Swansea University
Prifysgol Abertawe

HEALTH & SAFETY
IECHYD A DIOGELWCH

# Work with Genetically Modified Organisms
# Policy Arrangements

## HSA-10127

## Contents

## Document Control

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| Reviewed by | Biological Hazards & GMO Sub-Committee |
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| **1.1** | Jan 2020 | Rewritten and reviewed by Sub Committee |
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## 1. Scope

The standards set out in these arrangements are the minimum requirements for work with genetically modified biological organisms at Swansea University. These arrangements are written in accordance with University Health and Safety Policy arrangements (HSA-10100-01 Health and Safety Statement of Intent and HSA-10100-02 Health, Safety, Resilience and sustainability policy part 2, organisation document).

These arrangements should be read in conjunction with the Biological Safety arrangements (HSA-10126) as work with the strain non-GM strain should also be considered and risk assessed.

All Faculties are required to manage genetically modified organisms in accordance with these arrangements. It may be necessary in some areas to supplement these arrangements with a set of local rules for where a rare hazard and/ or highly specialised work is being carried out.

## 2. Legislative Context

These policy arrangements set out what, staff and students must 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. These regulations replaced 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 with the UBSO.

### 2.1 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 advises 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).

The HSE have provided further guidance The Genetically Modified Organisms (contained use) Regulations 2014 (L29) on how employers can comply with these regulations:

Further information on these requirements can be found in the roles and responsibilities section of these policy arrangements.

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

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

## 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 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 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 UBSO consulted.

## 3. Definitions

- **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, viruses, 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" and includes plants and animals.

## 4. Roles and Responsibilities

In addition to the roles and responsibilities set out in the Health, Safety, Resilience and Sustainability Policy HSA-10100-02, the following are required to manage work with GMOs in accordance with these arrangements:

### 4.1 Executive Dean of Faculty PVC, Deputy Executive Dean, Directors of Faculty Operations, Associate Dean (Research Innovation and Impact) and Head of School

Are responsible for managing health and safety within their function. This includes ensuring adequate resources and appropriate measures are in place for the management of risks from activities involving GMOs. They must have arrangements in place to ensure:

- Local management of GM safety meets the requirements as set out in these arrangements.
- Risk assessments are carried out prior to work with GM commencing, and that class 2 work is not carried out until approved by the Biological Hazards and GMO sub-committee.
- Containment level laboratory facilities are fit for purpose and maintained.
- Recommendations of all internal and external inspections/ audits are implemented.
- That a faculty GM Officer(s) are appointed where GM work is undertaken.
- The Faculty GM officers have occupational competence and academic qualification in the field, appropriate scientific and lab experience, time and resources to enable them to assist in undertaking the measures required to meet all the statutory provisions.
- New facilities and modifications are notified to the University Biological Hazards and Genetically Modified Organisms Sub-Committee for approval.

## 4.2 Principal Investigators (Academic leading a grant funded project) Supervisors (including GM Supervisors, Research and Academic / Teaching and Learning) and where appropriate the Supervisor of the Specific Research Activity

PIs and GM project supervisors are responsible for managing the health and safety of their research projects and ensuring that all their genetic modification activities meet the requirements of this Policy arrangement, and must ensure that:

- Appropriate licenses are in place for the non-GM aspects of their work, such as licences to work with plant or animal pathogens.
- Payment of the appropriate notification or significant change fee (for class 2/3 or “harmful” larger GMO projects only).
- A suitable and sufficient risk assessment is carried out for all activities involving genetic modification, using the GM Risk Assessment form available on Staff H&S Pages or PG MyUni H&S Pages
- The assessment is approved by the Biological Hazards and GMO sub-committee (or for low risk activities the Faculty GM officer) ***before*** any work starts or GMOs are acquired.
- 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 approvals and keep copies of all project assessments and approvals.
- Work with/ liaise with Faculty GM officer when required.
- All persons working under their supervision have received appropriate training and information, including awareness of risks, appropriate control measures to apply, the waste and emergency procedures. All training records to be stored electronically and should be accessible.
- They provide or organise appropriate supervision to assess and monitor competence of persons under their control to work safely.
- 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, see section 17.
- That only appropriate containment level laboratory facilities are used for the work and that a good standard of housekeeping is maintained.
- All adverse events, involving GM material, including accidents and spillages are reported via the report it online reporting system on Report It and are required to assist the Health, Safety & Resilience (HS&R) team in investigating these.
- Carry out or ensure periodic inspections of GM work activities and lab space.
- Ensure all actions identified following internal and external inspections/ audits are implemented.

