Requirements for the Identification of Genetically Modified Organisms in Storage Guideline

Section 1 - Purpose and Objectives

(1) This Guideline outlines labelling, record keeping and storage requirements for genetically modified organisms. This Guideline supplements the UQ Biosafety Policy and requirements specified by the Office of the Gene Technology Regulator's Guidelines for the Transport, Storage and Disposal of GMOs.

Section 2 - Definitions, Terms, Acronyms

Term	Definition
Biological Material	Includes but is not limited to: blood, blood products, tissues, body fluids and any derivatives produced by chemical or physical means; micro-organisms – wild type or mutant; plants and plant material.
Biosafety	Measures relating to the protection of an environment or population etc. from contamination with or infection by a biological agent.
Deal with, in Relation to a GMO	As defined by the OGTR: Conduct experiments with GMOs; make, develop, produce, manufacture GMOs; breed; propagate; use GMOs in the manufacturing of non GM products; grow, raise, culture GMOs; import GMOs; transport; store or dispose of GMOs; and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned previously.
DIR	Dealing Involving Intentional Release. This is a licence issued to an Accredited Organisation to undertake high risk dealings outside a certified facility, e.g. field trial.
DNIR	Dealing Not Involving an Intentional Release. This is a licence issued to an Accredited Organisation to undertake high risk dealings within a certified facility such as laboratory or glasshouse.
Exempt Dealing	A type of GM dealing, one that poses a very low risk, a dealing specified by the regulations to be an exempt dealing.
GM/GMO	Genetically Modified/Genetically Modified Organism.
IBC	Institutional Biosafety Committee, established by an Accredited Organisation, as required by the OGTR.
NLRD	Notifiable Low Risk Dealing
NLRD Category Material	Material that still falls under classification of a NLRD whilst in storage, e.g. viral vectors, seeds, competent cell lines/glycerol stocks (if the work is covered by a NLRD), cDNA library if the donor nucleic acid is derived from a pathogen or toxin-producing organism.
OGTR	Office of the Gene Technology Regulator (the Regulator).
PC1, PC2, PC3 and PC4 Certified Facilities	Physical Containment facilities certified by the OGTR. PC1 is the lowest level of containment and PC4 is the highest level of containment.
Primary Container	A container immediately surrounding the GMO, e.g. Eppendorf tube or a sealed bag containing genetically modified bacteria, eggs or seeds.

Term	Definition
Secondary Container	The container immediately surrounding the primary container, e.g. a cryobox or Falcon tube containing one or more Eppendorf tubes containing GMOs.
Storage Unit	Unit for long-term storage of a collection of GMOs, e.g. a fridge, freezer, cold room or cabinet.
TSD	OGTR Guidelines for the Transport, Storage and Disposal and GMOs (2011).

Section 3 - Guideline Scope/Coverage

(2) This Guideline applies to all staff, students, visitors, volunteers and contractors who are working with genetically modified organisms or genetically modified microorganisms.

(3) This Guideline applies to GMOs that are in storage. Material covered by a licence (i.e. DNIR/DIR) must be stored and labelled and records kept as per the conditions of the licence. Exempt category material should be stored, labelled and recorded in accordance with good laboratory practices.

(4) This Guideline does not apply to material or animals being actively worked on, i.e. live animals or plants, eukaryotic cell cultures or bacterial cultures under experimental conditions prior to storage.

Section 4 - Guideline Statement

(5) All persons working with GMOs are to be aware of the relevant legislation, regulations and guidelines that apply to storage of GMOs. It is a requirement of the Office of the Gene Technology Regulator (OGTR) that adequate storage records and labelling are in place in order to easily identify biological samples stored both inside and outside certified facilities. This enables both the separation and identification of different types of biological material stored and the easy identification of stored GMO samples during audits by the OGTR. In shared spaces and group storage areas, accurate labelling and record keeping is also important.

(6) This Guideline provides detailed instructions and examples for storage and labelling of samples in fridges, freezers, cold rooms, liquid nitrogen dewars, etc., to meet these requirements.

