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

Guidelines for the Transport, Storage and Disposal of GMOs

I, DR ROLAND JOSEPH SMITH, the Gene Technology Regulator, acting under paragraph 27(d) of the *Gene Technology Act 2000*, hereby issue these guidelines.

Dated this 2nd day of June 2011

DR ROLAND JOSEPH SMITH
Gene Technology Regulator

Guidelines for the Transport, Storage and Disposal of GMOs

made under the Gene Technology Act 2000

Name of Guidelines

These Guidelines are the Guidelines for the Transport, Storage and Disposal of GMOs

Purpose

Firstly, these guidelines are issued for the purposes of paragraph 13(3)(b) of the Gene Technology Regulations 2001.

Secondly, these guidelines may also be invoked as necessary or convenient in the performance of the Regulator's functions under section 27 of *Gene Technology Act 2000* ('the Act'), and in the exercise of the Regulator's powers under section 28 of the Act.

In particular these guidelines may be invoked for the purposes of the imposition of licence conditions in accordance with section 61 of the Act and of certification conditions in accordance with section 86 of the Act.

Commencement

These Guidelines commence on 1 September 2011.

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Definitions and Acronyms

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

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

References to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears.

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.

aerosol	Suspension in air of finely dispersed solids and liquids.
authorised physical containment facility or authorised PC(1, 2, 3 or 4) facility	A physical containment facility that is: • certified by the Regulator under section 84 of the Act; • permitted to contain GMO dealings under conditions of a licence issued by the Regulator; or • otherwise authorised in writing by the Regulator under regulation 13(2)(c) of the Regulations. 'PC(1, 2, 3 or 4)' means Physical Containment level 1, 2, 3 or 4.
decontamination or decontaminate	A physical or chemical process which removes, kills or renders non-viable the GMOs used. In the case of micro-organisms this may not necessarily result in sterility.
disposal	The destruction, discarding, or throwing away of decontaminated GMOs.
GMO	Genetically Modified Organism.
GM	Genetically Modified
flood	For the purposes of these guidelines 'flood' includes: • mainstream flooding (an event where water from a creek, river, lake, estuary or coastal waters overflows the natural or artificial banks of the principal watercourses in a catchment); • flash flooding (flooding that occurs within six hours of the rain which causes the flooding); and • stormwater flooding (local runoff exceeding the capacity of an urban stormwater drainage system).

IBC	Institutional Biosafety Committee.
NLRD	Notifiable Low Risk Dealing.
micro-organism	An organism too small to be viewed by the unaided eye, including bacteria, fungi, viruses and some multicellular organisms. For the purposes of these guidelines, this definition includes viral vectors.
PC1	Physical Containment Level 1.
PC2	Physical Containment Level 2.
PC3	Physical Containment Level 3.
PC4	Physical Containment Level 4.
primary container	A container immediately surrounding the GMO.
prone to flooding	For the purposes of these guidelines, the determination of whether the location of a site is prone to flooding or storm surges depends on the expected frequency of these events. A site will be regarded as being prone to flooding if the floor of the site would be inundated by a 100 year Average Recurrence Interval (ARI) flood or storm surge event. (This equates to a 1 in 100 year flood level, or an Annual Exceedance Probability (AEP) of 1%.). If it is not possible to obtain the 100 year ARI flood level from the relevant local authority, then the highest ARI or Defined Flood level used by that authority will be taken to be the level for determining if the location is prone to flooding or storm surges.
qualified person	A person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skill enabling that person to accomplish the relevant task competently.
sealed	Able to contain all GMOs or the reproductive material of GM plants or GM aquatic organisms (including pollen or gametes) being transported or stored, and able to remain closed during all reasonably expected conditions of transport and storage.
secondary container	The container immediately surrounding the primary container.

storage	The act of holding or keeping of GMOs or parts of GMOs without undertaking any experimentation or other procedures on the GMOs or parts of GMOs. NOTE: It would normally be expected that there would be no metabolic activity or minimal metabolic activity in the GMOs. This may involve low temperatures or freezing of cultures but may also involve the holding of stocks of diapausing insects or cell cultures for relatively short periods of time. It would not include the holding of actively growing plants and animals.
storm surge	For the purposes of these guidelines, a storm surge is a rise in coastal water levels caused by the low pressure area of a storm or cyclone and wind driving water shoreward.
substantive amount of liquid	That amount of liquid more than that which adheres to the inside of a container (such as a bottle) when its contents have been emptied out.
the Act	*Gene Technology Act 2000* and, as applicable, corresponding State legislation.
the Regulations	The Commonwealth *Gene Technology Regulations 2001*.

transport

Includes:

- movement of GMOs between one authorised physical containment facility and another;
- movement of GMOs between one authorised physical containment facility and storage outside of an authorised physical containment facility;
- movement of GMOs between a place of storage outside of an authorised physical containment facility to another place of storage outside of an authorised physical containment facility;
- movement of GMOs between any points specified in a licence;
- movement of GMOs from any point specified in a licence to an authorised physical containment facility;
- movement of GMOs from an authorised physical containment facility, or from storage outside of an authorised physical containment facility, to a place where the GMOs are to be decontaminated or disposed of (e.g. to an autoclave or incinerator);
- movement of GMOs imported into Australia from the Australian border to: an authorised physical containment facility; storage outside of an authorised physical containment facility; or a point of export from Australia or to a place where the GMOs are to be decontaminated or disposed of;
- movement of GMOs to be exported from Australia, to the Australian border from an authorised physical containment facility or from storage outside of an authorised physical containment facility;
- movement of liquid waste containing GMOs via piping or tubing from an authorised physical containment facility to a place outside the boundary of the facility for further transport, storage, decontamination or disposal.

Within these guidelines transport does not include movement of GMOs:

- from an area in an authorised physical containment facility to another area entirely within the same facility; or
- from one part of an area authorised by a licence to another part of the same area (for example, from one part of a field planting location to another part of the same field planting location).

unbreakable

Able to withstand all reasonably expected conditions of transport and storage such as: the forces, shocks and impacts expected during handling; or changes of temperature, humidity or air pressure.

viable	Micro-organisms, cells and cell cultures: • able to survive or multiply even though resuscitation procedures may be required, e.g. when sub-lethally damaged by being frozen, dried, heated, or affected by chemicals, including decontamination agents. Other organisms, whole or part: • able to live and grow independently of its parent or source organism, or able to reproduce or contribute genetic material to reproduction (e.g. sperm, ova, pollen, seeds, vegetative propagules).

Summary Table of Applicable Sections for the Transport of GMOs

Table 1 **Summary of the sections of the guidelines which apply to dealings involving transport**

		Containment level			
		PC1	**PC2**	**PC3**	**PC4**
Type of GMO	**Micro-organism**	1.1.1 (page 11) and 1.1.2 (page 13)	1.2.1 (page 16) and 1.2.2 (page 19)	1.3.1 (page 23)	1.4.1 (page 26)
	Animal	1.1.1 (page 11) and 1.1.3 (page 14)	1.2.1 (page 16) and 1.2.3 (page 21)	1.3.1 (page 23)	
	Plant	1.1.1 (page 11) and 1.1.4 (page 15)	1.2.1 (page 16) and 1.2.4 (page 22)	1.3.1 (page 23)	

Part 1 Requirements for Transport of GMOs

1.1 Requirements for Transport of PC1 GMOs

This Part applies to the following dealings with GMOs:

- NLRDs that are listed in Part 1 of Schedule 3 of the Regulations ; or
- any other dealings that are permitted, in writing, by the Regulator to be conducted in authorised PC1 facilities or transported under this Part of these guidelines.

1.1.1 PC1 General Requirements

Where any Specific Requirements (Parts 1.1.2, 1.1.3 or 1.1.4) applicable to the dealings conflicts with a General Requirement, the Specific Requirement prevails.

Labelling

1.1.1.1 A person or accredited organisation supplying the GMO for transport must label the material to be transported in a manner capable of notifying any other handler of the material that the item to be transported is, or contains a GMO.

1.1.1.2 Where transport is being undertaken by a service provider then the outermost container must be labelled to clearly show the name, address and contact details of the sender, so that the sender can be contacted should the container be lost, damaged or misdirected.

Loss, spill or escape of GMOs during transport

1.1.1.3 In the event of the escape, unintentional release, spill, leak, or loss of GMOs, including failure of the GMOs to be delivered to the recipient:

- efforts must be implemented as soon as reasonably practicable to locate and/or retrieve the GMOs and return the GMOs to containment or render them non-viable; and
- the incident must be reported to the Regulator as soon as reasonably practicable.

Accounting requirements

1.1.1.4 Procedures must be in place to ensure that all GMOs or the number of primary containers of cultures of GMOs transported, can be accounted for and that a loss of GMOs during transport, or the failure of delivery, can be detected. These procedures must be implemented for all transport events, except where transport takes place entirely within a building and the GMOs are accompanied by a person mentioned in an IBC's record of assessment as having the appropriate training and experience to deal with the GMOs at all times.

Security arrangements

1.1.1.5 Access to the GMOs must be restricted, by any means that is effective, to only a person or class of persons mentioned in an IBC's record of assessment as having the appropriate training and experience to deal with the GMOs. This includes

situations where containers are left for collection in a loading area, or left unattended prior to decontamination.

NOTE: Access in such cases could be restricted, for example, by keeping the containers in a locked area until collection.

Decontamination of containers

1.1.1.6 The external surface of the outermost container must be decontaminated prior to transport.

NOTE: Where appropriate, visual inspection of the container(s) may be used to confirm whether decontamination is necessary (e.g. in the case of macroscopic organisms which are easy to see).

