UCC
Coláiste na hOllscoile Corcaigh, Éire
University College Cork, Ireland

UCC Biosafety

UCC Laboratory Biosafety Class 1 GMM Guidelines

The UCC Biosafety Guidelines aim to provide assistance and guidance to researchers handling biological agents in a safe manner using Good Microbial Practices (GMP) and Good Occupational Safety and Hygiene (GOSH). These guidelines are for a Class 1 Genetically Modified Micro-organism (GMM) Laboratory.

Please note that these guidelines do not replace the Environmental Protection Agency (EPA: http://www.epa.ie/) conditions on your GMM consented registry nor do they replace the S.I. No. 73/2001 – Genetically Modified Organisms (Contained Use) Regulations, 2001 (http://www.irishstatutebook.ie/2001/en/si/0073.html).

Checklist	
☐	Annual Report Submitted? (*deadline 31st March 2011)*
☐	Limiting Access to GMM facility (e.g. Biohazard sign)
☐	Disposal of GMM waste (e.g. Autoclave inactivation record)
☐	SOPs – Training of New Staff (e.g. Staff training record)
☐	SOPs – Treatment of Spills
☐	SOPs – Cleaning & Disinfection of equipment
☐	SOPs – Maintenance of Equipment
☐	SOPs – Transport of GMMs within Lab/Dept/Building
☐	Risk Assessments
☐	GM Identification & Characterization
☐	Maintenance of records & Log Books: training records/inactivation records/Storage of GMMs

(A) Access to GMM Class 1 Laboratory

1) Access to laboratory working areas should be for authorised personnel only. Visitors should grant access from Principal Investigator or designated responsible person. Children should not be allowed to enter the lab and under no circumstances should vermin/pests and pets be authorised to enter.

2) Lab doors should be kept closed and locked when unoccupied.

3) A **biohazard symbol and sign** (**e.g. Figure 1 Biohazard Sign**) should be placed on the entrance to the laboratory if biological agents are handled in that laboratory including details of the Principal Investigator/Responsible person and phone number.

(B) Personal Protection

1) Lab coats must be worn at all times when working in the laboratory but removed before leaving the laboratory suite (such as bathroom, offices and canteen).

2) Gloves should be worn when handling biological agents and animals but removed when touching door handles, computers, telephone etc. Hands should be washed after gloves are removed.

3) Safety glasses/visor or other protective devices should be worn to protect against impacting objects, splashes or UV radiation.

(C) Lab Procedures

1) Mouth pipetting is prohibited

2) Eating and drinking, applying cosmetics/contact lenses or storage of food and drinks is not permitted in the laboratory.

3) Open-toed footwear not permitted in the laboratory.

4) Limit the use of hypodermic needles and syringes. The must only be used for injection or aspiration of fluids from laboratory materials/animals.

5) Technical procedures should minimize aerosol dissemination.

6) **Standard Operating Procedures** should be in place and followed especially in relation to:

- Accidents and spills of GMM materials

7) Inactivation of biological material (**e.g. Table 2 Autoclave inactivation record**)

8) Contaminated waste liquids and solids must be inactivated and/or safely contained, and must not pose a hazard to persons exposed to or handling the material while in the waste management process.

9) Packaging and transportation of biological agents outside the University must follow National/International regulations.

10) Personnel must wash their hands after touching infectious materials and animals and before leaving the laboratory working area

11) Suitable arrangement must be made for the safe handling and transport of biological agents within the workplace.

(D) Class 1 Laboratory

1) The Laboratory should be kept clean and tidy.

2) Work surfaces should impervious to water and resistant to acids, alkalis, solvents and disinfectants

3) Work surfaces must be decontaminated after any spill of potentially hazardous material and at the end of the working day.

4) Laboratories should be subject to vermin/pest control where necessary.

5) Written documents that are expected to be removed from the laboratory need to be protected from contamination while in the laboratory.

