University of Reading

Safety Code of Practice 15

4th Edition, Jan 2015

GENETIC MODIFICATION

Contents

1 SCOPE

This Safety Code of Practice sets out what managers, staff, students and tenants have to do to ensure legal compliance when working with genetically modified organisms at the University of Reading. This CoP is of particular importance to GM Project supervisors.

This Code covers:

- Management responsibilities within the University
- Approval of work with genetically modified organisms
- Risk assessment
- Control measures and safe working practices

Details on laboratory requirements and working practices are limited to Containment Level 1 and 2 laboratories. Further details on requirements for work at higher levels e.g. CL3 can be provided by H&S Services as required.

2 INTRODUCTION

This code of practice is intended for those wishing to undertake work with genetically modified organisms (GMOs) in contained use facilities. Such work is regulated by the Genetically Modified Organisms (Contained Use) Regulations 2014 which came into force on 1 October 2014. These regulations replace the earlier the Genetically Modified Organisms (Contained Use) Regulations 2000 (as amended).

Users should also be aware of a complementary set of Regulations, the Genetically Modified Organisms (Deliberate Release) Regulations 2002, which apply to situations where living GMOs are intentionally caused to enter the environment. Anyone wishing to conduct a deliberate release of GMOs to the environment must consult H&S Services.

For work with genetically modified microorganisms, this Safety Code of Practice must be read in conjunction with Safety Code of Practice 14 part 1 Biological hazards in University Laboratories.

2.1 Definitions

The following definitions have been taken from the approved code of practice for the regulations:

Contained use	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."
Activity	A GM activity not only includes the generation of genetically modified organisms but also its culture, storage, disposal or any other use.
Barriers	Physical – a building, room, container, equipment, or physical process used

<table>
<tr><td></td><td>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>Connected programme of work</td><td>A series of activities involving contained use which form a coherent and integrated programme.</td></tr>
<tr><td>Genetic modification</td><td>Is the alteration of the genetic material in that organism in a way that does not occur naturally (by mating or natural recombination or both) ... through the use of the techniques listed."</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>
<tr><td>Genetically modified microorganism</td><td>Genetically modified microorganism (GMM) - a microorganism that has been genetically modified.</td></tr>
<tr><td>Genetically modified organism</td><td>Genetically modified organism (GMO) - an organism created through use of one of the techniques listed (defined) as "genetic modification."</td></tr>
<tr><td>Larger GMO</td><td>An organism which is genetically modified or is the subject of genetic</td></tr>
</table>

	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."
Person responsible for contained use	A person who has the authority to determine whether a particular contained use takes place or A person who has control of the planning or conduct (or both) of that contained use, and there may be more than one person responsible for the same contained use

2.2 What is genetic modification?

Genetic modification is defined as any alteration of the genetic material 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 regulations.

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.

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 as normal and H&S Services consulted.

2.3 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).

