



Australian Government
Department of Health
Office of the Gene Technology Regulator

Guidelines for Certification

of a

Physical Containment Level 2

Large Grazing Animal Facility

Version 1.1 – Effective 12 February 2014

The guidelines (Part A) contain the requirements for certification of a Physical Containment Level 2 (PC2) Large Grazing Animal Facility issued pursuant to section 90 of the *Gene Technology Act 2000* (the Act).

Once a facility is certified, the certification instrument imposes conditions on the facility pursuant to section 86 of the Act. The conditions of certification (Part B) detail the usual conditions that will apply to a PC2 Large Grazing Animal Facility. Individual certification conditions may differ from these in some respect but generally an applicant can expect that their conditions will closely follow those published here. Once issued, the conditions may be varied by the Gene Technology Regulator as necessary and appropriate.

When planning a new facility, proposing to apply for certification of an existing facility or varying an existing certification, an assessment of the risks of genetically modified organisms (GMOs) escaping during an emergency event should be undertaken. Emergency events include, but are not limited to, flooding, coastal storm surges, land slippage or bush fires. If the risk assessment determines that there is a greater than negligible risk from the emergency event, then the applicant should develop a risk management plan to assist them in minimising the risks of loss of containment of GMOs posed by the emergency event.

The risk management plan may include removal or euthanasia of GMOs and other measures well before the event impacts the facility. Consideration should be given to the resources needed to implement the risk management plan, and their availability during such events.

A separate document - *Explanatory Information on Guidelines for Certification of Physical Containment Facilities* - contains details about the process of certification. This document can be downloaded from the OGTR website <www.ogtr.gov.au>.

Contents

Part A: Requirements for Certification.....	3
Definitions and acronyms	3
Facility requirements	4
Capacity to comply with certification conditions	5
Information required with application forms	5
Part B: Conditions of Certification	6
Definitions and acronyms	6
Obligations of the certification holder in respect of users of the facility.....	6
Work not permitted in this facility type	8
General conditions	8
Facility conditions	8
Part C: Behavioural Requirements	10

Requirements for Certification

Physical Containment Level 2 Large Grazing Animal Facility Version 1.1 – Effective 12 February 2014

CONTAINMENT REQUIREMENTS THAT MUST BE MET IN ORDER FOR A
PHYSICAL CONTAINMENT LEVEL 2 (PC2) LARGE GRAZING ANIMAL FACILITY
TO BE CERTIFIED BY THE GENE TECHNOLOGY REGULATOR.

Section 90 of the *Gene Technology Act 2000*

These are the requirements for the certification of a PC2 Large Grazing Animal Facility issued under section 90 of the *Gene Technology Act 2000* (the Act) and, as applicable, corresponding State legislation. These requirements apply to applications for certification of PC2 Large Grazing Animal Facilities received on or after the day on which these guidelines take effect.

The Gene Technology Regulator (the Regulator) will not usually authorise the use of this facility type where a proposed dealing involves large grazing animals containing genetically modified micro-organisms.

To be granted certification, a facility must meet each of the requirements for certification of a PC2 Large Grazing Animal Facility, unless the facility receives a written exemption from meeting a particular requirement from the Regulator or a delegate of the Regulator. Additional conditions may also be imposed on the facility by the Regulator or a delegate of the Regulator.

Definitions and acronyms

Unless defined otherwise in these guidelines, words and phrases used in the guidelines have the same meaning as 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.

dealing 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 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 or area that is to be certified by the Regulator to a specific level of containment. A certified large grazing animal facility comprises the area within the secondary physical barrier.
GM	Genetically modified.
GMO	Genetically modified organism.
large grazing animal	Any large animal which grazes for food in its preferred natural habitat, including, but not limited to, sheep, cattle, goats, pigs and horses. NOTE: Applicants must seek advice from the OGTR if planning to contain GM animals other than typical large grazing animals in this facility type.
OGTR	Office of the Gene Technology Regulator.
PC2	Physical Containment Level 2.
primary barrier	The barrier directly surrounding the GMO.
secondary barrier	The barrier immediately surrounding the primary barrier.
the Regulator	The Gene Technology Regulator.

Facility requirements

1. The facility to be certified must be constructed with at least two physical barriers that prevent the escape of the GM animals proposed to be contained and prevent the entry of animals of the same species or species that can interbreed with the species proposed to be contained in the facility. The two physical barriers could, for example, consist of two fences or a building and a fence.

If the primary barrier is a building (for example a shed or a barn), it must be fully enclosed and all entry and exit points of the building must be surrounded by a secondary barrier.

If escape of animals proposed to be contained is to be prevented by fencing alone, the perimeter fencing must comprise of at least two complete rows of fencing.