Section 5 - Categories of GMOs

(7) GMOs are categorised by the OGTR as belonging to one of four main categories:

a. Exempt (i.e. Dealings defined by the Gene Technology (Queensland) Act 2016 and Regulations as exempt dealings requiring assessment by the UQ Biosafety Advisors).

   and those that require consideration by the OGTR:

b. NLRD (Notifiable Low Risk Dealing, assessed by the UQ IBC and reported to the OGTR).
c. DNIR (Dealing Not involving Intentional Release, assessed by the OGTR).
d. DIR (Dealing involving Intentional Release, assessed by the OGTR).

(8) NLRDs and DNIRs are further classified into four categories according to the physical containment they require. See linked diagram: NLRD and DNIRs Four Categories.

Category	Type and containment	Condition
Exempt	Recommend meet PC1 standards	Good lab practice

Category	Type and containment	Condition
NLRD	PC1 PC2 PC3	OGTR storage and labelling requirements apply, as per the OGTR TSD and this Guideline.
DNIR	PC2 PC3 PC4	OGTR storage and labelling requirements apply, as per the OGTR TSD and this Guideline. **Any conditions as stipulated in the individual permit must be followed**
DIR	"Controlled release"	**Any conditions as stipulated in the individual permit must be followed.**

(9) The OGTR Guidelines clearly stipulate that the storage and labelling requirements apply to GMOs categories in PC1-PC4.

> *Any material covered by a DNIR, regardless of the PC category, must be stored and labelled according to the conditions stipulated in the individual licence as issued by the OGTR.

(10) In some cases research projects may contain GM material from more than one category of dealing. It is important to distinguish between the different material and their storage, labelling and disposal requirements. Please see the OGTR Guidelines for the Transport, Storage and Disposal of GMOs for more information.

(11) A general overview and examples of Exempt dealings and NLRD material is given in the following provisions. Information regarding DNIR and DIR material will be specific to the permits issued by the Regulator.

Exempt Dealings

(12) Note: Material in the Exempt category is not required to meet the conditions stipulated in the OGTR Guidelines for the Transport, Storage and Disposal because Exempt material does not fall into any PC categories. However it is strongly recommended that research involving Exempt material is done in a laboratory that meets at least PC1 standards, whether or not it is certified.

(13) Exempt dealings are defined in Part 1 of Schedule 2 of the Gene Technology Regulations 2001 (Cth) and involve GM dealings that pose a very low risk, e.g.:

a. An exempt host/vector system, e.g. bacteria - E.coli K12, B & C, DH5a, TOP10, BL12, BLR or DH10Bac with non-conjugative plasmids;
b. Agrobacterium with non-tumourigenic disarmed Ti plasmids or Ri plasmids;
c. Dealings with cell lines and unfixed tissue samples from GM animals;
d. Mammalian cell culture (e.g. HEK-293, HeLa cells) with non-conjugative plasmids and DNA not implicated in causing disease in otherwise healthy human beings, animals, plants or fungi, or characterised DNA that is unlikely to increase the capacity of the host or vector to cause harm; or
e. Early non-human mammalian embryos cultured in vitro.

(14) Please see Low Risk Genetically Modified Dealings Procedure for more information.

Notifiable Low Risk Dealings (NLRDs)

(15) NLRDs are defined in Part 2 of Schedule 2 of the Gene Technology Regulations 2001 (Cth).

(16) Some examples of GM material/work that falls under NLRD classification are as follows:

a. Viral vectors including replication defective vectors - retroviral (including lentiviral vectors) with mammalian cultured cells;

b. Replication defective viral vectors - non-retroviral (adeno or adeno associated viral vectors) with mammalian cultured cells;
c. Competent cell lines/glycerol stocks, cDNA library if donor nucleic acid is derived from pathogen or toxin-producing organism;
d. A dealing involving an Exempt host-vector system and producing more than 25L of GMO culture in each vessel containing the resultant culture;
e. A dealing involving a whole animal (not guinea pig, mouse, rabbit or rat) that involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism;
f. A dealing involving a genetically modified lab rodent; or
g. A dealing involving a genetically modified plant.