Please note additional requirements will apply to GM project supervisors of class 3 GM activities, please consult the UBSO for further information.

## 4.3 Staff and Students

All staff and students who work with GMOs must ensure that they:

- Are familiar with and understand the GM risk assessments that apply to their work and ensure that they stay within the project boundary.
- Follow the requirements of any local rules and safe operating procedures.
- Adopt safe practices in activities involving GMOs, including the principles of good microbiological/ laboratory practice.
- Wear the appropriate protective equipment and clothing.
- Where appropriate, e.g. for work with class 2 genetically modified organisms, comply with the requirement for occupational health clearance and health surveillance.
- Dispose of waste in the specified manner according to the Risk Assessment/ Local rules. Please see Waste management Guidance Notes
- Report any incident, accident or defect in equipment relating to the handling of GMOs; to PI/ supervisor initially, then via online reporting system.
- Co-operate with their supervisors, Faculty operations and HS&R team to monitor safety in the School/ Faculty.
- Attend the relevant training courses.
- Lab staff to carry out periodic inspections where required of GM work activities and lab space and implement any recommended actions accordingly.

**Please note:** Children 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.

## 4.4 Faculty GM Officers

Faculty GM Officers are appointed by Executive Dean of Faculty PVC. They specialise in GM and may also be Faculty BSO officers. Their duties include:

- Represent the faculty on consultation committees and contribute to the development and implementation of policies relating to genetically modified organisms (GMO) hazards.
- Act as a competent person to provide advice to the Head of School/ Faculty and senior managers on the management of GMO work.
- Act as the first point of contact for Faculty staff for information and advice on procedures, hazards and control measures relating to GM activities.
- Provide expert advice to the Biological Hazards and GMO Sub-Committee on risk assessment, classification and facilities.
- Advise staff on the development and review of risk assessments for GM work and to approve Hazard Group 1 risk assessment in conjunction with University Biological Safety Officer.
- Ensure that local rules for work with GM are in place and suitable.
- Participate in inspection/ audit programme within own Faculty, agree report and monitor completion of actions within the school/ faculty (with the Faculty HS&R Advisor) and feed back to committee.
- Ensure adverse events involving biological/ GMO are reported and assist with the investigation.
- Assist with the preparation and testing of emergency plans where required.
- Participate in visits by external regulators (e.g. HSE) as required.
- Attend relevant training courses.

## 4.5 Biological Hazards and GMO Sub-committee

The Biological Hazards and GMO sub-committee acts as the Genetic Modification Safety Committee for the University. The role of the committee is to monitor and review all Biological and GM work carried out at the University. The committee also contributes to the development of the Biological and GM safety arrangements.

The committee includes Faculty 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.

## 4.6 University Biological Safety Officer (UBSO)

The role of University Biological Safety Officer is subsumed in the remit of the Scientific Safety Advisor in the HS&R team and overseas the biological safety management system at the University. Their duties include:

- Developing policy arrangements, standards and providing advice on local rules and systems of work with GM material.
- Advise on and approve risk assessments (class 1 or “safe” larger GMOs) in conjunction with the appropriate Faculty GM officer.

- Advise the Biological Hazards and GMO sub-committee on risk assessments for class 2 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 GM safety performance.
- Investigating adverse events involving GMOs and the provision of advice on remedial actions.
- Advising Faculties 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 UBSO has the authority to stop activities where the containment measures are considered insufficient to control the risks and refer issues to the appropriate Executive Dean of Faculty and the Biological Hazards and GMO sub-committee.

## 4.7 Faculty Health, Safety and Resilience Advisors

- 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.
- Assist tenant to complete the Organisation Document - Governance Arrangements: University Partnerships, Tenants, Collaborations, Subsidiaries and Spinouts HSA-10100-02b.

## 4.8 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 HS&R 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.

### 4.9 Tenants

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

- Complete the Organisation Document - Governance Arrangements: University Partnerships, Tenants, Collaborations, Subsidiaries and Spinouts HSA-10100-02b with a member of the HS&R team.
- 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.

## 5. 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 assessment of the risks to human health and the environment is carried out and approved following the approval process below.

The GM project 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 risk assessment should be proportionate to the level of risk and should assess the hazards, the means by which harm could be realised, the likelihood of this occurring, the control measures required and should provide sufficient detail for the committee to review.

