Section 5.1.3 Approval of work*).
		A person responsible for contained use must keep a record of the risk assessment, and any review of the risk assessment, for at least 10 years from the date the contained use stops; and	H&SS will keep copies of all approved risk assessments, including risk assessments for closed GM projects, for at least 10 years after closure.

		• Make the record available to the competent authority when requested to do so	
8	Advice from a genetic modification safety committee	A person responsible for contained use must obtain advice on a risk assessment from either: • a competent person (class 1 only) • a genetic modification safety committee (required for class 2 or above)	Project supervisors must submit all projects for advice and approval to H&S Services (on behalf of the SCBS) Class 1/"safe" larger GMO projects will be reviewed by SSA, with assistance from technical specialist if required. Projects may be referred to the next SCBS committee meeting for approval. Class 2 or above / "harmful" larger GMO projects – reviewed by SCBS at quarterly committee meeting. *See Section 5 .1.3 Approval of work*.
9	Notification of premises to be used for contained use	A user must not use premises for contained use unless the premises have been notified to the competent authority Before premises are used for contained use for the first time, a person responsible for the contained use must: • Submit a notification to the competent authority • Have received an acknowledgement of receipt • A single notification may include more than premises	H&SS are responsible for notifying premises. • Premises were originally notified in 2000 and additional buildings have been added as GM work has started. • An update has been sent to HSE in Dec 2014 confirming buildings used for GM work. A list of notified buildings is kept by H&SS in the GM folder. • H&SS are responsible for notifying new buildings when first GM project in that building is submitted for approval.
10	Notification of class 2 contained use	A user must not undertake a contained use involving microorganisms classified as class 2 unless: • A person responsible for the contained use must submit a notification to the competent authority containing the information specified in Schedule 6. • A letter acknowledging receipt by the HSE has been received. • The premises have been notified and the conditions of notification have been met.	H&SS are responsible for notifying class 2 projects and will only issue a letter of approval to start work to the project supervisor once conditions of notifications have been met (*see Section 5.1.3 Approval of work*).

11	Notification of class 3 or 4 contained use	A user must not undertake a contained use involving microorganisms classified as class 3 or 4 unless written consent for that contained use has been granted by the competent authority and the premises have been notified accordingly.	H&SS are responsible for notifying class 3 projects and will only issue a letter of approval to start work to the project supervisor once conditions of notifications have been met (*See Section 5.1.3 Approval of work*).
12	Notification of contained use involving larger GMOs	A user must not undertake a contained use involving larger GMOs that pose a greater risk to humans than its unmodified parental organism unless: • A person responsible for the contained use must submit a notification to the competent authority containing the information specified in Schedule 6. • A letter acknowledging receipt by the HSE has been received. • The premises have been notified and the conditions of notification have been met.	H&SS are responsible for notifying projects involving "harmful" larger GMOs and will only issue a letter of approval to start work to the project supervisor once conditions of notifications have been met (*See Section 5.1.3 Approval of work*).
13	Single notifications to the joint competent authority and for connected programmes of work.	Allow a single notification to the HSE to be submitted to cover a connected programme of work. This might involve a programme covering more than one contained use at a single premises. To form a connected programme of work, all contained uses must be part of a coherent and integrated programme of work i.e. the different types of contained use should all form part of a common scientific research goal.	Project supervisors are responsible for coordinating the submission of a connected programme of work to the SCBS. Where connected programmes involve more than one academic and their research group, each individual academic will be required to hold, and be responsible for, a project under that connected programme of work. Applications to join a connected programme of work will be reviewed by the SCBS to ensure the proposed work is covered and consistent with the aims of the connected programme. H&SS are responsible for notifying the HSE of a connected programme of work. *See Section 5.1.3 Approval of work.*
14	Changes of circumstances relating to notifications	Full details in writing must be sent immediately to the competent authority of any changes in the information provided with respect to premises or contained use notifications.	H&SS are responsible for notifying the HSE of any changes in premises or contained use notifications. *See Section 5.1.3 Approval of work.*