1.1.1.7 Containers must be decontaminated after transport.

Packaging with coolants

1.1.1.8 If the material being transported is to be cooled using dry ice, liquid nitrogen or any other coolant that will release a gas, then a mechanism to allow the escape of the gas must be included. If water ice is used as a coolant then the outer packaging should be constructed so as to prevent any leakage. All containers must be able to withstand the temperatures to which they will be subjected.

1.1.2 PC1 GM micro-organisms (including plants or animals containing GM micro-organisms)

The following requirements, in addition to the General Requirements (Part 1.1.1), apply to the transport of GM micro-organisms (including GM or non-GM plants or GM or non-GM animals containing GM micro-organisms) to which Part 1.1 of these guidelines apply.

Containment

1.1.2.1 GM micro-organisms to be transported, including plants or animals containing GM micro-organisms, must be wholly contained inside a sealed, unbreakable primary container.

Labelling

1.1.2.2 Animals containing GM micro-organisms or their containers must be tagged or labelled so as to indicate that they contain GMOs. Large animals, such as pigs, sheep, cattle etc., must be individually tagged (e.g. by microchip, tattoos, ear tags or ear notches).

1.1.2.3 Plants containing GM micro-organisms or their containers must be tagged or labelled so as to indicate that they contain GMOs.

Decontamination of material transported with GM micro-organisms

1.1.2.4 Any materials transported with the GM micro-organisms (such as soil, anti-desiccation agents or soil substitute in the case of plants, or bedding materials or feed in the case of animals) must be either retained with the organisms under containment or decontaminated after transport has occurred.

1.1.3 PC1 GM animals not containing GM micro-organisms

The following requirements, in addition to the General Requirements (Part 1.1.1), apply to the transport of GM animals that do not contain GM micro-organisms.

NOTE: Animals containing PC1 GM micro-organisms are dealt with under Part 1.1.2.

Containment

1.1.3.1 GM animals to be transported must be wholly contained inside a sealed, unbreakable primary container.

NOTE: The type of containment necessary to prevent the GM animals from escaping will vary depending on the type of animal being transported. For example, in the case of transgenic mice, the primary container may be a cage that is closed or taped to enable it to maintain its integrity under all reasonably expected conditions of transport. For large grazing animals, such as sheep, cattle, horses etc., a sealed trailer, truck or specialised livestock transport vehicle may be used as the primary container.

1.1.3.2 GM large grazing animals, such as sheep, cattle, horses etc., may be herded or led between two authorised physical containment facilities, or between a transport vehicle and an authorised physical containment facility, provided:

- the animals are supervised and adequately controlled to prevent their escape (e.g. by the use of temporary fencing, closed gates, or by keeping doors closed in a corridor); and
- the distance being travelled is reasonably short (e.g. transfer from a vehicle to a room in an adjacent building, or transfer across a road between two PC1 Large Grazing Animal facilities where the person conducting the transfer is able to control all movements of people, traffic, and other animals on the road).

Labelling

1.1.3.3 GM animals or container(s) of GM animals must be tagged or labelled so as to indicate that they are GMOs. Large animals, such as pigs, sheep, cattle etc., must be individually tagged (e.g. by microchip, tattoos, ear tags or ear notches).

Segregation

1.1.3.4 GM and non-GM animals, capable of interbreeding, must be kept physically separated from each other during transport unless they form part of the same dealing. If the separation fails, then any non-GM animals must be transported in accordance with the requirements in these guidelines as if they were GM animals.

Decontamination of containers

1.1.3.5 After the transport of animals, containers must be decontaminated, including by ensuring no individual animals are hidden in any bedding or media.

1.1.4 PC1 GM plants not containing GM micro-organisms

The following requirements, in addition to the General Requirements (Part 1.1.1), apply to the transport of GM plants that do not contain GM micro-organisms.

NOTE: Plants containing GM micro-organisms are dealt with under Part 1.1.2.

Containment

1.1.4.1 GM plants and GM plant material containing living cells must be wholly contained inside a sealed, unbreakable primary container, e.g. leaves or roots in soil.

NOTE: In the case of non-viable GM plant material containing living cells, 'sealed' means able to contain the material, e.g. a wheeled bin with a lid that is not leak proof or airtight, but is secured so that it would not fall open if the bin tipped over, and would not allow any of the GM plant material in the bin to escape.

A sealed, unbreakable container can also be a pot, provided that there are no spores, pollen, seeds or cones from GM plants.

Labelling

1.1.4.2 GM plants and other viable GM plant material must be labelled to indicate that they are GMOs. This may be achieved by labelling plants or containers as appropriate.

Decontamination of material transported with the GMOs

1.1.4.3 Any materials transported with the GM plant material (such as soil, anti-desiccation agents, soil substitute, or water) must be either retained with the GM plant materials under containment or decontaminated after transport has occurred.

1.2 Requirements for Transport of PC2 GMOs

This Part applies to the following dealings with GMOs:

- NLRDs that are listed in Part 2 of Schedule 3 of the Regulations; and
- any other dealings that are permitted, in writing, by the Regulator to be conducted in authorised PC2 facilities or transported under this Part of these guidelines.