The risk assessment should include foreseeable emergencies, spillages, needle stick injuries etc. and plans to deal with foreseeable incidents should be in place. When drawing up emergency plans several 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.

GM risk assessments should be submitted UBSO by email to a.c.lee@swansea.ac.uk. (see section 5 for Approval process and appendix 1 for authorisation flow chart).

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

## 6. Review and Approval Process

### 6.1 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 USBO in conjunction with a Faculty 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 in writing via email from the UBSO.

### 6.2 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.

### 6.3 Class 2 Genetically modified microorganisms or "harmful" larger GMOs

- Risk assessments will be initially reviewed by the UBSO and Faculty GM Officer who may suggest changes/ ask for clarification.
- 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.
- PI's/ GM supervisors may be invited to attend the meeting to explain their project in further detail.
- 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 UBSO will notify the HSE accordingly.

### 6.4 Extensions to Notified Projects

- Updated risk assessments should be submitted to the UBSO, 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

https://www.hse.gov.uk/pubns/priced/l29.pdf 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.

For GM Approval process flow please see Appendix 1.

## 7. Connected programmes

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.

## 8. Undergraduate Teaching

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 unless this material is used).
- The activities are risk assessed and approved by the Biological Hazards and GMO sub-committee for use in teaching practicals.
- Activities are adequate supervised and appropriate containment facilities are used.

## 9. Confidentiality

Project supervisors should be aware that all the information (except for 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.

## 10. Supervision and Training

Training and supervision for GM work should be conducted and recorded. All training records should be held by the PI and can be stored electronically and should be accessible, see Appendix 2 for example training record.

The following competencies are required:

- **University BSO** - Appropriate scientific and lab experience. Minimum Biological Safety Practitioner Level 1.
- **Faculty GM Officer** – Occupational competence and academic qualification in the field, appropriate scientific and lab experience, completion of and attendance at internal University Biosafety management course.
- **Principal Investigators (PI's)** - Occupational competence and academic qualification in the field, appropriate scientific and lab experience, completion of and attendance at internal University biosafety management course.
- **Staff and Student** (who work with GM material) – local induction and training on risk assessments, procedures, and local rules, completion of and attendance at internal University Biosafety user training. All users must be competent to carry out GM work unsupervised. Undergraduate students should not perform experiments on class 2 organisms unsupervised.

To access internal University Courses email corporateresponsibility@swansea.ac.uk

## 11. Inspection and Audit

Inspections and audits are carried out to ensure that the laboratory and equipment and lab users are operating safely and complying with any appropriate legal standards.

Lab inspections should be carried out periodically by the PI/ Supervisor, the Faculty BSO Officer or appropriate lab staff. The inspection is a set of pre-determined questions and will look at laboratory and equipment to ensure it is working correctly, ensure SOPs and Local rules are being followed, PPE is worn correctly, and waste is being disposed of correctly (this is not an exhaustive list). The inspection should be recorded and any actions from the inspection should be closed out in a timely manner.

Audits will be planned and carried out by a team of people led by the UBSO. The auditor will look to ensure all legal standards are complied with and may look at any significant risks, compliance with any risk assessments and SOP's, relevant training records or general management practice. This will include asking for and reviewing evidence along with talking to staff and students during the visit.

A written report will be prepared and presented to the Faculty CR committee and the Biological and GMO hazards sub-committee. The report must include details of any issues highlighted, the remedial actions required, and an action plan detailing who is responsible for the action and timescales.

Faculty procedures should be in place to follow up and ensure recommendations are carried out.

## 12. Adverse Event Reporting

All adverse events involving GMOs should be reported to HS&R using the on-line adverse event reporting form Report It. 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 the PI/ supervisor, Faculty operations teams and Faculty BSO, UBSO and Faculty HS&R Advisor.

All incidents will be investigated by HS&R (with sustainability and security teams when appropriate) and the PI / supervisor with the aim of identifying lessons learned and preventing through root cause analysis, similar occurrences in future. Any remedial actions required must be implemented immediately where possible and lessons learnt communicated widely to all who can benefit

In some cases, the HSE must be notified by the HS&R team under the Reportable Incidents, Diseases and Dangerous Occurrences (RIDDOR) regulations. Examples of situations which need to be notified to HSE 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.

## 13. Good Microbiological/ Laboratory Practice

The Principles of good microbiological/ laboratory practice aim to protect laboratory workers from contamination by biological 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. These principles should form the basis of the Laboratory Local rules/ SOPs and be well adhered to.