6) There must be clearly defined storage areas for biological agents in the laboratory (**e.g. Table 3. Example of GMM storage records** and **Figure 1. Biohazard Sign**).

(E) Biosafety Management

1) It is the responsibility of the principal investigator to ensure the development and execution of a written biosafety management plan and an operations manual. Such documents may include risk assessments, safety training records, standard operating procedures, licences, and emergency plans (e.g. **Table 1. Example of Staff training record**, **SOPs**, **Risk Assessments**).

2) Laboratory personnel, university maintenance, house-keeping staff, and other authorised persons must be trained in, advised of, or consulted by laboratory management of, any special hazards involving biological agents and they must comply with safety procedures that are in place to minimise the risk of exposure to the biological agents.

3) Annual reports must be submitted to the EPA.

BIOHAZARD

*****Authorised Personnel only*****

Biosafety Level _____

Principal Investigator _____

Contact Details _____

Authorization for visitor access must be obtained from the Principal Investigator listed above

Do not remove items from this lab without prior authorization

Please keep this door locked when not attended

Figure 1 Example of Biohazard symbol for entrance to Laboratory and/or Growth facility/Animal houses.

Table 1. Example of Staff training record.

Signature of this record states that I have received full training in appropriate GMP and GLP. I am familiar with all SOPs relevant to Class 1/Class 2 GMOs/GMMs and safe disposal of GMOs/GMMs. I am familiar with the Irish and EU guidelines relevant to the contained use of GMMs

Staff training Record		
Date:	**Name:**	**Principal Investigator**

Table 2: Example of Autoclaves Inactivation record

Autoclave GMM/GMO inactivation record		
Date:	**Name:**	**Program settings:** **121°C x 15 min**

Table 3 Example of GMM storage records.

GMM Storage Record			
Date:	**Name:**	**GMM Details**	**Location**

Checklist for UCC Laboratory Biosafety Inspections: **1st Visit**

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University College Cork, Ireland

UCC Biosafety

Department: _____	**Building:** _____	**Room: (PI)** _____
Room: (Lab) _____	**Autoclave Location**: _____	
PI: _____	**Responsible Person:** _____	
Containment Level (GMM):	**1**☐	
Inspected by:_____		**Date:**__/__/__

GMM Class 1

Key: X = no √ = yes N/A = not applicable

(example documents available for items in **bold**)

(A) Other Requirements	
☐	Annual Report Submitted (2010)? *deadline 31st March 2011*

(B) Good Microbiological Practice (GMP) *[GMM Class 1 & 2 & GMO]*	
☐	The laboratory should be easy to clean. Bench surfaces should be impervious to water and resistant to acids, alkalis, solvents and disinfectants
☐	Benches should be clean and free from clutter & Bench tops should be cleaned after use
☐	The laboratory door should be closed when work is in progress
☐	**Biohazard sign** at entrance to lab, autoclave area, freezer area
☐	Minimise the production of aerosols
☐	The identity of GMOs should be regularly checked to avoid the culturing of incorrect strains.
☐	Appropriate training of personnel - **Staff training record**
☐	Maintenance of equipment – Autoclave/Fume cupboards/Laminar Flow Hoods ….
☐	**Inactivation Record** (Autoclave)
☐	Washing and decontamination facilities