1.2.0.1 Dealings that are permitted to be conducted in an authorised PC1 physical containment facility but which are conducted in an authorised PC2 physical containment facility, may be transported according to the requirements relating to the transport of dealings conducted in an authorised PC1 physical containment facility under Part 1.1 of these guidelines, provided:

- procedures are implemented to ensure that PC1 dealings are not cross-contaminated or mixed with GMO dealings that are required to be contained in an authorised PC2 physical containment facility; and
- the above procedures are documented.

1.2.0.2 If the above documented procedures to prevent cross-contamination are <u>not</u> in place, then PC1 dealings conducted in an authorised PC2 physical containment facility must be transported in accordance with the PC2 transport requirements below.

1.2.1 PC2 General Requirements

These General Requirements apply to all dealings with GMOs to which Part 1.2 of these guidelines apply. Where any Specific Requirements (Parts 1.2.2, 1.2.3 and 1.2.4) applicable to the dealings conflicts with a General Requirement, the Specific Requirement prevails.

Labelling

1.2.1.1 A person or accredited organisation supplying the GMO for transport must label the material to be transported in a manner capable of notifying any other handler of the material that the item to be transported is, or contains a GMO.

1.2.1.2 The outermost container must be labelled to clearly show the name, address and contact details of the sender, so that the sender can be contacted should the container be lost, damaged or misdirected.

This is not required where transport takes place entirely within a building, or when clinical or infectious waste containing viable GMOs is being transported to a place of decontamination by a transport, storage or disposal service provider licensed or otherwise authorised to do so under state or territory legislation.

Loss, spill or escape of GMOs during transport

1.2.1.3 In the event of the escape, unintentional release, spill, leak, or loss of GMOs, including failure of the GMOs to be delivered to the recipient:

- efforts must be implemented as soon as reasonably practicable to locate and/or retrieve the GMOs and return the GMOs to containment or render them non-viable; and
- the incident must be reported to the Regulator as soon as reasonably practicable.

NOTE: A person consigning the GMO for transport should consider whether the transported material should be accompanied by:

- instructions on how to decontaminate any material in the event of a spill or leak;
- sufficient volume of effective decontamination agent to decontaminate any spill;
- appropriate protective clothing for persons undertaking the decontamination; and
- any other equipment necessary to undertake decontamination.

Accounting requirements

1.2.1.4 Procedures must be in place to ensure that all GMOs or, for micro-organisms and cell cultures, the number of primary containers of cultures of GMOs transported, can be accounted for and that a loss of GMOs during transport, or the failure of delivery, can be detected. These procedures must be implemented for all transport events, except where transport takes place entirely within a building and the GMOs are accompanied by a person or class of persons mentioned in an IBC's record of assessment as having the appropriate training and experience to deal with the GMOs at all times.

Security arrangements

1.2.1.5 Access to the GMOs must be restricted, by any means that is effective, to only a person or class of persons mentioned in an IBC's record of assessment as having the appropriate training and experience to deal with the GMOs. This includes situations where containers are left for collection in a loading area, or left unattended prior to decontamination.

NOTE: Access in such cases could be restricted, for example, by keeping the containers in a locked area until collection.

Decontamination of containers

1.2.1.6 The external surface of the primary and any required secondary container must be decontaminated prior to transport.

NOTE: Where appropriate, visual inspection of the container(s) may be used to confirm whether decontamination is necessary (e.g. in the case of macroscopic organisms which are easy to see).

1.2.1.7 Containers must be decontaminated after transport.

Packaging with coolants

1.2.1.8 If the material being transported is to be cooled using dry ice, liquid nitrogen or any other coolant that will release a gas, then a mechanism to allow the escape of the gas must be included. If water ice is used as a coolant then the outer packaging should be constructed so as to prevent any leakage. All containers must be able to withstand the temperatures to which they will be subjected.

NOTE: When transporting with coolants, it is preferable for coolants to be used outside of the secondary container.

1.2.2 PC2 GM micro-organisms (including plants or animals containing GM micro-organisms)

The following requirements, in addition to the General Requirements (Part 1.2.1), apply to the transport of GM micro-organisms (including GM or non-GM plants or GM or non-GM animals containing GM micro-organisms) to which Part 1.2 of these guidelines apply.

NOTE: Consideration should be given to alternatives to the transport of animals or plants that host pathogenic GM micro-organisms, such as transporting cultures of the micro-organisms for later inoculation.

Containment

1.2.2.1 GM micro-organisms to be transported, including plants or animals containing GM micro-organisms, must be wholly contained inside a sealed, unbreakable primary container.

When transporting animals or plants that require ventilation during transport and which contain GM micro-organisms that could form aerosols during transport, consideration must be given to whether the vents of the primary or secondary containers should be HEPA-filtered.

