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

Guidance Notes for the Containment
of
Exempt Dealings

These notes are provided as guidance only to persons conducting exempt dealings pursuant to regulation 6 of the *Gene Technology Regulations 2001* (the Regulations) as in force from 1 July 2007 and/or pursuant to any applicable corresponding law.

Exempt dealings are dealings described in Part 1 of Schedule 2 of the regulations. The only further legislative requirements for exempt dealings is that they do not involve an intentional release of the GMOs into the environment, or a retroviral vector that is able to transduce human cells.

Note that a dealing with a GMO listed as an exempt dealing will cease to be exempt from licensing if the GMO is intentionally released.

These Guidance Notes, which are effectively equivalent to those for facilities certified by the Regulator to Physical Containment Level 1 (PC1), may be of assistance to organisations or persons in determining how to undertake exempt dealings to satisfy themselves with regard to avoiding intentional release. Please note that **these Guidance Notes are not Guidelines for Certification of a PC1 Facility.**

A list of the Australian/New Zealand standards that are referenced in the Guidance Notes is also attached to this document.

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Explanatory Information

Guidance Notes for the Containment of Exempt Dealings

This document comprises Guidance Notes for the containment of exempt dealings as described in regulation 6 of the *Gene Technology Regulations 2001* as in force from 1 July 2007.

The Guidance Notes are based on a Physical Containment (PC) Level equivalent to PC1 in AS/NZS 2243.3:2002.

The Guidance Notes are only applicable to exempt dealings conducted under the *Gene Technology Act 2000* (the Act). They do not provide comprehensive guidance for laboratory safety, good laboratory practice or broader occupational health and safety issues, nor do they provide comprehensive guidance for laboratory design and construction. For these purposes, refer to AS/NZS 2243.3:2002 and AS/NZS 2982.1:1997.

Containment of Exempt Dealings

Definitions and acronyms

Unless defined otherwise in these Guidance Notes, words and phrases used in the Guidance Notes have the same meaning as in the *Gene Technology Act 2000* and *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).

aerosol	Particulate matter, solid or liquid, small enough to remain suspended in air.
autoclave	Pressure steam steriliser.
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 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).
decontamination	A physical or chemical process which removes, kills or renders non-viable the **GMOs** being **dealt** with in the **facility**, but does not necessarily result in sterility.
environment	Includes: (a) ecosystems and their constituent parts; (b) natural and physical resources; and (c) the qualities and characteristics of locations, places and areas.

exempt dealing	A **dealing** conducted pursuant to regulation 6 of the regulations.
facility	The non-certified laboratory or other work area within which **exempt dealings** are contained.
GM	Genetically Modified.
GMO	Genetically Modified Organism.
primary container	The container directly surrounding the **GMO**.
sealed	Able to contain and prevent the escape/release of all **GMOs** or **GM** reproductive material, including during standard transport conditions.
unbreakable	Able to maintain integrity under all reasonably expected conditions of transport such as pressures, forces, impacts, temperatures and moisture.

Which parts are applicable?

If you are conducting **exempt dealings** with **GM** micro-organisms only, you should refer to:	Part 1 (A) and Part 2 (A)
If you are conducting **exempt dealings** with animals containing **GM** micro-organisms, you should refer to:	Parts 1 (A) & (B) and Parts 2 (A) & (B)

Part 1 – Facilities and fittings

A) Exempt dealings with GMOs

1. **Exempt dealings** with **GMOs** should be conducted in a **facility** that is a fully enclosable space bounded by walls, doors, windows, floors and ceilings.

   NOTE: The walls, doors, windows, floors and ceilings form the physical containment barrier around the area where **exempt dealings** with **GMOs** will be conducted.

2. Floors and benches in the **facility** should be cleanable, easily **decontaminated** and resistant to damage by the cleaning agents and/or disinfectants that will be used in the **facility**.

3. The **facility** should contain either a wash basin or some other means of **decontaminating** hands.

> NOTE: **Decontamination** of hands is considered an important means of preventing unintentional release of **GMOs**. Alternatives to wash basins, such as dispensers filled with **decontaminant** solutions, are considered suitable.

B) Exempt dealings with animals containing GMOs

4. Doors, and windows that are able to be opened, should be lockable. Windows that are able to be opened should be screened to prevent the entry or exit of arthropods.

5. The **facility** boundaries (doors, walls, floors, ceilings etc.) should be designed to prevent the escape of the animals containing **GMOs** being contained.

6. Any openings in the **facility** walls, ceiling or roof, such as air vents, should be screened with rodent-proof mesh.

7. If the **facility** has drainage exits, they should be fitted with barriers (e.g. floor wastes or mesh) to prevent rodents or any other animal from entering the **facility** via the drains and to prevent the escape of animals containing **GMOs** from the **facility**.