### 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 refer to HWG produced by the Waste and Recycling Officer.
- Emergency procedures such as spillage, first aid and back up storage facilities.

## 14. Safe storage and Inventory

Any GM modified material must be stored securely in the laboratory or green house, well labelled and the fridge/freezer must be on a back-up power supply and temperature monitored. If the contents are subject to the Human Tissue Act, then these are essential requirements to maintain the licence. The inventory should include details of the owner, amount stored, location and type of sample. The inventory should be stored centrally but should also be available to the central faculty team.

## 15. 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. Arrangements for expectant and breastfeeding person are available on the University Website, this contains guidance for working with microorganisms and should be considered as part of the pregnancy risk assessment process found on Staff H&S pages or PG MyUni H&S Pages or contact healthandsafety@swansea.ac.uk

## 16. Transportation of GM materials

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. GMMs or GMOs that do not meet the definition of an infectious substance but can alter animals, plants or microbiological substances in a way not normally the result of natural reproduction are assigned to Class 9 (UN 3245).

**Transportation of hazardous biological material by public transport e.g. tube, or passenger rail is prohibited. Transportation via private vehicle in the UK may be permissible if 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 UBSO.

## 17. Occupational Health

The University Occupational Health service provides services to protect the health of staff and students, at work, in training, and in study, to assess fitness for work, training and study, and to help manage health issues effectively.

There are effective vaccines against some biological agents. Based on a specific risk assessment, the Occupational Health Service can make arrangements for vaccination, to workers who are considered vulnerable to the biological agents to which they are exposed or are likely to be exposed at work.

Health surveillance is required under COSHH where:

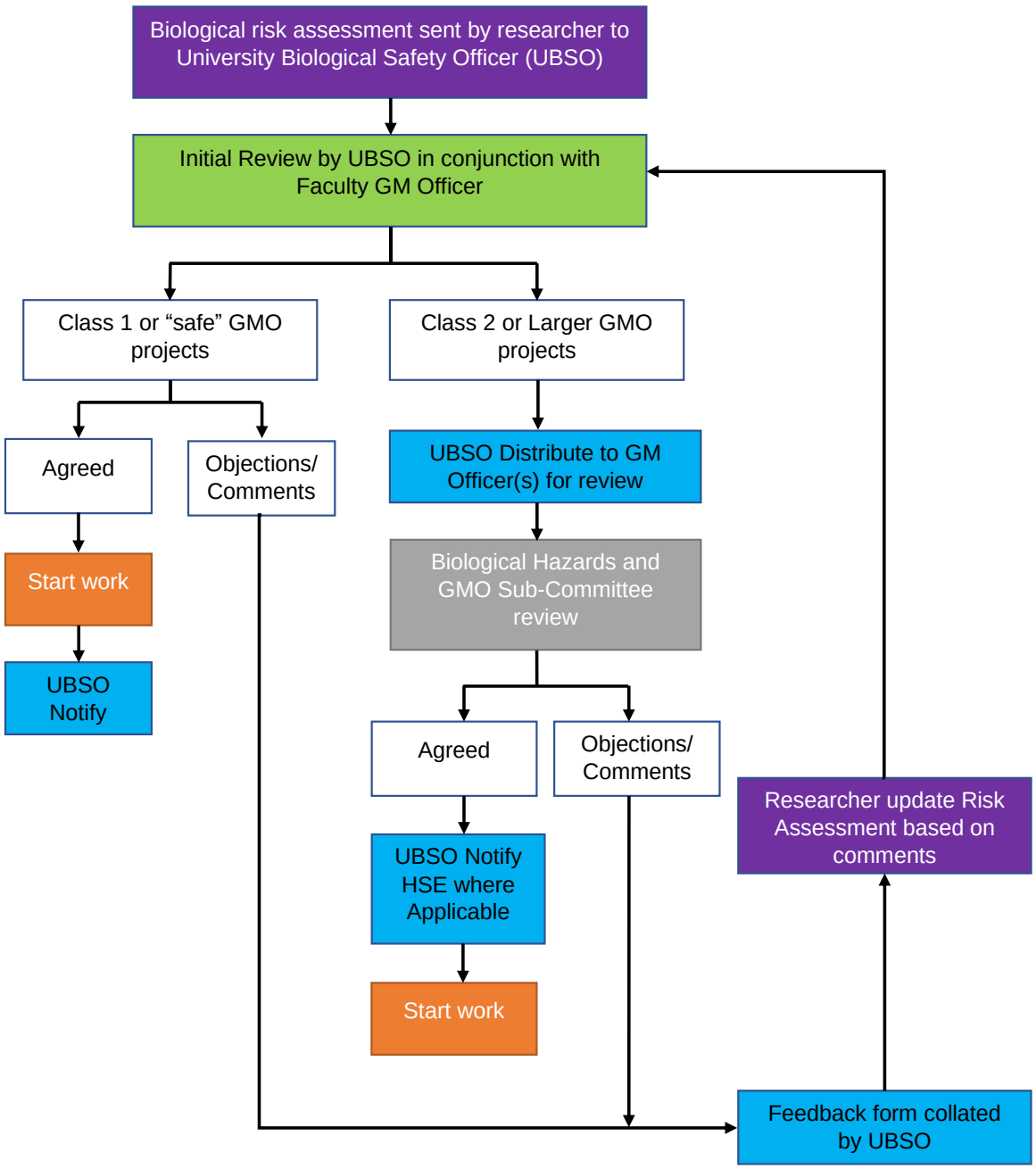
- There is an identifiable disease or health effect, which may be related to workplace exposure.
- The disease will occur in reasonable likelihood.
- There are valid techniques for detecting indications of the disease or its effects. Visiting researchers are included in health surveillance where this is appropriate.
- Monitoring/ checking employee's health to detect workplace illness e.g. following up sickness absence or explaining symptoms to workers so they can monitor their own health.