☐	Hands must be disinfected or washed immediately when contamination is suspected, after handling viable materials and also before leaving the laboratory
☐	Effective disinfectants should be available for immediate use in the event of spillage
☐	Used laboratory glassware and other materials awaiting disinfection must be stored in a safe manner
☐	Use of sharps should be avoided. Contaminated syringes and sharps must be disposed of in a "sharps bin" and incinerated
☐	Materials for disposal must be transported in robust and leakproof containers without spillage
☐	Eating, chewing, drinking, taking medication, smoking, storing of food and applying cosmetics must not take place in the work area
☐	Mouth pipetting must not take place
☐	Laboratory coats should be worn in the laboratory and removed when leaving the laboratory suite
☐	Personal protective equipment, including protective clothing, must be - stored in a well defined place - checked and cleaned at suitable intervals - when discovered to be defective, repaired or replaced before further use
☐	Personal protective equipment which may be contaminated by biological agents must be: - removed on leaving the working area - kept apart from uncontaminated clothing - decontaminated and cleaned, or if necessary, destroyed
☐	**Biosafety Manual with SOPs**
☐	All accidents and incidents should be immediately reported to and recorded by the person responsible for the work or other delegated person
☐	Animals must not be allowed to enter into the laboratory
(C) Physical Control Measures: Facility Design *Class 1*	
☐	process with viable micro-organisms separated from the environment (closed system)
☐	Accessability of window that opens
☐ **optional**	biohazard sign on the door
☐	signs at laboratory entrance: - special hazard signs if an organism containing rDNA needs special provision for persons entering the laboratory

optional	- names of occupants who have access to the laboratory
☐	Outward opening of Laboratory doors
☐ optional	Observation window or alternative to enable occupants to be seen
(D) Physical Control Measures: Containment equipment *GMM Class 1*	
☐ Optional	check the suitability of any chemical disinfectants in use
☐ on site	check position of the autoclave with respect to the GMO installation
☐	wash hand basin or sink that can be used for hand washing with: - dispenser containing soap - dispenser containing hand disinfectant - paper towels
☐ optional	check position and design of biological safety hoods
☐	Check design of the equipment for the safe storage of GMOs. Storage is not allowed in floors as long it is not part of the facility
☐ optional	check design of waste transport containers
☐ optional	check design of containers for the transport of GMOs inside the facility
☐	check design of centrifuge buckets
☐	Provision of eye wash stations / bottles / equipment
(E) Safety Management – Work Procedures *GMM Class 1*	
☐	doors closed while working
☐	workers should be given adequate information on safety matters and be suitably trained. Training should include the following points: a) the existence and application of written work procedures b) the procedures for using particular pieces of equipment c) spillage control and other emergency procedures
☐ optional	check at which process steps hazardous quantities of aerosols are formed. Any operation that may involve the formation of aerosols (e.g. sonicating, centrifuging, pipetting) shall be performed in such a way as to ensure that these do not find their way into the working area.

☐	GMO's are only to be transported within the facility in closed, robust and leakproof containers
☐	work surfaces must be decontaminated daily and after a spillage
☐ optional	inactivation of GMOs in contaminated material and waste
☐	users should ensure that the performance of safety equipment is validated (e.g. autoclaves and safety hoods) - validation of equipment (e.g. autoclaves, safety hoods) - maintenance of the equipment - markers used to verify the efficiency of autoclaves
☐	skin contact with rDNA material must be avoided
☐	decontaminate protective clothing before laundering
☐	protective clothing and street wear must be kept separate
☐ optional	*Gloves* (Optional)
☐ optional	*implementation of an insect and rodent control programme*
☐	sample collection, addition of materials to closed system and transfer of viable micro-organisms to another closed system, should be performed as appropriate
☐	safe storage of biological agents
☐	Regular identification and confirmation of purity of microbial strains
☐	Safe storage of contaminated laboratory equipment
☐	Personnel to remove protective clothing on leaving the facility
☐	Worker required to wear closed shoes
☐ optional	Regular maintenance of safety equipment such as safety cabinets
(E) **Safety Management – Organisational matters and documentation relating to the safe handling of GMOs**	
☐	provide documentation of: - the appointment of the Biological Safety Officer (BSO) by the licensee
☐	the appointment of project leader by the licensee

