Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

Explanatory Information

Guide to Physical Containment Levels and Facility Types

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Contents

DEFINITIONS

Unless defined otherwise in this document, words and phrases used in the requirements have the same meaning as in the *Gene Technology Act 2000* (the Act) and the Gene Technology Regulations 2001 (the Regulations).

Words in the singular include the plural and words in the plural include the singular.

Where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning.

dealings or deal with	In relation to a GMO, means the following: (a) conduct experiments with the GMO; (b) make, develop, produce or manufacture the GMO; (c) breed the GMO; (d) propagate the GMO; (e) use the GMO in the course of manufacture of a thing that is not the GMO; (f) grow, raise or culture the GMO; (g) import the GMO; (h) transport the GMO; (i) dispose of the GMO; and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (i).
facility	The whole of the space that is to be certified by the Regulator to a specific level of containment.
GMO	Genetically modified organism.
PC	physical containment, physical containment level

INTRODUCTION

Section 84 of the Act allows the Gene Technology Regulator (the Regulator) to certify facilities to a specified containment level if the facility meets the containment requirements specified in guidelines issued by the Regulator under section 90 of the Act.

This document describes the Physical Containment (PC) levels used by the Regulator in the certification of facilities under the Act and explains the categories of organisms and types of dealings intended to be contained in each facility type and PC level.

Applicants may use this section to guide their decision about which PC level and facility type to apply for. If you have any queries about the different categories, please contact the Office of the Gene Technology Regulator (OGTR) to discuss the options.

PHYSICAL CONTAINMENT LEVELS

There are four levels of physical containment applied to facilities certified by the Regulator. These are arranged in order of ascending stringency of containment requirements, which reflect the level of risk involved in the dealings that can be undertaken at each level. The four levels are:

- Physical Containment Level 1 (PC 1)
- Physical Containment Level 2 (PC 2)
- Physical Containment Level 3 (PC 3)
- Physical Containment Level 4 (PC 4)

These levels are intended to harmonise as closely as possible with the PC levels described in AS/NZS 2243.3[1].

The required PC level for the containment of a dealing is governed by the gene technology legislation as follows:

- Conditions of licences can specify the level of containment required for the conduct of the dealing. Typically, such conditions will be found in a licence to conduct dealings not involving an intentional release into the environment (DNIR). However, licences permitting dealings involving intentional release (DIR) of a GMO may also contain conditions requiring containment of a GMO to a specific level of containment.
- Notifiable Low Risk Dealings (NLRDs) mentioned in Part 1 of Schedule 3 of the Regulations, as in force from 8 October 2020, must be undertaken in a facility certified by the Regulator to at least PC level 1.
- NLRDs mentioned in 2.1 of Part 2 of Schedule 3 of the Regulations, as in force from 8 October 2020, must be undertaken in a facility certified by the Regulator to at least PC level 2.
- NLRDs mentioned in 2.2 of Part 2 of Schedule 3 of the Regulations, as in force from 8 October 2020, must be undertaken in a facility certified by the Regulator to at least PC level 3.
- When determining the required PC level for a DNIR involving GM micro-organisms, or GM animals or plants containing pathogenic organisms, the Regulator may be guided by the PC levels described in AS/NZS 2243.3.

The tables of example organisms in AS/NZS 2243.3 are not exhaustive and so, if applicants have any queries about which PC level is likely to be appropriate for the GMOs being dealt with in the facility, they should contact the OGTR to discuss the matter.

A PC level determined by one of the above methods is the minimum PC level at which a dealing can be conducted. A dealing may be conducted in a facility that is certified to a higher PC level, provided the higher level facility type is appropriate for the organisms involved, is certified by the Regulator, and that the conditions of certification do not prevent the dealing being conducted there.

Table 1 summarises the dealings that can be conducted at the four PC levels.

[1] Australian/New Zealand Standard 2243.3 *Safety in laboratories Part 3: Microbiological aspects and containment facilities*.

