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HEALTH & SAFETY
IECHYD A DIOGELWCH

Work with Genetically Modified Organisms
Policy Arrangements

HSA-10127

Contents

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1. Introduction

These policy arrangements sets out what managers, staff and students have to do to ensure legal compliance when undertaking 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).

Contained use is defined as "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*** (e.g. a building, room or equipment), ***chemical*** (e.g. chemical inactivation) or ***biological*** (inherent or engineered attenuated, disabled or rendered unable to survive outside of a specialised environment), 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."

A **microorganism** is defined as "a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, and includes bacteria, fungi, virus, a viroid and an animal or plant cell in culture."

A **Larger GMO** is defined as “an organism which is genetically modified or is the subject of genetic modification but which is not a microorganism”

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 with the University GM Advisor.

1.1 Genetically Modified Organisms (Contained Use) Regulations 2014

The major requirements of the regulations 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 these policy arrangements, and a summary, including details of how the University complies with the regulations, and responsibilities for compliance can be found in Appendix 1.

The Scientific Advisory Committee on Genetic Modification has also produced a detailed compendium of guidance:

- Part 1: Introduction to the legislation and general health and safety issues
- Part 2: Risk assessment of genetically modified microorganisms (other than those associated with plants)
- Part 3: Containment and control of activities involving genetically modified microorganisms
- Part 4: Genetic modification work that involves plants (including plant-associated genetically modified microorganisms)
- Part 5: Genetic modification of animals
- Part 6: Guidance on the use of genetically modified microorganisms in a clinical setting

1.2 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 The University GM Advisor consulted.

2. Responsibilities

In addition to the roles and responsibilities set out in the Health and Safety Policy, the following responsibilities are required to manage the risks from work with GMOs:

2.1 Heads of College/ PSU

Heads of College are responsible ensuring adequate resources and appropriate measures are in place for the management of risks from activities involving GMOs. Heads of College must have arrangements in place to ensure:

- requirements of this University Policy arrangements are implemented;
- risk assessments are carried out prior to work with GMOs commencing, and that work is not carried out until approved by, or on behalf of the Biological Hazards and GMO sub-committee;
- containment level 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 and that all equipment is in good repair;
- staff and students receive adequate training and supervision;
- adverse events, such as accidents and spillages are reported via the online reporting system and investigated appropriately;
- 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 College and University inspections are implemented.

2.2 GM Project Supervisors

GM project supervisors are responsible for ensuring that all their genetic modification activities meet the requirements of this Policy arrangements, 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 Biological Hazards and GMO sub-committee (or for low risk activities the University GM Advisor) ***before*** any work starts or GMOs 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 class 2 GMOs or above which are harmful to human health are in receipt of an in-date health clearance from Occupational Health and, where necessary, 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 adverse events, including accidents and spillages are reported via the online reporting system;
- 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 the University GM Advisor for further information.

2.3 GM Workers

All workers with GMOs must ensure they:

- are familiar with, and understand the GM risk assessments that apply to their work, and ensure that they stay within the project boundary;
- adopt safe practices in activities involving GMOs, 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 GMOs;
- co-operate with their supervisors, College and H&S team to monitor safety in the College;
- Where appropriate, e.g. for work with class 2 or 3 genetically modified organisms, comply with the requirement for occupational health clearance and 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 non-harmful" larger GMOs.

Young persons (16-18 year olds) may work with class 1 or non-harmful 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

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

2.4 College GM Officers

- Represent their College on consultation committees and contribute to the development and implementation of policies relating to GMOs;
- Act as a competent person to provide advice to the Head of College and senior managers on the management of Genetic Modification work;

- Act as the first point of contact for College staff within for information and advice on procedures, hazards and control measures relating to GM activities;
- Participate in visits by external regulators (e.g. HSE) as required;
- Represent the College on the Biological Hazards and GMO sub-committee including participating in peer review of risk assessments and of facilities;
- Act as a focal point for the College to feed into the sub-committee and vice versa;
- Participate in inspection programme within own College, agree report and monitor completion of actions within college (with the College H&S Lead) and feed back to committee;
- Participate in the competency framework (i.e. attend relevant training) and promote training within College.

2.5 College H&S Leads

- Signpost information and advice on procedures, hazards and control measures relating to GM activities to staff and student;
- Participate in visits by external regulators (e.g. HSE) as required;
- Participate in audits and inspections and monitor completion of actions and escalation of outstanding actions when required.

2.6 Biological Hazards and GMO Sub-committee

The Biological Hazards and GMO sub-committee acts of the Genetic Modification Safety Committee for the University.