(17) Refer to Low Risk Genetically Modified Dealings Procedure for more information.

Examples of Exempt Versus Non-exempt (NLRD/DNIR PC1-PC4)

Animal

(18) Exempt:

a. Rodents containing genetically modified somatic cells, provided the somatic cells are not capable of giving rise to infectious agents and the animal is not infected with a virus capable of recombining with the genetically modified nucleic acid in the somatic cells.
b. A living rodent that has been subjected to GMOs but that no longer contains the GMOs.
c. A dead GM rodent or tissue samples from a GM rodent, regardless of whether it contains a GMO.

(19) Not-exempt (NLRD/DNIR):

a. Rodents containing GMOs may be regarded as NLRD or DNIR whilst the GMO is in the rodent and is capable of replicating.

Nucleic Acids

(20) DNA, RNA and plasmids are not considered GMOs in the Gene Technology Regulations providing they cannot give rise to infectious agents.

(21) Exempt:

a. While using exempt host/vector systems, if the donor nucleic acid does not contain nucleic acids that are:
    i. Derived from organisms that can cause disease in humans, animals, plants or fungi;
    ii. Increase capacity of the host/vector to cause harm;
    iii. Code for toxins with an LD50 of less than 100µg/kg; or
    iv. From toxin producing organisms.

(22) Exceptions apply. If you are unsure, contact OHS Biosafety (biosafety@uq.edu.au) or refer to the details in your IBC approved Exempt, NLRD, DNIR or DIR proposal.

Section 6 - Physical Storage Requirements

(23) GMOs may be stored either within or outside of certified facilities, provided the OGTR Guidelines for the Transport, Storage and Disposal of GMOs and the relevant OGTR - Guidelines for Certification of a Physical

Containment Level 2 Animal Facility are adhered to. These guidelines are mandatory instruments for dealings involving GMOs.

(24) Whole, viable GM plants or animals must not be stored outside of a certified facility without written permission from the Regulator (to organise this, contact OHS Biosafety Advisor on biosafety@uq.edu.au).

(25) GMOs must not be stored in a site that is prone to flooding, storm surges or other natural disasters.

(26) Many researchers at UQ have GM work that falls into Exempt and NLRD categories and therefore may currently treat the material in the same way. In order to determine if these guidelines apply to your research, it is important that you distinguish between exempt and other GM work. If your material is mixed, it must be treated at the higher requirement, e.g. if Exempt and PC2 NLRD GM material is stored together in the same freezer box, then all material must be treated as PC2 NLRD GM material.

> Note: Either GM and non-GM items must be segregated, and records kept to show this; or all items must be treated as GM including labelling the secondary container and storage unit with "Contains GM items/GMO".

(27) Furthermore, if any non-GM items that have not been segregated are to be moved or transported, they must be treated the same as GM items from that facility, e.g. if moved from a PC2 facility, they must be treated as PC2 material and only moved to or used in other PC2 certified facilities.

Storage of PC1 and PC2 GMOs, Including Organisms that Contain GMOs

(28) Must be contained inside a sealed, unbreakable primary container, e.g. Eppendorf tube or sealed zip lock bag.

(29) The primary container must be stored inside a sealed, unbreakable secondary container, e.g. Eppendorf tube inside a sealed plastic container; sealed zip lock bag inside a sealed plastic container; sealed plastic container inside a refrigerator, freezer, or other cryogenic storage unit.

(30) If stored outside a certified facility, access must be restricted to authorised persons only, e.g.:

a. locked fridge/freezer/liquid nitrogen vessel;
b. fridge/freezer/liquid nitrogen vessel stored in a locked/swipe card access room.

(31) Storage locations must be listed on the relevant NLRD.