☐	- a description of the tasks of the BSO a.o. with respect to - safety - internal control - accident/incident response and preparedness - internal counselling, advice and education - reporting
☐	a description of the tasks of the project leader a.o. with respect to: - everyday management - drawing-up and executing work-protocol
☐	a clear description of the separation of responsibilities and tasks between the BSO and the project leader the discretionary powers/mandate that the BSO has received in order to fulfill his duty
☐	the status of the BSO should be defined. The job description should include - mechanisms whereby the BSO can report directly to the licensee - instructions that the BSO should hand his function over to a deputy in situations where he is involved in carrying out the practical work himself. - an indication as to the amount of time that the BSO will be allocated to undertake their role
☐	there should be written procedures that cover the following: - undertaking risk assessments - the training of new staff - emergency procedures including the treatment of spillages with disinfectants - cleaning and disinfection of equipment - transport of GMOs - operation, testing and maintenance of containment equipment - measures for limiting access to facilities - health surveillance of workers
☐	written instructions should be in the language of the personnel working in the facility
☐	documents that should be centrally held within an institution undertaking GM work: a) records indicating working areas and their containment levels (these records may include plans of buildings) b) all of the documents listed in point 8 above c) a copy of all risk assessments and notifications d) these records should also cover any sites for storage of GMOs outside of containment facilities e) records of internally organised inspections f) records of incidents and accidents, including evaluation and any remedial action g) a list of other data and documents that are held at

	other locations within the institution
☐	examples of documents that can be held separately from the main records: a) records of staff involved in GM work indicating their experience and training and the type of projects in which they have been employed b) results of procedures for checking the purity and identity of the GMOs c) results of the testing of containment equipment (e.g. autoclaves and safety cabinets) d) a list of stored GMOs for each storage facility e) work protocols for particular experimental procedures
☐	Implementation of measures to minimise worker exposure, where work with class 1 GMMs with sensitising or toxic properties is being carried out (e.g. safety cabinet, provision of inhalation equipment when working with sporulating fungi)
(F) **Risk Assessment**	
☐	check that risk assessments have been undertaken for all projects and that individual risk assessments contain sufficient information and have addressed all relevant issues.
☐	Ensure accurate descriptions/ characterisations of GMO's or groups of GMO's
☐	description of the host-organism and name of the GMO
☐	description of the genetic material used to construct this GMO comprising at least the composition and the donors it was derived from
☐	in case of a Class 1 GMMs (requiring only reporting) gene functions should be documented
☐	for GMO's requiring notification the number of notification/licence should also be mentioned
☐	classification of the micro-organism(s) to be used
☐	classification of the operation
☐	check that ongoing projects have not diversified into areas of research that were not covered in the original risk assessment (e.g. by the help of a literature search or discussion with other members of staff)
☐	check that notifications have been made where necessary
☐	check to see that risk assessments are reviewed by a local safety committee, if necessary
☐	check that people actually handling a particular GMO are aware of the content of the corresponding risk assessment

Emergency Responses:	
☐	check information on accidents (reporting of accidents and near – misses and records of corrective actions that have been taken)
☐	provide written procedures for: - a procedure for internal notification of incidents (e.g. spillages) - a procedure for external notification in case of serious risk - a procedure for incident/accident response (measures, reporting, evaluation) - emergency preparedness actions and countermeasures in case of accidents or incidents

IMPORTANT: Please refer back to your **EPA GMO registry** to see the **conditions** that apply to your lab. Some items that are **optional** for one lab may be **required** for another. This checklist is for guideline purposes only.

Recommendations/Comments:

Next Visit Date: __/__/__

Copy to be given to Principal Investigator/Responsible person.

Annex I

Tables adapted from S.I No.73/2001 – Genetically Modified Organisms (Contained Use) Regulations, 2001.