Part 2 – Behavioural conditions

A) Exempt dealings with GMOs

8. Access to the **facility** should be restricted to persons authorised to enter.

9. Dedicated "emergency only" exits should not be used except in emergencies.

10. Persons performing procedures with **GMOs** in the **facility** should wear protective clothing to protect the front part of the body from exposure to the **GMOs**.

11. Protective clothing should be removed and disposed of, or stored, before leaving the **facility**.

> NOTE: Consideration should be given to the provision of hooks or other storage for protective clothing.

12. Protective clothing contaminated or suspected to be contaminated with **GMOs** should be removed as soon as reasonably possible and **decontaminated** prior to reuse. Protective clothing that has not been contaminated with **GMOs** may be washed using normal laundry methods.

13. Precautions should be taken to minimise the production of **aerosols** where procedures involving **GMOs** are carried out on an open bench.

14. All cultures of **GMOs** should be labelled.

    NOTE: Labelling assists the separation of **GM** work from non-**GM** work and enhances the control of **GMOs** within the **facility**.

15. **GMOs** should be **decontaminated** prior to disposal.

16. Liquid and solid wastes potentially containing **GMOs** should be **decontaminated** prior to disposal.

17. Work benches, surfaces and equipment where procedures involving **GMOs** have taken place should be **decontaminated** when the procedures are completed.

    NOTE: This is to minimise any persistence of **GMOs** inside the **facility** and minimise cross-contamination with any other work.

18. Any equipment that is, or may be, contaminated with **GMOs** should be **decontaminated** prior to being removed from the **facility**.

19. **Decontamination** can be achieved by any method effective in rendering the **GMO** non-viable, including **autoclaving** or other heat treatment; chemical treatment; or incineration.

    Incineration should be performed in a high temperature, high efficiency incinerator that has been approved by the relevant government authority in the jurisdiction where the incinerator is located.

    NOTES: **Decontamination** can take place in the **facility** or at another location.

    AS/NZS 2243.3:2002 is a recommended source of information when selecting chemical disinfectant agents.

20. A supply of disinfectants effective against the **GMOs** used in the **facility** should be available in the **facility** for **decontamination** purposes. Containers of disinfectants, including any solutions for **decontaminating** hands, should be clearly labelled with the contents and, where necessary, the expiry date. Solutions should not be used after the expiry date.

21. **GMOs** may be stored outside the **facility** in a storage unit (freezer, fridge, controlled temperature room or other container). Access to the storage unit should be restricted or controlled to prevent unintentional release of **GMOs** into the **environment**.

22. **GMOs** being stored outside the **facility** should be stored in a labelled, **sealed**, **unbreakable primary container** to prevent the escape or release of the **GMO**.

23. All cultures of **GMOs** being stored inside the **facility** should be **sealed** during storage to prevent dissemination of the **GMOs**.

    NOTE: The type of containment necessary to prevent the **GMOs** from escaping will vary depending on the type of **GMO** being stored.

24. If any spills of **GMOs** occur outside the **facility**, the contaminated surfaces should be **decontaminated** as soon as reasonably possible.

25. Persons who have been performing procedures with **GMOs** in the **facility** should **decontaminate** their hands before leaving the **facility**.

    NOTE: This may include the use of soap and water, if appropriate.

B) Exempt dealings with animals containing GMOs

26. Except during the entry and exit of personnel, supplies and/or equipment, doors of the **facility** should be closed while procedures with animals containing **GMOs** are being conducted. Windows and doors should be locked when **facility** personnel are not in attendance.

27. Handling of and any experimental procedures conducted on the animals containing **GMOs** should be carried out in a way that minimises the chance of escape.

28. When not being handled, the animals containing **GMOs** should be kept in containers or cages designed to prevent the escape of the animals being contained.

    NOTE: The **facility** physical boundaries alone are not sufficient for containment.

29. All animal cages or containers should be labelled. Cages or containers must be labelled to enable identification of the animals containing **GMOs** being contained and to indicate the number of animals in the containers. Large animals containing **GMOs** should be clearly marked so that they can be readily identified (eg. with a tattoo, permanent tag, microchip or permanent brand). Some documented system of accounting for the animals containing **GMOs** in the **facility** should be used.

30. If an animal containing **GMOs** escapes within the **facility**, trapping devices should be used to capture the animal and the animal should be returned to its container or cage or euthanased.

Standards referenced in this document

'AS' followed by a number or other identification is a reference to the Australian Standard so numbered or identified.

'AS/NZS' followed by a number or other identification is a reference to the Australian New/Zealand Standard so numbered or identified.

AS/NZS 2243.3:2002	Safety in laboratories Part 3: Microbiological aspects and containment facilities
AS/NZS 2982.1:1997	Laboratory design and construction Part 1: General requirements