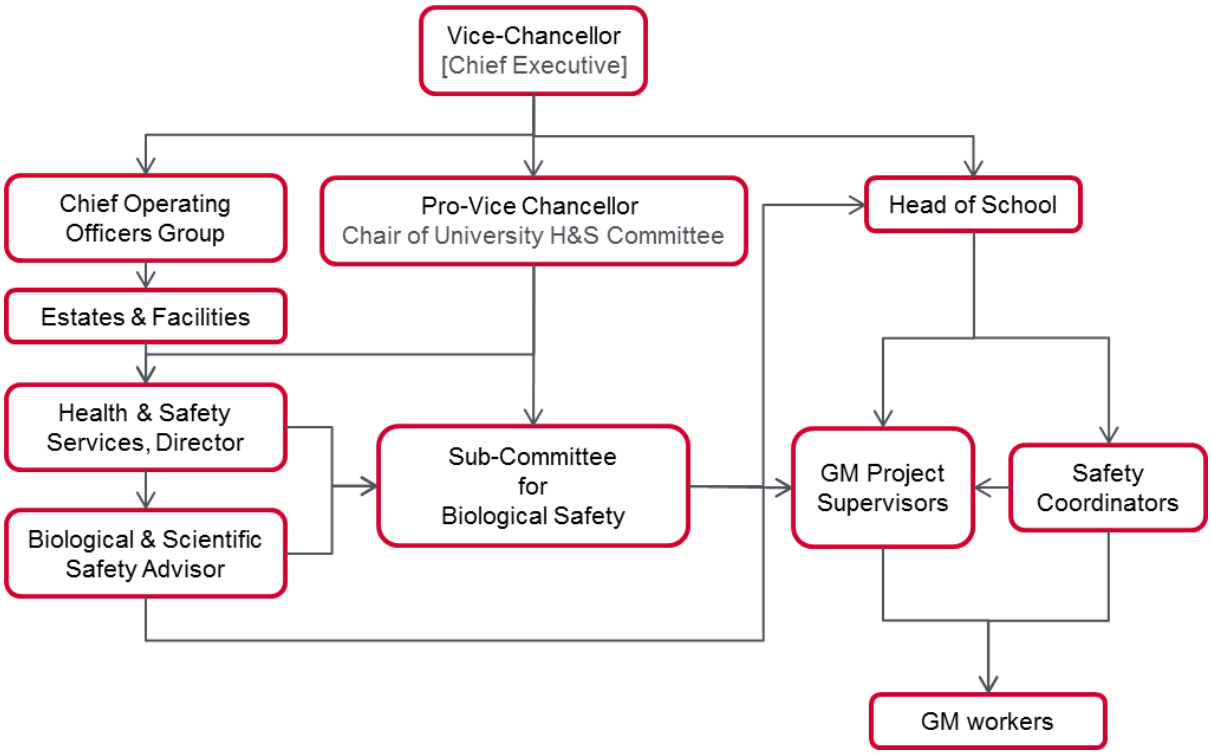
Further information on these requirements can be found in the appropriate sections of this code, and a summary, including details of how the University complies with the regulations, and responsibilities for compliance can be found in Appendix 1.

3 ORGANISATIONAL STRUCTURE AND RESPONSIBILITIES

3.1 University management structure

The structure for the management of Genetic Modification activities at the University is given in Figure 1 below.

Figure 1 University of Reading Biological Safety Management Structure



3.2 Sub-Committee for Biological Safety

The Sub-Committee for Biological Safety acts of the Genetic Modification Safety Committee for the University. The terms of reference and powers of this committee are set out in Appendix 2.

The committee includes of a number of independent technical experts, who have experience of contained use of genetically modified organisms and an understanding of the relevant legislation and guidance.

3.3 Management Responsibilities

The responsibilities outlined below are supplementary to the responsibilities detailed in the University Safety Management system (Safety Code of Practice 2).

3.3.1 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 is approved by the Sub-Committee for Biological Safety (or for low risk activities the Biological & Scientific Safety Advisor) ***before*** any work starts or genetically modified organisms are acquired;
- payment 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;
- keep 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;
- all workers with genetically modified organisms are registered with Health & Safety Services;
- all workers with class 2 genetically modified organisms, or above are enrolled on the occupational health surveillance programme;
- 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 requirements will apply to GM project supervisors of class 3 GM activities, please consult H&S Services for further information.

3.3.2 Heads of School

Heads of School are responsible ensuring adequate resources and appropriate measures are in place for the protection of all persons working with genetically modified organisms. Heads of School must have arrangements in place to ensure:

- requirements of this University 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 investigated and reported to H&S Services;
- laboratories are inspected on a regular basis and remedial action taken where working practices, housekeeping and maintenance are found not to meet an acceptable standard;
- recommendations of School and University inspections are implemented.

3.3.3 Biological & Scientific Safety Advisor

The Biological & Scientific Safety Advisor overseas the genetic modification safety management system at the University. Their duties include:

- Developing policies, standards and providing advice on local rules and systems of work with genetically modified organisms;
- Advise on and approve risk assessments (class 1 or "safe" larger GMOs)*;
- Advise the Sub-Committee for Biological Safety on risk assessments for class 2 and 3 and "harmful" larger GMOs;
- Liaison with the relevant regulatory authorities, including carrying out any notifications required under the regulations;
- Maintain a register of all genetic modification projects;
- Retain copies of all risk assessments, including risk assessments for closed projects;
- Maintain a register of all genetic modification workers;
- Advise 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;
- Assist in the provision of suitable training for those involved in activities using genetic modification;
- Operation of the Sub-Committee for Biological Safety.