1.2.2.2 The primary container must be packed inside a sealed, unbreakable secondary container. Secondary containment is not required for small animals containing GM micro-organisms (e.g. mice) when transported in a sealed cage fitted with HEPA-filtered vents.

NOTE: The type of containment necessary to prevent the GM micro-organisms from escaping will vary depending on the type of organism being transported. For example, dry waste containing GMOs that does not contain sharps may be contained in two sealed plastic bags that are supported inside a third, unsealed, rigid-sided container that protects the bags from being torn or pierced during transport.

Containment of waste transported inside the same building

1.2.2.3 Waste being transported for decontamination inside the same building, and which has no substantive amount of liquid containing GMOs, and will not give rise to aerosols containing GMOs during transport, must be contained in two unbreakable containers, at least one of which must be sealed.

NOTE: For waste transported in accordance with this requirement, a ‘sealed’ container means one that is able to contain the waste material. An example would be waste in a sealed bag, placed inside a wheeled bin with a lid that is not leak proof or airtight, but is secured so that it would not fall open if the bin tipped over, and would not allow any of the waste in the bin to escape.

Labelling

1.2.2.4 A biohazard label must be attached to the outermost container when transporting any GMOs where the parent organism satisfies the criteria for classification as a Risk Group 2 organism under Section 3.2 of AS/NZS 2243.3:2010.

This is not required where transport takes place entirely within a building.

1.2.2.5 Animals containing GM micro-organisms or their containers must be tagged or labelled so as to indicate that they contain GMOs. Large animals, such as pigs, sheep, cattle etc., must be individually tagged (e.g. by microchip, tattoos, ear tags or ear notches).

1.2.2.6 Plants containing GM micro-organisms must be labelled to indicate that they contain GMOs. This may be achieved by labelling plants or containers as appropriate.

Decontamination of material transported with GM micro-organisms

1.2.2.7 Any materials transported with the GM micro-organisms (such as soil, anti-desiccation agents or soil substitute in the case of plants, or bedding materials or feed in the case of animals) must be either retained with the organisms under containment or decontaminated after transport has occurred.

1.2.3 PC2 GM animals, not containing GM micro-organisms

The following requirements, in addition to the General Requirements (Part 1.2.1), apply to the transport of GM animals that do not contain GM micro-organisms and to which Part 1.2 of these guidelines apply.

NOTE: Animals containing GM micro-organisms are dealt with under Part 1.2.2.

Containment

1.2.3.1 GM animals to be transported must be wholly contained inside a sealed, unbreakable primary container.

NOTE: The type of containment necessary to prevent the GM animals from escaping will vary depending on the type of animal being transported. For example, the primary container may be a cage that is closed or taped to enable it to maintain its integrity under all reasonably expected requirements of transport. As another example, for livestock, a sealed trailer, truck or specialised livestock transport vehicle may be used as the primary container. For large GM animals, such as pigs, sheep, cattle etc., consideration should be given as to whether a single primary container is sufficient, or whether additional measures might be prudent (e.g. tethering animals inside the vehicle; sedation; or attaching remote tracking devices to the animals).

1.2.3.2 Except for GM *Drosophila (Sophophora) melanogaster*, where transport involves GM invertebrates, the primary container must be packed inside a sealed, unbreakable secondary container.

Labelling

1.2.3.3 GM animals must be tagged or labelled so as to indicate that they are GMOs. Large animals, such as pigs, sheep, cattle etc., must be individually tagged (e.g. by microchip, tattoos, ear tags or ear notches). Small animals must be identified by labelling the cage or container, or individually as above.

Segregation

1.2.3.4 GM and non-GM animals capable of interbreeding, must be kept physically separated from each other unless they form part of the same dealing. If the separation fails, then any non-GM animals must be transported in accordance with the requirements in these guidelines as if they were GM animals.

Decontamination of containers

1.2.3.5 After the transport of small animals, containers must be decontaminated, including by ensuring no individual animals are hidden in any bedding or media.

1.2.4 PC2 GM plants, not containing GM micro-organisms

The following requirements, in addition to the General Requirements (Part 1.2.1), apply to the transport of GM plants that do not contain GM micro-organisms and to which Part 1.2 of these guidelines apply.

NOTE: Plants containing GM micro-organisms are dealt with under Part 1.2.2.

Containment

1.2.4.1 GM plants and GM plant material (e.g. leaves or roots in soil) containing living cells must be wholly contained inside a sealed, unbreakable primary container.

NOTE: In the case of non-viable GM plant material containing living cells, 'sealed' means able to contain the material, e.g. a wheeled bin with a lid that is not leak proof or airtight, but is secured so that it would not fall open if the bin tipped over, and would not allow any of the GM plant material in the bin to escape.

A sealed, unbreakable container can also be a pot, provided that there are no spores, pollen, seeds or cones from GM plants.

1.2.4.2 GM plants and GM plant material that is viable must also be packed inside a sealed, unbreakable, secondary container, except when:

- transported within a building; and
- the GM plants or GM plant material does not contain spores, pollen, seeds, or cones from GM plants.