15	Duty to notify significant changes affecting risk	Where, after submitting a notification, a notifier: • Makes a change in the premises or the contained use to which the notification related which may have significant consequences for the risk arising from the contained use; or • Becomes aware of any new information which may have significant consequences' for the risk arising from the contained use, the notifier must immediately send to the competent authority full details in writing of the change or the new information. As long as the change or new information does not affect the class of the contained use, the new information will be treated as a modification of the original notification.	The SCBS are responsible of identifying if any changes to a notified projects could meet the definition of "significant change", paying due notice to table 2 in the guidance giving examples of the types of changes that would be deemed significant and any associated guidance. Where the project risk assessment has been extended or changed previously, the extent of the total change should be judged against the original notification. H&SS are responsible for notifying the HSE of significant changes. The project supervisor will be responsible for payment of the respective notification fee. *See Section 5.1.3 Approval of work.*
16	Action of notified and user on receipt of request for additional information	If additional information relating to a notification is requested by the HSE, a user must not commence the contained use that is the subject of the notification. For class 2 work, where work has begun following acknowledgement of receipt, the contained use must only continue to the extent necessary to store or destroy the material. The HSE may give instructions for the contained use to stop. HSE will acknowledge receipt of the additional information within 10 working days, but work cannot restart until the HSE has given written approval to do so.	H&SS will notify the Project supervisor of any request for additional information and conditions. The project supervisor must provide additional information and may not restart work until HSE has given written approval. *See Section 5.1.3 Approval of work*
18	Principles of occupational and environmental safety	A user who undertakes a contained use involving microorganisms must ensure that the risks to human health and the environment arising from the contained use are reduced to the lowest level that is reasonably practicable. This must include the general principles of good microbiological practice and of good occupational safety and hygiene. A user who undertakes a contained use involving larger GMOs must ensure that the risks to human health arising from the contained use are reduced to the lowest level that is reasonably practicable, including applying appropriate principles of good microbiological practice and of good occupational safety and hygiene.	

		(a) keeping workplace and environmental exposure to any genetically modified micro-organism to the lowest reasonably practicable level;	Measures identified in project risk assessment (*See Guidance on completion of GM risk assessments)*
		(b) exercising engineering control measures at source and supplementing these with appropriate personal protective clothing and equipment where necessary;	Measures identified in project risk assessment (*See Guidance on completion of GM risk assessments)*
		(c) testing adequately and maintaining control measures and equipment;	For example, Schools to ensure microbiological safety cabinets and autoclaves are tested and maintained accordingly. (*See Safety guide 14 parts 6 and 7 on requirements for testing Microbiological Safety Cabinets and Autoclaves).* Maintenance of containment level 2 laboratories – routinely inspected by School and defects reported to E&F.
		(d) testing, where necessary, for the presence of viable process organisms outside the primary physical containment;	To be decided by risk assessment. Usually not required for class 1 or 2.
		(e) providing appropriate training of personnel;	Training for Project supervisors – this code of practice, guidance on risk assessment document. Training of workers – at local level, responsibility of project supervisors (*see section 7.1 Training*)
		(f) establishing a genetic modification safety committee, if required;	*See regulation 8 above, sections 4.1 Sub Committee for Biological Safety.*
		(g) formulating and implementing local codes of practice for the safety of personnel, as required;	As required, *see section 5.1.6 Information,*
		(h) displaying biohazard signs where appropriate;	School to ensure all containment level 2 laboratories display biohazard signage. Not required in containment level 1 laboratories. *See COP14 pt 1*
		(i) providing washing and decontamination facilities for personnel;	Mandatory for all containment level 2 laboratories, where reasonably practicable in containment level 1 laboratories. *See COP14 pt 1*
		(j) keeping adequate records;	e.g. keeping of records of training, thorough examination and testing of equipment, validation of waste – determined in local rules/ SOPs.