2. Both physical barriers must be of appropriate height, depth, strength and material to contain the species of GM animals proposed to be contained in the facility.
3. Both physical barriers must be of material strong enough to withstand damage by all types of weather and possible damage by animals approaching from outside the facility.
4. The gap between the two physical barriers should be of an appropriate distance to prevent escape of the species of GM animals proposed to be contained in the facility.
5. All gates and doors in the facility must be designed to prevent the escape of the species proposed to be contained in the facility and to prevent the unintended entry of animals of the same species or species that can interbreed with the species proposed to be contained in the facility. Gates and doors must be lockable or otherwise able to be secured.

Capacity to comply with certification conditions

6. The applicant must be able to demonstrate capacity to comply with the conditions of certification that will be generally applied to a certified PC2 Large Grazing Animal Facility. These conditions are found in Part B of this document.

Information required with application forms

7. The layout of the area to be certified, clearly identifying the GPS coordinates (for paddocks), doors, gates and physical barriers that make up the facility must be submitted with the application for certification.

Conditions of Certification

Physical Containment Level 2 Large Grazing Animal Facility Version 1.1 – Effective 12 February 2014

Conditions are imposed on facilities by the Regulator at the time of certification pursuant to section 86 of the *Gene Technology Act 2000* (the Act) and, as applicable, corresponding State legislation. The condition clauses in this section are the ones that can be expected, in most cases, to be included in the certification instrument as the conditions of certification of a Physical Containment Level 2 (PC2) Large Grazing Animal Facility.

Where a specific condition in this document conflicts with a condition of a licence, the Gene Technology Regulations 2001 (the Regulations), or any applicable guidelines issued under Section 27(d) of the Act, then the condition of a licence, the Regulations, or applicable guidelines prevails.

Definitions and acronyms

The definitions and acronyms found in Part A of this document also apply to Parts B and C.

Obligations of the certification holder in respect of users of the facility

1. While any GM animals are being held/housed in the facility, the certification holder must ensure that access to the facility is restricted to authorised persons.
2. For purposes of condition 1, an authorised person is a person who:
 - (a) intends to undertake dealings, including growing and/or breeding GM animals, and has been trained in accordance with the Behavioural Requirements listed at Part C of this document;
 - (b) has signed, dated and provided to the certification holder a record of the training referred to in paragraph 2(a) above; and
 - (c) has not been excluded from the facility by the certification holder on the direction of the Regulator; or
 - (d) is an individual or class of person, who does not intend to undertake dealings and has the permission of the certification holder, the facility manager or other representative of the certification holder, to enter the facility.

3. If the Regulator requests the certification holder to provide a signed and dated record of the training provided to a particular authorised person, or a class of person, the signed and dated record of that training must be available to the Regulator within a time period stipulated by the Regulator.

NOTE: These records may be in an electronic format.

4. If the Regulator directs the certification holder to exclude a person, or class of person, from entry to the facility on the grounds that the person, or class of person has behaved, or is behaving, in a manner which has caused, or which may cause, GM animals to escape from the facility, the certification holder must exclude that person, or class of person from the facility unless and until otherwise directed by the Regulator.
5. If the Regulator directs the certification holder to admit a person, or class of person to the facility subject to conditions, the certification holder must only admit the person or class of person subject to those conditions.
6. For the purpose of condition 5, before admitting a person, or class of person, subject to conditions, the certification holder must notify the person(s) of any conditions that would apply to them.
7. If the Regulator invites the certification holder to make a submission on whether or not a person, or class of person, should:
 - (a) be excluded from entry to the facility; or
 - (b) be admitted to the facility subject to conditions;the certification holder may make such a submission within a time period stipulated by the Regulator.
8. If the certification holder is not the owner of the facility and does not have the authority to admit and exclude persons from the premises, the certification holder must not allow dealings in the facility until such authority is obtained in writing from the owner of the facility. If the certification holder does not have the capacity to prevent dealings from occurring, the certification holder must notify the Regulator of this in writing as soon as practicable.
9. The Regulator or a person authorised by the Regulator must, at all reasonable times, be allowed to enter the facility for the purposes of auditing or monitoring the conditions applying to the facility and any dealings being conducted in it.

Work not permitted in this facility type

10. Unless otherwise agreed to in writing by the Regulator, the following work must not be conducted in this facility:
 - (a) dealings with any animal that is not classified as a typical large grazing animal; or
 - (b) any work with GM micro-organisms, including GM viral vectors; or
 - (c) any other work prohibited in writing by the Regulator.