Labelling

1.2.4.3 GM plants and other viable GM plant material must be labelled to indicate that they are GMOs. This may be achieved by labelling plants or containers as appropriate.

Decontamination of material transported with the GMOs

1.2.4.4 Any materials transported with the GM plant material (such as soil, anti-desiccation agents, soil substitute, or water) must be either retained with the GM plant materials under containment or decontaminated after transport has occurred.

1.3 Requirements for Transport of PC3 GMOs

The requirements in this Part apply to all dealings with GMOs that are:

- required to be contained in a PC3 facility certified by the Regulator; or
- have been involved in dealings conducted in a PC3 facility certified by the Regulator, whether or not the dealings would be permitted to be conducted in an authorised PC1 or PC2 facility.

1.3.1 PC3 Requirements

Notice that item to be transported is a GMO

1.3.1.1 A person or accredited organisation supplying the GMO for transport must label the material to be transported in a manner capable of notifying any other handler of the material that the item to be transported is, or contains a GMO.

1.3.1.2 The transport of animals or plants containing GM microorganisms that are required to be contained in an authorized PC3 containment facility is not permitted without prior, written approval from the Regulator.

Labelling

1.3.1.3 The outermost container must be labelled to clearly show the name, address and contact details of the sender, so that the sender can be contacted should the container be lost, damaged or misdirected.

1.3.1.4 A biohazard label must be attached to the outermost container.

Containment

1.3.1.5 GMOs to be transported must be wholly contained inside a sealed, unbreakable primary container.

1.3.1.6 The primary container must be packed inside a sealed, unbreakable secondary container, which must be packed inside a sealed tertiary container.

Loss, spill or escape of GMOs during transport

1.3.1.7 In the event of the escape, unintentional release, spill, leak, or loss of GMOs, during transport or failure of the GMOs to be delivered to the recipient:

- the GMOs must be contained to prevent further dispersal, including preventing any insect vectors from coming in contact with the spill;
- efforts must be implemented as soon as reasonably practicable to locate and/or retrieve the GMOs and return the GMOs to containment or render them non-viable;
- in the case of a spill or leak, efforts must be made to isolate the area to prevent inadvertent ingress by persons or animals;

- the exposed area must be immediately decontaminated with an appropriate decontaminating agent effective against the GMOs;
- any material used in the clean up of a spill or personal protective clothing worn during the clean up of the spill must be decontaminated;
- the incident must be reported to the Regulator as soon as reasonably possible; and
- if water ice coolants were used during transportation, these must be decontaminated after transport has occurred.

1.3.1.8 A person consigning the GMO for transport must take into account the risk associated with the GMOs being transported and must transport the material with accompanying:

- instructions on how to decontaminate any material in the event of a spill or leak;
- sufficient volume of effective decontamination agent to decontaminate any spill;
- appropriate protective clothing for persons undertaking the decontamination; and
- any other equipment necessary to undertake decontamination.

1.3.1.9 Persons accompanying the GMOs being transported must also carry a functioning means of communication (e.g. mobile phone) to enable communication with the sender in the event of the unintentional release, spill, leak, or loss of GMOs.

Accounting requirements

1.3.1.10 Documented procedures must be in place to ensure that all GMOs or, for micro-organisms, the number of primary containers of cultures of GMOs transported, can be accounted for and that a loss of GMOs during transport, or the failure of delivery, can be detected. These procedures must be implemented for all transport events.

1.3.1.11 Except for transport entirely within a building, records of the transport of GMOs must be made and kept for at least three years after the transport event. These records must be made available to the Regulator, if requested.

The record of transport must include:

- the name of the parent species of the GMO;
- the genetic modification(s);
- the number of individual containers transported and total amount: if the GMO is in a liquid such as a microbiological culture then the total volume; alternatively, if the consignment were a solid in a bulk amount, then the total net mass of the contents being transported;
- the mode of transport (e.g. by hand, rail and road, road and air);
- the name and contact details of the transporter(s) if transport or other service providers are used;
- the name and contact details of the sender;
- the name and contact details of the recipient;
- the date sent; and
- confirmation that the full consignment was received.

Security arrangements

1.3.1.12 Access to the GMOs must be restricted, by any means that is effective, to only a person or class of persons mentioned in an IBC's record of assessment as having the appropriate training and experience to deal with the GMOs.

Decontamination of containers

1.3.1.13 The external surface of the primary and secondary containers must be decontaminated prior to transport.

1.3.1.14 Secondary containers must be decontaminated after transport.

Packaging with coolants

1.3.1.15 If the coolant used is dry ice, liquid nitrogen or any other coolant that will release a gas, then a mechanism to allow the escape of the gas must be included. If water ice is used as a coolant then the outer packaging must be constructed so as to prevent any leakage. All containers must be able to withstand the temperatures to which they will be subjected.

