



# **Guidelines for Certification of a Physical Containment Level 1 Large Grazing Animal Facility**

**Version 2.1 – issued 30 March 2007**

These guidelines contain the requirements for certification of a Physical Containment Level 1 (PC1) 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, attached to this document, detail the usual conditions that will apply to a PC1 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.

A separate document - *Explanatory Information on Guidelines for Certification of Physical Containment Facilities* - contains details about obtaining and maintaining certification.

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# Requirements for Certification

## Physical Containment Level 1 Large Grazing Animal Facility Version 2.1 – issued 30 March 2007

CONTAINMENT REQUIREMENTS THAT MUST BE MET IN ORDER FOR A  
PHYSICAL CONTAINMENT LEVEL 1 (PC1) 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 PC1 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 PC1 Large Grazing Animal Facilities received on or after the day on which these guidelines take effect.

Permission may be given by the Gene Technology Regulator (the Regulator) to adopt this containment level 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 accordance with the requirements of this containment level.

In the absence of an express, written authorisation from the Regulator to conduct a particular dealing in accordance with the requirements of this containment level, dealings with large grazing animals must only be conducted in animal facilities certified to at least Physical Containment Level 2 (PC2). The particular containment level will be dependent on the specific nature of the dealings proposed to be conducted.

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.

To be granted certification, a facility must meet each of the requirements for certification of a PC1 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.

## Definitions

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*.

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.

Where a word in the text is **bolded**, it indicates that the word has been defined (see below).

<b>facility</b>	The whole of the space that is to be certified by <b>the Regulator</b> to a specific level of containment. A certified <b>large grazing animal facility</b> comprises the area within the second (outermost) physical barrier.
<b>large grazing animal</b>	Any large animal which grazes for food in its preferred natural habitat, including, but not limited to, sheep, cattle, goats, pigs and horses.
<b>PC1</b>	Physical Containment Level 1.

## Facilities and fittings requirements

1. The **facility** must be constructed with at least two physical barriers that prevent the escape of the species being contained and prevent the entry of animals of the same species. The double physical barrier could, for example, consist of two fences, or a building and a fence.

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

If the first physical barrier is a building, it must be fully enclosed and must be surrounded by a second physical barrier.

2. Any gates and doors in the **facility** must be designed to prevent the escape of the species being contained within the **facility** and to prevent the entry of animals of the same species. Gates and doors must be lockable.
3. The **facility** must be labelled with a sign on the outermost barrier displaying a unique identifier.

## Capacity to comply with certification conditions

4. The applicant must be able to demonstrate a capacity to comply with the conditions of certification that will be generally applied to a certified PC1 Large Grazing Animal Facility. These conditions are attached to this document.

# Conditions of Certification

## Physical Containment Level 1 Large Grazing Animal Facility Version 2.1 – issued 30 March 2007

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). 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 1 (PC1) Large Grazing Animal Facility.

### Definitions

Unless defined otherwise in these conditions, words and phrases used in the conditions have the same meaning as the Act and the *Gene Technology Regulations 2001*.

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.

Where a word in the text is **bolded**, it indicates that the word has been defined (see below).

<b>dealing or deal with</b>	In relation to a <b>GMO</b> , means the following: <ul style="list-style-type: none"><li>(a) conduct experiments with the <b>GMO</b>;</li><li>(b) make, develop, produce or manufacture the <b>GMO</b>;</li><li>(c) breed the <b>GMO</b>;</li><li>(d) propagate the <b>GMO</b>;</li><li>(e) use the <b>GMO</b> in the course of manufacture of a thing that is not the <b>GMO</b>;</li><li>(f) grow, raise or culture the <b>GMO</b>;</li><li>(g) import the <b>GMO</b>;</li></ul> and includes the possession, supply, use, transport or disposal of the <b>GMO</b> for the purposes of, or in the course of, a <b>dealing</b> mentioned in any of the paragraphs (a) to (g).
<b>facility</b>	The whole of the space that is to be certified by <b>the Regulator</b> to a specific level of containment. A certified <b>large grazing animal facility</b> comprises the area within the second (outermost) physical barrier.
<b>large grazing animal</b>	Any large animal which grazes for food in its preferred natural habitat, including, but not limited to, sheep, cattle, goats, pigs and horses.