The requirement for health surveillance should be identified in the risk assessment for the work being undertaken.

## 18. Appendices

### Appendix 1

**GM Risk Assessment Approval Process**



## Appendix 2

### Training Record (Local)

| | |
|---|---|
| **Trainee Name** | |
| **Staff/ Student** | |
| **Start Date** | |
| **PI/ Supervisor/ Line manager(s)** | |
| **Project title (Students only)** | |

**Key: Level of attained competency**

| |
|---|
| **A:** The task must be directly supervised |
| **B:** The supervisor's advice and approval must be sought before the task is started |
| **C:** The work entails risks which require careful attention to the safety related aspects of it. The student has been trained in the task and demonstrated competence |
| **D:** The risks are insignificant and carry no special supervision considerations |

**Add additional rows to record additional training in specialised areas of work.**

| Activity/ Procedure/ Course | Training Received (Trainee's signature) | Trainers name (block capitals) Signature | Method by which competence assessed Written/ Oral/ Practical | Required competence attained (or indicate level of supervision required A, B or C above) | Date |
|---|---|---|---|---|---|
| Staff/ student local induction | | | | | |
| Staff/ student introduction to laboratory | | | | | |
| Fire safety awareness course | | | | | |
| Laboratory training: Use of pipettes | | | | | |

| Activity/ Procedure/ Course | Training Received<br><br>(Trainee's signature) | Trainers name (block capitals)<br><br>Signature | Method by which competence assessed Written/ Oral/ Practical | Required competence attained (or indicate level of supervision required A, B or C above) | Date |
|---|---|---|---|---|---|
| Laboratory training: Use of fume cupboards | | | | | |
| Laboratory training: Use of laminar flow hoods | | | | | |
| Laboratory training: Use of microbiological safety cabinets | | | | | |
| Laboratory training: ACGM training | | | | | |
| Laboratory training: Working with cryogens | | | | | |
| Laboratory training: Use & transport of gas cylinders | | | | | |
| Laboratory training: Use of toxic chemicals | | | | | |
| Laboratory training: Use of Carcinogens, mutagens or STR's | | | | | |
| Laboratory training: Handling phenol | | | | | |
| Laboratory training: Use of corrosive material (strong bases) | | | | | |

| Activity/ Procedure/ Course | Training Received<br><br>(Trainee's signature) | Trainers name (block capitals)<br><br>Signature | Method by which competence assessed Written/ Oral/ Practical | Required competence attained (or indicate level of supervision required A, B or C above) | Date |
|---|---|---|---|---|---|
| Laboratory training: Handling glass and sharp objects – e.g. pipettes, plates, Pasteur pipettes, blades, needles, syringes | | | | | |
| Laboratory training: Use of microwaves in the laboratory | | | | | |
| Laboratory training: Use of high voltage electrophoresis equipment | | | | | |
| Use of radioactive substances **(by local RPS)** | | | | | |