1.3.1.16 Coolants must not be used inside either the primary or secondary container.

1.4 Requirements for Transport of PC4 GMOs

1.4.1 All GMOs

The transport of GMOs that are required to be contained in a PC4 facility certified by the Regulator is not permitted without prior, written approval from the Regulator.

Part 2 Requirements for the Storage of GMOs

2.1 Storage requirements for PC1 and PC2 GMOs stored outside of authorised physical containment facilities.

Part 2 applies to the following dealings with GMOs:

- NLRDs that are permitted to be stored outside of authorised PC1 or PC2 facilities by regulation 13(3)(b) of the Regulations; or
- any other dealings that are permitted, in writing, by the Regulator to be stored under Part 2 of these guidelines.

NOTE: If any of the above are held in an authorised PC3 or PC4 physical containment facility then Part 2.2 applies.

Restrictions on storage

2.1.1 Whole, viable GM animals must not be stored outside of an authorised physical containment facility without permission, in writing, from the Regulator. This restriction does not apply to the sperm, fertilised eggs or embryos of GM animals.

2.1.2 Whole, viable GM plants must not be stored outside of an authorised physical containment facility without permission, in writing, from the Regulator. This restriction does not apply to the pollen, seeds, tubers, bulbs, corms or dormant stems of GM plants.

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

Containment

2.1.4 GMOs, including organisms containing GMOs, being stored must be wholly contained inside a sealed, unbreakable primary container.

NOTE: The type of containment necessary to prevent the GMO from being released will vary depending on the type of organism being stored. For example, in the case of plant seeds or tubers the primary container may be a bag that is closed or taped to enable it to maintain its integrity under all reasonably expected requirements of storage. A sealed plastic tube or bottle may be used as the primary container for a culture of micro-organisms.

2.1.5 GMOs for which the minimum permitted physical containment level is PC2, must be packed inside a sealed, unbreakable secondary container. In the case of a small storage unit, such as a refrigerator, freezer, or cryogenic storage container, the storage unit is permitted to be the secondary container.

Loss, spill or escape of GMOs during storage

2.1.6 In the event of the escape, unintentional release, spill, leak or loss of GMOs from storage:

- efforts must be implemented as soon as reasonably practicable to locate and/or retrieve the GMOs and return the GMOs to containment or render them non-viable; and
- the incident must be reported to the Regulator as soon as reasonably practicable.

NOTE: Consideration should also be given to the type of surfaces in the storage unit or room. Ideally they would be smooth, impermeable to water, cleanable, and resistant to damage by the decontamination agents that would be used to decontaminate any spill.

2.1.7 GMOs must not be stored unless a supply of decontamination agents effective against the GMOs being stored is readily available for decontamination purposes. All containers of decontamination agents, including any solutions for decontaminating hands, must be labelled with the contents and, where necessary, the expiry date. Decontamination agents must not be used after their expiry date.

NOTE: Consideration should also be given to whether the stored material should be accompanied by:

- instructions on how to decontaminate any material in the event of a spill or leak;
- appropriate protective clothing for persons undertaking the decontamination; and
- any other equipment necessary to undertake decontamination.

Labelling

2.1.8 A person or accredited organisation supplying the GMO for storage must label the material to be stored in a manner capable of notifying any other handler of the material that the item to be stored is, or contains a GMO.

2.1.9 The primary container must be labelled to clearly show the name or other identifier of the GMO being stored.

2.1.10 The storage unit, or any other secondary container, must be labelled to clearly show the name and contact details of the person responsible for the dealings, so that the person can be contacted should any GMOs be spilled or lost.

2.1.11 A biohazard label must be attached to the storage unit when storing any GM micro-organisms that satisfy the criteria for classification as a Risk Group 2 organism under Section 3.2 of AS/NZS 2243.3:2010.

Accounting requirements

2.1.12 Procedures must be in place to ensure that all GMOs stored can be accounted for.

2.1.13 A record(s) of GMOs being stored must be maintained and made available to the Regulator upon request.

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

Security

2.1.15 During the storage of GMOs outside of an authorised physical containment facility, access to the GMOs must be restricted, by any means that is effective, to only a person or class of persons mentioned in an IBC's record of assessment as having the appropriate training and experience to deal with the GMOs.

2.2 Storage requirements for PC3 and PC4 GMOs stored outside of authorised physical containment facilities.

Part 2.2 applies to GMOs that require containment in a PC3 or PC4 facility certified by the Regulator.

2.2.1 Organisms to which Part 2.2 applies must not be stored outside of the relevant certified facility unless permitted, in writing, by the Regulator, for example by way of a licence condition.

2.2.2 If storage of any of the GMOs under 2.2.1 is permitted, in writing, by the Regulator, the storage must comply with any conditions specified in the written approval.

Part 3 Requirements for the Disposal of GMOs.