Table 1 - Physical Containment Levels

PC level	Type of GMO dealings that can be conducted at PC level
1	NLRDs mentioned in Part 1 of Schedule 3 of the Regulations, as in force from 8 October 2020, must be undertaken in a facility certified by the Regulator to at least PC 1.
	Some DNIRs – only when permitted by licence
2	NLRDs mentioned in 2.1 of Part 2 of Schedule 3 of the Regulations, as in force from 8 October 2020, must be undertaken in a facility certified by the Regulator to at least PC 2.
	DNIRs – when specified by licence
3	NLRDs mentioned in 2.2 of Part 2 of Schedule 3 of the Regulations, as in force from 8 October 2020, must be undertaken in a facility certified by the Regulator to at least PC 3.
	Other NLRDs – permitted but not recommended – all dealings (including any NLRDs) undertaken in a certified PC 3 facility must be conducted according PC 3 conditions.
	DNIRs – when specified by licence
4	DNIRs – when specified by licence

FACILITY TYPES

For the purposes of an application for a licence to conduct a dealing with a GMO, or for the conduct of a NLRD, the following categories of PC level and facility type can be used as a guide to the appropriate certified facility.

There may be reasons to depart from these categories where the dealings in a facility are proposed to involve more than one category of organism. Applications for certification, or for variation to the conditions of certification should include the reasons for needing to contain the different categories of organisms, along with supporting information about how the facility is designed to contain them and how any risks of escape will be managed.

Physical Containment Level 1

A facility certified as a PC 1 Facility is appropriate for the conduct of the dealings listed below, provided it meets the specific requirements described in the PC 1 Facility guidelines for the dealing type:

- GM micro-organisms (when there is less than or equal to 25 litres of culture of any one GMO);
- GM animals (whether or not they contain micro-organisms) as permitted by the Gene Technology Regulations 2001;
- non GM animals containing GM micro-organisms; and
- non-GM plants that contain or host GMOs.

A PC 1 Facility is not appropriate for the following:

- dealings with any GMO that under the Act, or under the conditions of a licence, requires containment in any PC level higher than PC 1.

Physical Containment Level 2

A physical containment facility Level 2 is designed to contain dealings with GMOs presenting low to moderate potential risk to people and the environment. Depending on the dealings conducted in this facility, different conditions and requirements would apply.

PC2 Laboratory

A facility certified as a PC 2 Laboratory is appropriate for the conduct of the dealings listed below:

- dealings with GM micro-organisms;
- dealings with GM plant tissue culture or GM plants contained in a plant growth cabinet or other containment device approved in writing by the Regulator; and
- performance of laboratory procedures involving animals, invertebrates, or aquatic organisms if not otherwise prohibited by licence conditions.

A PC 2 Laboratory is not appropriate for the following:

- dealings with any GMO that under the conditions of a licence or legislation requires containment in any PC level higher than PC 2;
- the housing/keeping/rearing of any animals, invertebrates, or aquatic organisms for longer than the minimum time required to complete laboratory procedures on them;
- the housing/keeping/rearing of any plants for longer than the minimum time required to complete laboratory procedures on them except those in tissue culture, contained in a plant growth cabinet or other containment device approved in writing by the Regulator;
- dealings producing more than 25 litres of liquid culture of GMOs in each vessel; or
- any other work prohibited in writing by the Regulator.

PC 2 Animal Facility

A facility certified as a PC 2 Animal Facility is appropriate for the conduct of the dealings listed below:

- the housing/keeping/rearing of GM animals (except invertebrates and aquatic organisms - including amphibians); or
- the housing/keeping/rearing of animals (except invertebrates and aquatic organisms - including amphibians) that contain GMOs.

A PC 2 Animal Facility is not appropriate for the following:

- dealings with any GMO that under the conditions of a licence or legislation requires containment in any PC level higher than PC 2;
- the housing/keeping/rearing of any invertebrates, or aquatic organisms, for longer than the minimum time required to complete procedures on them;
- the growing of any plants, unless they are integral to the dealing being conducted in the facility;
- dealings producing more than 25 litres of liquid culture of GMOs in each vessel; or
- any other work prohibited in writing by the Regulator.