<b>GM</b>	Genetically Modified.
<b>GMO</b>	Genetically Modified Organism.
<b>PC1</b>	Physical Containment Level 1.
<b>PC2</b>	Physical Containment Level 2.
<b>the Regulator</b>	The Gene Technology Regulator.

## Facilities and fittings conditions

1. The certification holder must ensure that the physical attributes of the facility and fittings are maintained so that the relevant ‘Facilities and fittings requirements’ for certification continue to be met, in particular:
  - 1.1 The **facility** must be maintained so that it has at least two physical barriers that prevent the escape of the species being contained within it and prevent the entry of animals of the same species. The double physical barrier may, for example, consist of two fences, or a building and a fence.
 

If escape is prevented by fencing alone, the perimeter fencing must at all times comprise at least two complete rows of fencing.

If the first physical barrier is a building, it must at all times be surrounded by a second physical barrier and the **large grazing animals** must not be allowed outside the building at any time.
  - 1.2 Any gates or doors in the **facility** must be maintained so that they prevent the escape of the species being contained within the **facility** and prevent the entry of animals of the same species which are not part of the **dealing**.
  - 1.3 The **facility** must always be labelled with a sign on the outermost barrier displaying a unique identifier.
2. If the certification holder is not the owner of the **facility** and does not have the authority to maintain the **facility** and fittings, 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 to continue to meet the ‘Facilities and fittings conditions’.
3. **Facility** barriers must be inspected for damage at least every three months and also immediately after any storms, heavy rain, flooding or any other events that could damage the barriers. Breaches or damage to the barriers must be repaired as soon as reasonably possible after they are detected.

4. The **facility** must be inspected at least once every 12 months and an inspection report must be made which records the extent of compliance with the conditions of 'Facility and fittings conditions'. A copy of the most recent inspection report must be kept and provided to the **Regulator** if requested.

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

5. While any **dealings** with a **GMO** are being conducted in the in the **facility**, the certification holder must ensure that access to the **facility** is restricted to authorised persons.
6. For purposes of the previous condition, an authorised person is:
  - (a) A person who:
    - (i) intends to undertake **dealings**, and has been notified of and trained in the **PC1** behavioural conditions listed below, and
    - (ii) has agreed to comply with those behavioural conditions, and
    - (iii) has not been excluded from the **facility** by the certification holder on the direction of **the Regulator**; or
  - (b) An individual, or class of person, who does not intend to undertake **dealings** and has the permission of the certification holder, its representative or the **facility** manager, to enter the **facility**.
7. If **the Regulator** directs the certification holder to exclude a person or class of person from entry to the **facility**, the certification holder must exclude that person or class of person from the **facility** unless and until otherwise directed by **the Regulator**.
8. 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.
9. Before admitting a person or class of person subject to conditions, the certification holder must notify the person of any conditions that would apply to them.
10. **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.

## Behavioural conditions relating to dealings conducted in the facility

11. 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 interbreeding does occur, or is suspected to have occurred, then any offspring must be dealt with as **GMOs**, in accordance with these conditions of certification.
12. All **facility** personnel working with animals in the **facility** must be trained in handling the **large grazing animals** contained in the **facility**, the use of any equipment present in the **facility** which they will use, and also in the procedures to be used in the **facility**.

NOTE: The required training should include decontamination, transport, disposal, emergency procedures, certification requirements and any licence conditions.

13. Other than during entry and exit of personnel, equipment and supplies, all gates or doors in and around a **facility** must be kept closed. Gates and doors must be locked when the **facility** is unattended.
14. 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). Procedures must be established and implemented to ensure that the number of **large grazing animals** in the **facility** is known.
15. **GMOs** and **large grazing animals** containing **GMOs** 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 PC1 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; or
  - (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.
16. All **GMOs** and **large grazing animals** containing **GMOs** being transported out of the **facility** must be transported in accordance with any transport guidelines and other relevant guidelines, issued by the **Regulator** and as in force from time to time.
17. All **GMOs** and **large grazing animals** containing **GMOs** from the **facility** must not be used for any purposes other than those permitted by the **dealings**, unless written permission has been obtained from the **Regulator**.
18. If a loss or release of **GMOs** or **large grazing animals** containing **GMOs** is detected then all reasonable efforts must be made to locate and either recover or destroy the **GMOs**.

19. Any real or suspected unintentional release of **GMOs** or **large grazing animals** containing **GMOs** from the **facility** must be reported to the **Regulator** as soon as reasonably possible.