(32) An approved, active NLRD is required to store any PC2 GMOs that are classified as NLRD category material (see Low Risk Genetically Modified Dealings Procedure, or contact OHS Biosafety on biosafety@uq.edu.au for more information).

Storage of PC3 and PC4 GMOs, Including Organisms that Contain GMOs

(33) Must not be stored outside of the relevant certified facility unless permitted, in writing, by the Regulator, e.g. as a licence condition. If storage is permitted, in writing, by the Regulator, storage must comply with the conditions specified in the written approval.

Storage of GMOs Assessed as DNIR or DIR

(34) Any material covered by a DNIR or DIR licence must be stored as per the licence conditions and according to its PC category, e.g. PC2 material should be double contained, PC3 material must be stored as per the written conditions.

(35) If the licence storage conditions are different to the OGTR Guidelines for the Transport, Storage and Disposal of GMOs, then the licence conditions must be followed.

Section 7 - Labelling Requirements

Labelling of PC1 and PC2 GMOs for Storage

(36) The primary container should be labelled to clearly show the name or other identifier of the GMO being stored.

(37) The samples should be labelled clearly showing the material is, or contains a GMO, e.g. where possible the primary container label should state GMO.

(38) If the primary container cannot be labelled GMO, the secondary container must state GMO and all material inside the secondary container treated as GM.

(39) The storage unit (e.g. fridge/freezer/cold room/Nally bin in cold room, etc.) must be clearly labelled GMO and clearly show the name and contact details of the person responsible for the dealings. This will enable the person to be contacted should any GMOs be spilled or lost. The following minimum details must be clearly displayed on the storage unit (e.g. fridge/freezer/cold room/Nally bin in cold room, etc.):

a. Freezer/Fridge Name.
b. Alarm point number (if applicable).
c. Name of Group leader/PI.
d. Phone number.
e. IBC number*.
f. Contact person & phone number.

> * If a GMO is being used under multiple NLRDs held by the same project supervisor, consider combining NLRDs.

(40) Refer to the Biosafety, Chemicals and Radiation website for information on labelling solutions.

Labelling of PC1 and PC2 GMOs for Transport

(41) Labelling requirements for transport are different to those for storage only.

(42) Please refer to the Transport of Biological Materials Procedure for details.

Section 8 - Record Keeping Requirements

(43) Procedures must be in place to ensure that all GMOs stored can be accounted for. A record of GMOs stored must be kept and made available to the OGTR upon request. You must ensure the method of record keeping:

a. can be found by others (in the event of absence of team members); and
b. can be understood by others.

(44) The records of the GMOs being stored must allow the person storing the GMOs to find the exact location of where the GMO is being stored.

(45) As long as the records meet the above requirements, they may be kept in the format that best suits the research group.

(46) Format examples of a hard copy of records kept in a folder beside the fridge or freezer, an Excel spreadsheet

kept on lab computer, or an online database, may all be suitable forms of maintaining records as long as they include:

a. Room Number;
b. Identifier number (i.e.; IBC number);
c. Group Leader/PI;
d. Freezer/Fridge Name;
e. Shelf Number;
f. Rack Number;
g. Box number.

Section 9 - Contingency Planning

(47) Contingency plans for fridge, freezer or cold room failure should also be considered, and should include ensuring any samples are transported and stored following the OGTR Guidelines for the Transport, Storage and Disposal of GMOs. Storage records should be updated to reflect the current location of GMOs, as should any GM dealings.

(48) Refer to the Biosafety, Chemicals and Radiation website on the OHS-Biosafety webpage for examples of how to manage specific scenarios.

Section 10 - Other Considerations

(49) When closing down a project, all GMOs must either be destroyed or transferred and maintained under an approved, active dealing.

(50) If GMOs are spilled while in storage or transit to storage, decontamination of the primary containment and associated melted ice/ice etc. is required prior to any maintenance. Refer to local biological spills procedures for specific clean up procedures.

Section 11 - Contact for Additional Information

Biosafety Advisor
UQ Occupational Health and Safety Unit
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