The BSSA 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.

* Under the 2014 regulations, low risk projects (class 1 or "safe" larger GMOs) can be reviewed by a competent individual (e.g. a registered biosafety practitioner with relevant knowledge and experience) rather than a GM committee.

3.3.4 Occupational Health

The Occupational Health Advisor/Physician shall:

- Advise on the need for vaccination prior to work commencing;
- Maintain a record of immunisation;
- Report (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;
- Advise where additional measures may be requirement 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.

3.3.5 Estates and Facilities

Estates and Facilities are responsible for the general maintenance of all containment level laboratories.

3.4 Responsibilities of people working with Genetically Modified Organisms

All workers with GM organisms must ensure 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 specified manner;
- follow the requirements of any 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;
- register with H&S Services;
- where appropriate, e.g. for work with class 2 or 3 genetically modified organisms, comply with the requirement for occupational health surveillance.

Please note:

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.

3.5 Responsibilities of University Tenants

Any third party working with genetic modification within University premises must:

- Establish their own GM committee or obtain competent advice;
- 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 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.

4 RISK ASSESSMENTS

Before any work with genetically modified microorganisms or larger GMOs the project supervisor must ensure that a suitable and sufficient assessments of the risks to human health and the environment is carried out. These risk assessments must be reviewed and approved by the Sub-Committee for Biological Safety or, for low risk work, the Biological & Scientific Safety Advisor, prior to work commencing (see section 5).

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.

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

Aspects that must be considered when carrying out a risk assessment for work with genetically modified organisms.

- Any "**potentially harmful effects**", in particular those associated with the:
  - recipient organism;
  - inserted genetic material;
  - vector;
  - donor organism (where that donor organism is used during the contained use);
  - resulting GMO (including consideration of any alteration in the existing properties of the organism i.e. *could the insert make the recipient more or less hazardous*);
- The risk assessment should take due notice of any relevant classification schemes for human, animal or plant pathogens and the guidance in the compendium of guidance;
- The characteristics of the contained use;
- The severity of the potentially harmful effects;
- The likelihood of the potentially harmful effects being realised;

- The disposal of waste and effluents;
- The containment measures required to control exposure (based on those specified in the applicable table in Schedule 8 of the regulations);
- The appropriate classification of the GM activity
    - For microorganisms – class 1/2/3/4;
    - For larger GMOs "safe (as safe as unmodified) or "harmful".

Potentially harmful effects for microorganisms include:

- Diseases to humans, including allergenic or toxic effects;
- Diseases to animals or plants;
- Adverse effects resulting from the inability to treat disease of offer an effective prophylaxis;
- Adverse effects from establishment or dissemination of the GMM in the environment;
- Adverse effects resulting from the natural transfer of genetic material to or from other organisms;
- Adverse effects resulting from the likely interaction of the genetically modified microorganisms with other organisms at the premises where the contained use is conducted.

Potential harmful effects for larger GMOs include:

- Disease of humans including allergenic or toxic effects;
- Acting as a human disease vector or reservoir;
- Adverse effects arising from the inability to treat human disease or offer effective prophylaxis.

Harm to the environment for larger GMOs includes a selective advantage over unmodified forms of the organism.

5 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, the Biological & Scientific Safety Advisor (BSSA). A full risk assessment, using the appropriate GM form, must be conducted and submitted for approval.

5.1 Approval Process

Project proposals and risk assessments should be submitted to H&S Services by email to safety@reading.ac.uk.

The process for assessment and subsequent approval of project proposals depends on the type of activities proposed in the project. All proposals will be initially triaged by the Biological & Scientific Safety Advisor.

NEW CLASS 1 OR "SAFE" LARGER GMOS

Risk assessments for projects that clearly fall within class 1 or "safe" larger GMOs, will be reviewed by the BSSA (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 to date of approval, although it may take longer, for example during the vacation periods or if independent advice is required.

All projects operating under BSSA 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 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.