		(k) prohibiting in the work area eating, drinking, smoking, applying cosmetics or the storing of food for human consumption;	Prohibited in all labs. Schools to ensure rules identified in Area H&S codes / local rules and reinforced at induction training. Signage no eating/drinking on lab doors. *See section 5.1.8 Containment measures and systems of work*
		(l) prohibiting mouth pipetting;	Prohibited in all labs. Schools to ensure rules identified in Area H&S codes/ local rules and reinforced at induction training. *See section 5.1.8 Containment measures and systems of work*
		(m) providing written standard operating procedures where appropriate to ensure safety;	School to ensure SOPs for safety critical processes such as use of microbiological safety cabinets, disposal of waste, treatment of spillages are in place and trained out. *See section 5.1.8 Containment measures and systems of work*
		(n) having effective disinfectants and specified disinfection procedures available in case of spillage of genetically modified micro-organisms;	Disinfectant identified in project risk assessment (*See Guidance on completion of GM risk assessments)*.
		(o) providing safe storage for contaminated laboratory equipment and materials where appropriate.	*See section 5.1.9 Facilities and Equipment* .
19	Containment and control measures for contained use involving microorganisms	A user who undertakes a contained use involving micro-organisms must apply the containment measures set up in the applicable table in Part 2 of Schedule 8, where and to the extent required in the column of the appropriate containment level. A user need not apply a containment measure required for the appropriate containment level where it has been justified by a risk assessment and HSE has agreed to the derogation. A person responsible for the contained use must review the containment measures applies at regular intervals, and immediately if that person suspects that the containment measures are no longer adequate, if the class is no longer appropriate or in light of new information.	Containment measures identified during risk assessment. Derogations must be approved by the Sub-committee for Biological Safety. Risk assessments reviewed at least annually. *See sections 5.1.2 Risk Assessment, 5.1.9 Facilities and equipment* .

20	Containment and control measures for contained use involving larger GMOs	A user who undertakes a contained use involving larger GMOs must apply the containment measures identified in the risk assessment for the contained use. A person responsible for the contained use must review the containment measures applies at regular intervals, and immediately if that person suspects that the containment measures are no longer adequate, if the class is no longer appropriate or in light of new information.	Containment measures identified during risk assessment. Risk assessments reviewed at least annually. *See sections 5.1.2 Risk Assessment, 5.1.9 Facilities and equipment.*
21	Emergency plans	Required where, as a result of any reasonable foreseeable accident that the health or safety of persons outside the premises in which the contained use is undertakes in liable to be seriously affected or there is a risk of serious damage to the environment from the contained use. If a plan is required, this should be submitted to the competent authority as part of a contained use notification.	The Scientific Safety Advisor is responsible for identifying when and emergency plan is needed and will work with the project supervisor and the Safety coordinator of the relevant school to complete. *See section 6.1*
22	Information relating to accidents	If an accident occurs, a person responsible for the contained use must immediately inform the competent authority of the accident. Accidents are defined as those which result in a significant and unintended release and which presents an immediate or delayed risk to human health or environment.	All incidents involving genetically modified organisms must be reported to H&S Services using the on-line incident reporting form. Where an incident involves a significant and unintended release and which presents an immediate or delayed risk to human health or environment this should be reported immediately to H&S Services by telephoning 8888, H&SS will investigate and where necessary notify the HSE of the incident. Occupational health are responsible for notifying H&SS of any workers who may present with a disease caused by a GMO they work with. *See section 4.1.3 Responsibilities of GM project supervisors, section 4.1.6 Responsibilities of individuals working with Genetically Modified Organisms and section 6.4 Reporting of accidents and incidents.*

Appendix 2: Version control

EDITION	KEEPER	REVIEWED	APPROVED BY	APPROVAL DATE
5	H&S Services	Every three years	SCBS	Oct 2022
4	H&S Services	Every three years	SCBS	Feb 2015
3	H&S Services		SCBS	2005