Table 4 **Containment measures for contained use of GMM in a Class 1 & 2 Laboratory**

Measures		**Containment Level**	
		Class 1	**Class 2**
1	Laboratory suite: isolation	Not required	Not required
2	Laboratory: sealable for fumigation	Not required	Not required
Equipment			
3	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required for bench	Required for bench
4	Entry to laboratory via airlock	Not required	Not required
5	Negative pressure relative to the pressure of the immediate environment	Not required	Not required
6	Extract and input air from the laboratory should be HEPA-filtered	Not required	Not required
7	Microbiological safety cabinet	Not required	Optional
8	Autoclave	On site	In the building
System of work			
9	Restricted access	Not required	Required
10	Biohazard sign on the door	Not required	Required
11	Specific measures to control aerosol dissemination	Not required	Required to minimize
12	Shower	Not required	Not required
13	Protective clothing	Suitable protective clothing	Suitable protective clothing; footwear optional
14	Gloves	Not required	Optional
15	Efficient vector control (e.g. for rodents and insects)	Optional	Required
Waste			
16	Inactivation of genetically modified micro-organisms in effluent from hand-washing sinks or drains and showers and similar effluents	Not required	Not required
17	Inactivation of genetically modified micro-organisms in contaminated material and waste	Optional	Required
Other measures			
18	Laboratory to contain its own equipment	Not required	Not required
19	Observation window or alternative to enable occupants to be seen	Optional	Optional

Table 5 **Containment measures for contained use of genetically modified micro-organisms in plant growth facilities**

Measures		Containment Level	
		Class 1	**Class 2**
Building			
1	Permanent structure	Not required	Required
Equipment			
2	Entry via a separated room with two interlocking doors	Not required	Optional
3	Control of contaminated run-off water	Optional	Required to minimise run-off
System of work			
4	Measures to control undesired species such as insects, rodents, arthropods	Required	Required
5	Procedures for transfer of living material between the plant growth facility and laboratory to control dissemination of genetically modified micro-organisms	Required to minimise dissemination	Required to minimise dissemination

Table 6 **Containment measures for contained use of genetically modified micro-organisms in animal units**

Measures		Containment Level	
		Class 1	**Class 2**
Facilities			
1	Isolation of animal unit	Optional	Required
2	Animal facilities separated by lockable doors	Optional	Required
3	Animal facilities designed to facilitate decontamination	Optional	Optional
4	Floor and walls easily washable	Optional	Required for floor
5	Animals kept in appropriate containment facilities	Optional	Optional
6	Filters on isolators or isolated room	Not required	Optional

Table 7 **Containment measures for contained use of genetically modified micro-organisms in facilities other than those covered by tables above**

Measures		Containment Level	
		Class 1	Class 2
General			
1	Viable micro-organisms contained in a system which separates the process from the environment, i.e. a closed system	Optional	Required
2	Control of exhaust gases from the closed system	Not required	Required to minimise dissemination
3	Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	Optional	Required to minimise dissemination
4	Inactivation of bulk culture fluids before removal from the closed system	Optional	Required, by validated means
5	Seals designed to minimise or prevent release	No specific requirement	Required to minimise dissemination
6	Designation of controlled area to contain spillage of the entire contents of the closed system	Optional	Optional
7	Controlled area sealable to permit fumigation	Not required	Optional
Equipment			
8	Entry via airlock	Not required	Not required
9	Surfaces resistant to water, acid, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required for bench	Required for bench
10	Specific measures adequately to ventilate the controlled area in order to minimise air contamination	Optional	Optional
11	Controlled area maintained at an air pressure negative to the immediate surroundings	Not required	Not required
12	Extract and input air from the controlled area to be high efficiency particulate air filtered	Not required	Not required
System of work			
13	Closed systems located within a controlled area	Not required	Optional
14	Access restricted to nominated personnel only	Not required	Required
15	Biohazard signs posted	Not required	Required
16	Personnel to shower before leaving the controlled area	Not required	Not required
17	Personnel to wear protective clothing	Required (work clothing)	Required (work clothing)
Waste			
18	Inactivation of GMM in effluent from hand-washing sinks or showers or similar effluents	Not required	Not required

19	Inactivation of GMM in contaminated material and waste including those in process effluent before final discharge	Optional	Required, by validated means