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 Biological & Scientific Advisor who may suggest changes/ ask for clarification and submit the project to the next SCBS committee meeting, together with further relevant information (such as relevant sections from the SACGM compendium of guidance).

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 may be invited to attend the SCBS committee meeting to explain their project in further detail.

In some circumstances, one or more lay members may be invited to join the group, especially where the implications may be wider than the purely technical aspects that are to be considered.

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 BSSA 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 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 TO NOTIFIED PROJECTS

Updated risk assessments should be submitted to the SCBS, with the changes clearly highlighted.

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.

The term "significant change" may be interpreted as where there is a significant change to the work which may have an effect on the risks of the activity - for example, where the existing risk assessment does not cover the proposed additional work. Even if the class of activity is not affected by the proposed change, the need for a new or significantly revised risk assessment acts as the trigger for notification.

Where the project risk assessment has been extended or changed previously, the extent of the total change will be judged against the original notification.

5.2 Connected programmes of activity

It is possible to submit a single notification for more than one contained use at the University to the HSE to cover a connected programme of work. 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.

Subsequent 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.

5.3 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.

Where teaching practicals do include GMO's the Schools must provide lists of participants and demonstrators to H&SS.

6 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.

7 WORKING PRACTICES AND CONTROL MEASURES

The *Principles of good occupational safety and hygiene* aim to protect laboratory workers from contamination by genetically modified organisms, to prevent the dispersal of organisms from the laboratory into the community at large, and to minimise the risk to others who may be affected by the work.

The following rules should be applied to ensure good occupational hygiene:

PERSONAL HYGIENE
• A suitable laboratory coat must be worn at all times when working in a containment level laboratory • At containment level 2 this must be side-fastening (Howie style), or back-fastening, with elasticated cuffs and should protect the arms, neck and lap. • Lab coats should be removed before leaving the laboratory suite, and stored properly, out of contact with outdoor clothing. Lab coats should be changed regularly or if they have been grossly contaminated. • Any wounds or skin abrasions should be covered with a waterproof dressing. • Disposable gloves must be worn when handling class 2 microorganisms. • Disposable gloves should be changed regularly or if they have become contaminated. Once removed they should be disposed as biological waste and should never be re-worn. • Hands should be washed with a suitable disinfectant soap before leaving the laboratory or whenever there is a suspicion that they may have been contaminated with viable microorganisms. • Glove(s) should be removed when using telephones, opening door handles etc. When transporting samples a gloved hand may be used to hold the samples and an un-gloved one to open doors.

- Workers must NEVER:
    - Pipette by mouth, pipetting aids must be used.
    - Store food or drink intended for human consumption in the laboratory. All such materials used for experimental purposes must be clearly marked "Not for human consumption".
    - Eat, chew gum, drink, apply cosmetics, take snuff or smoke within the laboratory.

LABORATORY AND PROCEDURES

- The laboratory door should be kept closed at all times and never propped open (doors between adjoining labs may be propped open during work to allow ease of movement).
- Windows to CL2 laboratories should be kept closed when work is in progress, to prevent positive-pressurisation with respect to the corridor and disruption of fume cupboards, microbiological safety cabinets and general ventilation airflows.
- Workbenches should be kept clean and free of clutter, there should be sufficient space to carry out work in an ergonomic and safe manner. Paperwork stored in the lab should be kept to a minimum (e.g. protocols, risk assessments, equipment manuals, lab books which are required for lab activities).
- Samples should be placed in appropriate racks to minimise the likelihood of spillages. All samples should be labelled with the identity of the organism/material, name of the worker generating the material and date.
- In general, work may be conducted on the open bench but care must be taken to minimise aerosol production. At containment level 2 where aerosol production is unavoidable, a suitable microbiological safety cabinet must be used.
- When centrifuging viable cultures of such organisms, use sealed tubes or a sealable rotor. These must then be opened in a Microbiological Safety Cabinet. Do not operate a centrifuge in an open-fronted Safety Cabinet, as the air currents created will disrupt the air flow in the cabinet.
- To prevent spillages outside the laboratory samples/materials should be placed in secondary containment during transfer between laboratories or buildings.
- Benches and safety cabinets must be cleaned with an approved disinfectant after work is completed.
- Housekeeping must be of a high standard. In containment level 2 laboratories storing items in cardboard or wooden boxes on or underneath benches must be avoided as these may become contaminated in the event of spillage.
- All contaminated material that is awaiting collection for sterilisation/disposal must be stored safely, in suitable leak-proof containers. These should not be overfilled - this includes pipette discard containers.