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

2.7 University GM Advisor

The role of University GM Advisor is subsumed in the remit of the Scientific H&S Advisor in the H&S team (Corporate Responsibility) and overseas the genetic modification safety management system at the University. Their duties include:

- Developing policy arrangements, standards and providing advice on local rules and systems of work with GMOs;
- Advise on and approve risk assessments (class 1 or “safe” larger GMOs)* in conjunction with the appropriate College representative;
- Advise the Biological Hazards and GMO sub-committee 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;
- Advise on the referral of staff and students to Occupational Health for health clearance or surveillance when necessary;
- Monitoring and auditing health and safety performance;
- Investigating adverse events involving GMOs and the provision of advice on remedial actions;

- Advising Colleges and Estates & Facilities Management on the suitability of containment level facilities;
- Assist in the provision of suitable training for those involved in activities using genetic modification;
- Support the operation of the Biological Hazards and GMO sub-committee.

The University GM Advisor has the authority to stop activities where the containment measures are considered insufficient to control the risks, and refer issues to the appropriate Head of College and the Biological Hazards and GMO sub-committee.

* Under the 2014 regulations, low risk projects (class 1 or “non-harmful” 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.

2.8 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 team) 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.

2.9 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 the risks associated with their GM projects;
- Report any adverse event, in communal areas or shared facilities, via the adverse event reporting system;
- Comply with **all** relevant policy arrangements issued by the University.

3. Risk assessment of GM activities

Before any activity (including storage) 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 and approved.

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 and provide 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.

Guidance on how to complete a GM risk assessment is available on the University website.

Risk assessment should include foreseeable emergencies, spillages, needle stick injuries etc. – further information in the risk assessment guide.

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.
- Waste.

Project proposals and risk assessments should be submitted to H&S by email to healthandsafety@swansea.ac.uk .

REVIEW AND APPROVAL PROCESS	
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 University GM Advisor (acting as “competent person”) in collaboration with the College GM Officer. • Projects may be approved, approve subject to changes, or referred to the next sub-committee 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 or sub-committee referral is required.
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	• Risk assessments will be initially reviewed by the University GM Advisor who may suggest changes/ ask for clarification.

modified microorganisms or "harmful" larger GMOs	• The project will be reviewed at the next Biological Hazards and GMO sub-committee meeting or a specially convened review panel. Where necessary additional specialists will be requested to advise on the project. • Project proposers may be invited to attend the 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 Biological Hazards and GMO sub-committee will decide on the final classification of the project, and may require modifications to the risk assessment, request further information, or require that the application should be revised and resubmitted to the next committee meeting. • Once approved by the Biological Hazards and GMO sub-committee, the University GM Advisor will notify the HSE accordingly. • FEES • Work cannot commence until a written letter of approval has been received from the Biological Hazards and GMO sub-committee, which will be issued once the appropriate notification conditions have been met.
EXTENSIONS TO NOTIFIED PROJECTS	• Updated risk assessments should be submitted to the Biological Hazards and GMO sub-committee, with the changes clearly highlighted. • The Biological Hazards and GMO sub-committee 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 the change to the work proposed which may have an effect on the risks of the activity. Even if the class of activity is not affected by the proposed change, the need for a new or significantly revised risk assessment may act as a trigger for notification of change. • Where the project risk assessment has been extended or changed previously, the extent of the total change will be judged against the original notification.

A note on HSE notification

- 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.

3.1 Connected programmes of activity

It is possible to submit a single notification for more than one contained use at the University to the HSE in the form of a connected programme of work. To be classified as a connected programme, all contained uses must be part of a coherent and integrated programme of work to form part of a common scientific research goal.

Project supervisors are responsible for coordinating the submission of a connected programme of work to the Biological Hazards and GMO sub-committee. 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 Biological Hazards and GMO sub-committee to ensure the proposed work is covered and consistent with the aims of the connected programme.

3.2 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.

3.3 Confidentiality issues

Project supervisors should be aware that all the information (with the exception of personal information) contained in a notification to HSE is disclose able 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.

4. Good laboratory practice

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.

5. 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 or 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 College.

6. Information, supervision and 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 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.

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

Undergraduates should not work unsupervised in 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.

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

7. Health clearance, surveillance

Within the University, work with genetically modified organisms which are harmful to human health and 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.

8. Pregnancy

Certain microorganisms within hazard groups 2, 3 and 4 can affect the unborn child if the pregnant person 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. Guidance of working with microorganisms during pregnancy can be found on the University website or contact healthandsafety@swansea.ac.uk

9. Transportation of GMOs 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.

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:

- 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.

Further information on transport of dangerous goods is available from the Health and Safety Team.

10. Reporting of accidents and incidents

All adverse events involving GMOs should be reported to H&S 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. H&S will investigate (with Sustainability and Security teams when appropriate) and where necessary notify the HSE of the incident.

Examples of situations which need to be notified to H&S immediately 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 of any such case of occupationally-acquired disease, so that the circumstances could be investigated. H&S are responsible for reporting the disease to the HSE.