General conditions

11. If the certification holder is not the owner of the facility, and does not have the authority to maintain the facility, the certification holder must notify the Regulator in writing if the owner of the facility is incapable of carrying out, or refuses to carry out, or otherwise does not carry out, any maintenance required in order for the certification holder to continue to comply with the conditions of certification.
12. The facility must be inspected at least once every 3 months by a person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skills enabling that person to assess the facility's compliance with the conditions listed under the 'General conditions' and 'Facility conditions'. An inspection report which records the extent of compliance with those conditions must be made. Copies of the last three years' inspection reports must be kept and made available to the Regulator if requested.
13. A sign must be placed on or next to each access point to the facility to indicate that access to the facility is allowed only for persons who are authorised to enter.

Facility conditions

14. The certification holder must ensure that the physical attributes of the facility and fittings are maintained so that the relevant 'Facility requirements' listed in Part A of this document continue to be met.
15. Facility barriers must be inspected by a person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skills enabling that person to assess for damage immediately after any storms, heavy rain or any other events that could damage the barriers. Breaches or damage to the barriers must be repaired as soon as practicable after they are detected. In the event of any damage to the barriers, immediate measures must be undertaken to prevent loss of containment of the GM animals in the facility.

NOTE: This could be achieved by, for example, construction of temporary fencing.

16. Prior to any structural changes that may affect the containment of GM animals in the facility, the applicant must either:
 - (a) request a suspension of the certification, in writing, from the Regulator;
or
 - (b) request a variation to the area of certification in writing, from the Regulator, to allow dealings to continue in a part of the facility unaffected by the structural changes.

NOTE: For example, it may be possible to apply for a variation to temporarily partition the facility to provide containment for GM animals at one end while the other end is being modified. Once the work is complete, another variation would be required to re-instate the area removed from certification.

17. Before a suspension of the certification can be lifted, the facility must be inspected by a person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skills enabling that person to assess the facility's compliance with the conditions listed under 'General conditions' and 'Facility conditions' to ensure that the facility meets the conditions of certification. Dealings with GM animals must not recommence in a facility which has its certification suspended until the Regulator has lifted the suspension by notice in writing.

Behavioural Requirements

Physical Containment Level 2 Large Grazing Animal Facility Version 1.1 – Effective 12 February 2014

1. Persons undertaking dealings in the facility with GM animals requiring PC2 containment must comply with these Behavioural Requirements.
2. Procedures must be implemented to ensure that large grazing animals involved in dealings do not breed with any other animals that are not part of the dealings. If unintended breeding does occur, or is suspected to have occurred, then any offspring must be dealt with as GMOs unless proven otherwise, in accordance with the requirements of certification.
3. All facility personnel working with animals in the facility must be trained in handling the type/s of large grazing animals contained in the facility, the use of any equipment present in the facility and in the procedures to be followed in the facility.

NOTE: The required training should include handling of relevant GM animals with regards to transport, emergency procedures and certification requirements.

4. Other than to allow entry and exit of personnel, large grazing animals, equipment and supplies, all gates and doors of the facility must be kept closed. Gates and doors must be locked, or the facility must be otherwise secured, when the facility personnel are not in attendance.
5. Handling of the GM animals and any experimental procedures conducted on the GM animals must be carried out in a way that minimises the chance of escape of the animals.
6. Each large grazing animal must be clearly marked so that it can be readily identified (e.g. with a tattoo, permanent tag, microchip or permanent brand).
7. A documented system of accounting for the number of animals in the facility must be used. This documentation must be made available to the Regulator if requested.
8. GM animals must not be removed from the facility unless:
 - (a) they are to be transported to an appropriate containment facility certified by the Regulator either as a PC2 Large Grazing Animal Facility, or to at least PC2 if any other type of facility;
 - (b) they are to be transported for euthanasia and disposal;

- (c) written permission has been given by the Regulator for transport to another destination within Australia; or
 - (d) subject to obtaining any required permits, they are to be transported to the Australian border for export.
9. Transport of GM animals out of the certified facility must be carried out in accordance with the applicable General Requirements for Transport of PC2 GMOs and the relevant Requirements of Transport of GM Animals in the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* as in force from time to time and other relevant guidelines issued by the Regulator.
10. Transport and storage of all GM sperm, GM ova, GM embryos and animal tissue containing GMOs outside of the facility must be conducted in accordance with the Regulator's *Guidelines for Transport, Storage and Disposal of GMOs* as in force from time to time and other relevant guidelines issued by the Regulator.
11. If the GM animals are herded or lead between two authorised physical containment facilities or between an authorised physical containment facility and a transport vehicle, procedures must be in place to ensure that the risk of escape of a GM animal is minimal and the GM animals can be accounted for and a loss of a GM animal during this transport can be detected.
12. In the event of escape of a GM animal, unintentional release or loss of GM animal from the facility:
- (a) all reasonable efforts must be made to locate and retrieve the GM animal and return the GM animal to containment or euthanise it; and
 - (b) the incident must be reported to the Regulator as soon as practicable.
13. Dealings with GM animals, other than transport, must not be undertaken in the gap between primary and secondary barriers.