SAFE STORAGE AND INVENTORY

Each project supervisor storing or using genetically modified organisms should keep a detailed inventory of all such material within the laboratory.

The inventory should record details of the identity of each sample, name of the person in charge, amount stored (in long-term storage, such as freeze-dried culture); and location and type of storage.

The detailed inventory should be kept in a secure location, but be accessible to all persons authorised to enter the particular laboratory and a copy of each laboratory inventory should be stored centrally in the School.

8 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 part 2 of Schedule 8 (tables 1a, 1b and 1c), together with guidance in the compendium of guidance.

Appendix 3 outlines the specified control measures for work with class 1 and 2 microorganisms in laboratories. 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.

9 INFORMATION, SUPERVISION AND TRAINING

9.1 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

9.2 Training

Before commencing work, all staff and students must have 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 that they are competent. It is expected that at containment level 2, records are keep 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.

9.3 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.

10 GM WORKER REGISTRATION

All GM workers must register with Health & Safety Services using the online form. For workers on class 2 or higher projects, they must also undergo health clearance and enrol on the health surveillance programme before starting work (see below). A copy of the registration form will be emailed to the project supervisor for their records.

Where the intention is to work with class 3 genetically modified microorganisms, H&SS will keep the list of workers (plus details of any exposures, accidents and incidents) be kept for a minimum of 40 years following the date of the last (potential) exposure (regarded as the last occasion of work with the agent).

11 HEALTH CLEARANCE AND SURVEILLANCE

Within the University, work with genetically modified organisms classified as class 2 or above requires pre-assessment of each individual worker for their suitability for the proposed work, normally based on the response to a health questionnaire with an annual review. All those who work with class 3 genetically modified microorganisms are required to be under annual health surveillance.

Workers should register for health clearance and annual surveillance using the form on the Universities occupational health web site.

Where health surveillance is undertaken, the records of that surveillance must also be maintained for 40 years, these are retained centrally by the Occupational Health Service.

12 PREGNANCY

Certain microorganisms within hazard groups 2,3 and 4 can affect the unborn child if the mother is infected during pregnancy. These may be transmitted across the placenta while the child is in the womb or during or after birth e.g. if the child is breast-fed. Examples of agents that might affect

the child in this way are hepatitis B & C, HIV, Herpes, rubella, toxoplasmosis, syphilis, chickenpox, brucella and typhoid.

If a worker expects to conceive or believes herself to be pregnant, she may wish to discuss this with the Occupational Health Advisor. If confidentiality is required the worker may complete the relevant sections of the OH line management referral form and send to the Occupational Health service with an explanatory email.

13 TRANSPORTATION ON AND OFF SITE

13.1 On site

Transportation off genetically modified organisms 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.

13.2 Off site

Transport of dangerous goods, which includes biological samples and specimens is regulated to prevent, as far as practicable, harm to persons or the environment and damage to property during all stages of the transport chain. The two main regulations are:

- Road and rail: The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2007.
- Air: The Air Navigation (Dangerous Goods) Regulations 2002 (as amended) implements the International Air Transport Association (IATA) Regulations and additional measures in the UK.

The UN harmonisation system describes nine hazard classes each relating to a different type of hazard and further subdivides some of the more wide-ranging classes into hazard divisions. Genetically modified organisms may be covered by Class 6.2 category A or B or Class 9. Some materials may be transported in chemicals that are themselves classified as dangerous goods (e.g. formaldehyde). In these circumstances the requirements of other relevant classes will also need to be addressed.

Transportation of hazardous biological material by public transport e.g. tube, bus or passenger rail is prohibited. Transportation via private vehicle in the UK may be permissible as long as the requirements of the *Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2007* are met.