PC 2 Aquatic Facility

A facility certified as a PC 2 Aquatic Facility is appropriate for the conduct of the dealings listed below:

- the keeping or rearing of GM aquatic organisms (including amphibians); or
- the keeping or rearing of aquatic organisms (including amphibians) that contain GMOs.

A PC 2 Aquatic Facility is not appropriate for the following:

- dealings with any GMO that under the conditions of a licence or legislation requires containment in any PC level higher than PC 2;
- the housing/keeping/rearing of non-aquatic vertebrates or invertebrates for longer than the minimum time required to complete procedures on them;
- the growing of any non-aquatic plants unless they are integral to the dealing being conducted in the facility; or
- any other work prohibited in writing by the Regulator.

PC 2 Constant Temperature Room

Constant Temperature Rooms are intended to store or grow GMOs. However, GMOs in the facility must always remain in primary containment.

Examples of uses of Constant Temperature Rooms include: storing samples, cultures and seeds and incubating cultures, growing plants tissue and cell shaking.

A PC 2 Constant Temperature Room is not appropriate for the following:

- dealings with any GMO that under the conditions of a licence or legislation requires containment in any PC level higher than PC 2;
- the housing of any animals including invertebrates and aquatic animals (except animals that are in diapause or another form of dormancy);
- any dealing with a GMO outside of a primary container or where the primary container is opened, except for:
    - GM animal tissue cultures which do not contain any GM micro-organisms
    - GM multi-cellular plant tissue cultures which do not contain any GM micro-organisms
    - whole GM plants which do not contain any GM micro-organisms and:
        - do not contain any pollen, seed or other propagule; or
        - are contained within a plant growth cabinet that is screened to prevent the escape of seeds and pollen.
- dealings producing 25 litres or more of liquid culture of GMOs in each vessel; and
- any other work prohibited in writing by the Regulator.

Applicants are welcome to contact the OGTR to discuss their needs prior to making an application.

PC 2 Invertebrate Facility

A facility certified as a PC 2 Invertebrate Facility is appropriate for the conduct of the dealings listed below:

- the keeping or rearing of GM terrestrial invertebrates; or
- the keeping or rearing of terrestrial invertebrates that contain GMOs.

A PC 2 Invertebrate Facility is not appropriate for the following:

- dealings with any GMO that under the Act, or under the conditions of a licence or legislation, requires containment in any PC level higher than PC 2;
- the housing/keeping/rearing of any terrestrial vertebrates, or aquatic organisms, for longer than the minimum time required to complete procedures on them;
- the growing of any plants unless they are integral to the dealing being conducted in the facility;
- dealings with GM invertebrates, or non GM invertebrates containing GM micro-organisms, where part of the life cycle is in water and where the volume in a single container is greater than 25 litres; or
- any other work prohibited in writing by the Regulator.

PC 2 Plant Facility

A facility certified as a PC 2 Plant Facility is appropriate for the conduct of the dealings listed below:

- the growing of GM terrestrial plants; or
- the growing of terrestrial plants that contain GMOs.

A PC 2 Plant Facility is not appropriate for the following:

- dealings with any GMO that under the conditions of a licence or legislation requires containment in any PC level higher than PC 2;
- the housing/keeping/rearing of any animals, invertebrates, or aquatic organisms unless they are integral to the dealing being contained in the facility;
- dealings producing more than 25 litres of liquid culture of GMOs in each vessel; or
- any other work prohibited in writing by the Regulator.

PC 2 Large Grazing Animals Facility

Permission may be given by the Regulator to use facilities of this type in certain limited circumstances in connection with dealings involving large grazing animals, which may include animals such as sheep, cattle, goats, pigs and horses. A person proposing to conduct such dealings may apply to the Regulator to conduct the dealings in this facility type.

The Regulator will not authorise the use of this containment level where a proposed dealing involves large grazing animals which could potentially shed or transmit GMOs.

PC 2 Large Scale Facility

A facility certified as a PC 2 Large Scale Facility is appropriate for the conduct of dealings when there is greater than 25 litres of culture of any one GMO.