In order to comply with the complex requirements each person who ships genetically modified organisms must:

- Complete the relevant on-line training module (Note - national and international Regulations dictate that any individuals involved in the transport of hazardous goods must be trained, tested, certified every two years and retain a record of their training)
- Classify the material to be transported into the appropriate category
- Identify the UN number and proper shipping names

- Check for carrier or state variations and limitations
- Select the proper packaging material and package items accordingly.

14 EMERGENCY PROCEDURES

14.1 Emergency planning

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.

14.2 Spillages

In the event of significant spillage inside the laboratory immediate evacuation may be required. This will depend upon the nature of the organism and should be identified in the risk assessment.

- For genetically modified organisms which present a risk to human health, if feasible the microbiological safety cabinet in the laboratory should be left running to clear the lab of infectious aerosol, or the laboratory evacuated for approximately 60 mins to allow infectious aerosol to settle. Doors should be secured and signs posted to prevent others entering.
- Organisms which do not present a risk of aerosol transmission can be mopped up using the appropriate disinfectant (at the correct final concentration). For organisms which do present a risk of infection via inhalation, appropriate face masks should be worn (recommended minimum of a half face ffp3 mask – note that this does not provide any protection in the event of a hazardous chemical spillage).
- In the event of *personal contamination*, any contaminated clothing should be removed and left in the laboratories, the clothing will need to be bagged up and sent for autoclaving.
- In most cases, *spillages inside a microbiological safety cabinet* can be cleaned up immediately with an appropriate disinfectant. Fumigation of the cabinet will be required for class 3 organisms and for gross contamination with certain class 2 organisms (subject to risk assessment).
- If there is reason to believe a breakage may have occurred in a *centrifuge* the lid should remain shut to contain the aerosol and left for 30 minutes to allow aerosols to settle. A notice should be left on the lid to alert other users to the problem. The lid should be opened carefully and the interior sprayed with an appropriate disinfectant (active against the agent spilled), followed by a neutral pH detergent and wiped down with 70% alcohol. The rotor /buckets should be inspected, and if intact transferred to a microbiological

safety cabinet for opening and disinfection. For class 2 organisms with risk of airborne transmission, respiratory protective equipment should be worn (as above).

- Users of *orbital shakers* should always check through the observation panel for signs of leaks or spills. If in doubt do not open the lid, turn off and leave at least 30 minutes before opening, following the procedures outlined for centrifuges above.

14.3 Needlestick injuries and first aid

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.

15 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.

16 FURTHER ADVICE AND INFORMATION

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

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).

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 Biological & Scientific Safety Advisor (BSSA) (class 1 or "safe" Larger GMO) or the Sub-Committee for Biological Safety (SCBS) before work begins or new work is added. *See sections 3.3.1 Responsibilities of project supervisors, 4 Risk assessment, and 5 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 3.3.1 Responsibilities of 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 4 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 • Make the record available to the competent authority when requested to do so	H&SS will keep copies of all approved risk assessments, including risk assessments for closed GM projects, for at least 10 years after closure.
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&SS (on behalf of the SCBS) Class 1/"safe" larger GMO projects will be reviewed by BSSA, 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 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.	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 Approval of work*).

		• A letter acknowledging receipt by the HSE has been received. • The premises have been notified and the conditions of notification have been met.	
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 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 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 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 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 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 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 9.2 Training*)
		(f) establishing a genetic modification safety committee, if required;	*See regulation 8 above, sections 3.2 Sub Committee for Biological Safety, and appendix 2 Terms of reference*
		(g) formulating and implementing local codes of practice for the safety of personnel, as required;	As required, *see section 9 Information, Instruction and Training*
		(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 appendix 3.*
		(i) providing washing and decontamination facilities for personnel;	Mandatory for all containment level 2 laboratories, where reasonably practicable in containment level 1 laboratories.

			See appendix 3 and safety guide 14 part 1 section 15.
		(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 7 Working practices*
		(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 7 Working practices*
		(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 7 Working practices and under section 9 Information, Instruction and Training.*
		(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 7 Working practices.*
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	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 4 Risk Assessment, 8 Facilities and equipment and appendix 3.*

		longer adequate, if the class is no longer appropriate or in light of new information.	
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 4 Risk Assessment, 8 Facilities and equipment and appendix 3.*
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 Biological & 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.
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 3.3.1 Responsibilities of project supervisors, section 3.4 Responsibilities of people working with Genetically Modified Organisms and section 14 Reporting of accidents and incidents.*

Appendix 2: Sub Committee for Biological Safety – Terms of Reference

To advise on and oversee all activities involving the use of, or potential exposure to Biological Agents and other biological materials within the University, and to oversee University compliance with all regulations pertaining to activities involving genetic modification.

Key Functions

- To advise on risk assessments for activities involving genetic modification and the use of biological materials, including biological agents
- To approve all applications to undertake work involving genetic modification whether in contained use or deliberate release activities and to require that changes be made to proposed activities where the sub-Committee fails to approve such proposals;
- To receive, consider and advise on reports and information provided by inspectors of the enforcing authorities.
- To consider formal reports submitted by members of the University where appropriate.
- To monitor the effectiveness of the University's health and safety policy and procedures for genetic modification and biological safety.
- To consider and advise on Genetic Modification and Biosafety training and its effectiveness.
- To consider reports and statistics relating to incidents, work-related ill health and dangerous occurrences involving either genetically modified organisms or biological materials, and recommend remedial action where appropriate
- To submit regular reports via the Chairman to the main Health and Safety Committee, and to receive, consider and (where appropriate) act on reports from the parent committee in relation to the sub-Committee's activities.

Powers of the Sub-Committee

The Sub-Committee can:

- Require changes in experimental protocol to improve safety prior to approving projects;
- Advise on the drawing up of local rules to cover work involving hazardous biological agents and/ or genetic modification;
- Define and review laboratory practice with regard to safety in biological work, including activities involving the use of genetically modified organisms;
- Consider all relevant accidents/incidents and review University policy if necessary; and halt projects if breaches of University procedures or legislation occur.

Appendix 3: Containment measures applicable to contained use involving microorganisms in laboratories

Extract from Schedule 8 part 2 table 1a of the regulations. Additional requirements required for containment level 3 and for micororganisms in plant growth facilities and in animal facilities (schedule 8 part 2 tables 1b and 1c, respectively).

	CONTROL MEASURES	CONTAINMENT LEVEL	
		1	2
1	Laboratory suite: isolation	Not required	Not required
2	Laboratory: sealable for fumigation	Not required	Not required
3	Surfaces impervious to water, resistant to acids, alkalis, solvents, disinfectant and decontamination agents and easy to clean	Required for any bench	Required for any bench
4	Entry to laboratory via airlock	Not required	Not required
5	Negative pressure relative to the pressure of the immediate surroundings	Not required	Not required*
6	Extract and input air from the laboratory must be HEPA filtered	Not required	Not required
7	Microbiological safety cabinet/enclosure	Not required	Required where and to extent the risk assessment shows it is required
8	Autoclave	Required on site	Required in the building
9	Access restricted to authorised personnel only	Not required	Required
10	Biohazard sign on door	Not required	Required
11	Specific measures to control aerosol dissemination	Not required	Required so as to minimise
12	Shower	Not required	Not required
13	Protective clothing	Suitable protective clothing required	Suitable protective clothing required
14	Gloves	Not required	Required where and to extent the risk assessment

			shows they are required
15	Efficient control of disease vectors (e.g. rodents and insects) which could disseminate GMMs	Required where and to extent the risk assessment shows it is required	Required
16	Inactivation of GMMs in effluent from hand washing sinks and showers and similar effluents	Not required	Not required
17	Inactivation of GMMs in contaminated material and waste	Required by validated means where and to extent the risk assessment shows it is required	Required by validated means
18	Laboratory to contain its own equipment	Not required	Not required
19	An observation window or alternative is to be present so that occupants can be seen	Required where and to extent the risk assessment shows it is required	Required where and to extent the risk assessment shows it is required
20	Safe storage of GMMs	Required where and to extent the risk assessment shows it is required	Required
21	Written records of staff training	Not required	Required where and to extent the risk assessment shows it is required

*For mechanically ventilated laboratories, requirements for negative pressure remains.

Appendix 4: Version control

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