A PC 2 Large Scale Facility is not appropriate for the following:

- dealings with any GMO that under the Act, or under the conditions of a licence, requires containment in any PC level higher than PC 2;
- the housing/keeping/rearing of any animals, invertebrates or aquatic organisms; or
- the growing of any plants.

Physical Containment Level 3

New Guidelines came into effect from the 1 December 2022. Previously, there were three PC3 facility types - Laboratory, Animal and Invertebrate. The newly issued PC3 Guidelines consist of one basic module with the requirements and conditions common to all facility types, and additional requirements and conditions specific to animal and invertebrate dealings, listed in two separate annexes. New facilities applying for certification are required to meet its requirements.

PC 3 Facility (previously called PC3 laboratory)

A facility certified as a PC 3 Facility is appropriate for the conduct of the dealings listed below:

- dealings with GM micro-organisms;

- laboratory procedures involving small terrestrial animals and invertebrates, if not otherwise prohibited by licence conditions;
- laboratory procedures involving aquatic organisms (including amphibians), subject to additional conditions and if not otherwise prohibited by licence conditions; and

A PC 3 Facility is not appropriate for the following:

- dealings with any GMO that, under the gene technology legislation or conditions of a licence, require containment in a physical containment level higher than PC3;
- dealings involving a micro-organism that satisfies the criteria in AS/NZS 2243.3 for classification as Risk Group 4;
- the housing/keeping/rearing of any plants, animals, including invertebrates and aquatic organisms, beyond the minimum time that they are required for conducting the dealings with GMOs; or
- any other work prohibited by notification in writing by the Regulator.

PC 3 Facility – Annex 1 A and B- Animal

A facility certified as a PC 3 Facility - Animal is appropriate for the conduct of the dealings listed below:

- the housing/keeping/rearing of GM animals (except invertebrates and aquatic organisms - including amphibians); or
- the housing/keeping/rearing of animals (except invertebrates and aquatic organisms - including amphibians) that contain GMOs.

A PC 3 Facility - Animal is not appropriate for the following:

- dealings with any GMO that, under the gene technology legislation or conditions of a licence, require containment in a physical containment level higher than PC3;
- unless otherwise authorised by the Regulator, dealings with animals infected with GMOs where the work area of the facility forms the primary containment measure;
- the housing/keeping/rearing/growing of any plants, invertebrates, or aquatic organisms beyond the minimum time that they are required for conducting the dealings with GMOs; or
- any other work prohibited by notification in writing by the Regulator.

PC 3 Facility – Annex 2A and B-Invertebrate

A facility certified as a PC 3 Facility - Invertebrate is appropriate for the conduct of the dealings listed below:

- the keeping or rearing of GM terrestrial invertebrates;
- the keeping or rearing of terrestrial invertebrates that contain GMOs; or
- dealings with aquatic life stages of invertebrates that are necessary for dealings being conducted in the facility.

A PC 3 Facility - Invertebrate is not appropriate for the following:

- dealings with any GMO that, under the gene technology legislation or

conditions of a licence, require containment in a physical containment level higher than PC3;

- unless otherwise authorised by the Regulator, dealings with any aquatic organism except for the aquatic life stage of invertebrates that are necessary for dealings being conducted in the facility;
- the housing/keeping/rearing/growing of plant, terrestrial vertebrates, beyond the minimum time that they are required for conducting the dealings with GMOs;
- dealing with invertebrates smaller than the aperture size of the screens fitted on the facility openings; or
- any other work prohibited in writing by the Regulator.

Physical Containment Level 4

A facility certified as a PC 4 Facility is appropriate for the conduct of dealings that are authorised by a licence requiring this level of containment This generally involves organisms classified as Risk group 4, or Risk group 3 (RG3) organisms which have been modified and as a result are more harmful than the RG3 parent organism. Dealings permitted to be conducted within the facility are therefore the result of an extensive risk assessment of proposed projects and the mandatory implementation of a risk management plan through licence conditions.

The Guidelines contains the requirement for certification of a PC 4 Facility to be certified, and the conditions a facility must continue to comply for the facility to remain certified. Given the type of dealings conducted within the facility and the characteristics of the facility, bespoke requirements and conditions are likely to be included in the certification instrument.