3.1 Requirements for the Disposal of PC1 & PC2 GMOs

Part 3.1 applies to the decontamination or disposal of GMOs or waste containing GMOs, and the decontamination of equipment involved in procedures with GMOs related to:

- NLRDs that are assessed as being able to be conducted in authorised PC1 facilities by Part 1 of Schedule 3 of the Regulations; or
- NLRDs that are assessed as being able to be conducted in authorised PC2 facilities by Part 2 of Schedule 3 of the Regulations; or
- any other dealings that are permitted, in writing, by the Regulator to be decontaminated and disposed of under this Part of these guidelines.

The following requirements principally cover the decontamination of GMOs prior to their subsequent disposal. Decontamination may be part of the disposal process where the disposal process also decontaminates the GMO (e.g. incineration), or a separate process prior to later disposal.

Other regulations

Other regulations may need to be complied with for the disposal of GMOs including, where relevant, State, Territory or Local Government regulations.

Notice that item to be disposed of is a GMO

3.1.1 A person or accredited organisation supplying the GMO for disposal must label the material in a manner capable of notifying any other handler of the material that the item to be disposed of is, or contains a GMO.

Decontamination Prior to Disposal

3.1.2 GMOs, or non-GM organisms containing GMOs, must be rendered non-viable prior to disposal if the method of disposal is not also the method of decontamination.

3.1.3 Any wastes containing GMOs must be decontaminated prior to disposal if the method of disposal is not also the method of decontamination.

3.1.4 Decontamination and disposal of GMOs must only be undertaken by a person or class of persons mentioned in an IBC's record of assessment as having the appropriate training and experience to deal with the GMOs.

3.1.5 Following use for transport or storage, the primary container, and any secondary container that is not itself a storage unit, must be decontaminated prior to reuse of the container or its disposal (if the method of disposal is not also the method of decontamination).

NOTE: Where appropriate, visual inspection of the container(s) may be used to confirm whether decontamination is necessary (e.g. in the case of macroscopic GMOs which are easy to see).

Decontamination methods

3.1.6 A person who personally conducts the decontamination process must ensure the requirements outlined below, for the respective method of decontamination, are complied with.

3.1.7 Decontamination may be effected by autoclaving using a combination of temperature and time that has been validated as effective for the decontamination of the GMOs.

3.1.8 The temperature and time controls of an autoclave used for decontaminating GMOs must be calibrated by a qualified person at least once every 12 months to determine the actual temperature and time at which the autoclave runs as compared to the autoclave gauges. The results of each year's calibration must be kept for the previous 5 years and made available to the Regulator if requested.

NOTE: Calibration does not necessarily require adjustment of the autoclave controls. If the autoclave cannot be adjusted and is significantly out, then the set temperature, for example, can be adjusted to compensate the difference by using the data from the calibration.

3.1.9 If an autoclave is used to decontaminate GMOs, the effectiveness of decontamination by the autoclave must be monitored at least once per month by the use of:

(a) thermocouples or resistance thermometers, to ensure that the required temperature has been achieved; or
(b) chemical indicators which use a combination of moisture, heat and time and which progressively change colour with the time exposed at the specified temperature; or
(c) biological indicators such as spore strips; or
(d) enzyme indicators.

The results of each month's monitoring tests must be kept for the previous 12 months and made available to the Regulator if requested.

NOTE: Autoclaving is considered the most reliable means of decontamination, however, it is recognised that this method is not applicable in all situations. The reliability of autoclaves is predicated on correct usage and monitoring of the process. AS/NZS 2243.3:2010, Section 10.6, is a recommended source of guidance on using autoclaves.

3.1.10 If using other heat-based equipment for decontaminating GMOs, the effectiveness of decontamination equipment must be monitored at least once per month. The results of each month's monitoring tests must be kept for the previous 12 months and made available to the Regulator if requested.

3.1.11 Decontamination may be effected by incineration in a high temperature, high efficiency incinerator that has been approved by the relevant government authority in the jurisdiction where the incinerator is located.

3.1.12 Decontamination may be effected by any other heat-based equipment using a combination of temperature and time that has been validated as effective for the decontamination of the GMOs.

3.1.13 If using other heat-based equipment for decontaminating GMOs the temperature and time controls of the equipment must be calibrated by a qualified person at least once every 12 months to determine the actual temperature and time at which the equipment runs as compared to the equipment gauges. The results of each year's calibration must be kept for the previous 5 years and made available to the Regulator if requested.

3.1.14 Decontamination may be effected by any chemical decontamination agent that has been validated as effective for the decontamination of the GMOs.

NOTE: AS/NZS 2243.3:2010, Appendix F, is a recommended source of information when selecting and using chemical decontamination agents.

3.1.15 Decontamination of GM plant material that does not contain any GM micro-organisms may also be effected by composting of the GM plant material, along with soil and other associated material, provided:

- the process is validated as effective for killing and/or decomposing the GM plant material;
- the composting occurs in a dedicated concrete bay;
- the concrete bay is not in a site that is prone to flooding or storm surges;
- the concrete bay is free of any gaps or cracks that could be penetrated by the plants being composted;
- the surface of the concrete bay is able to be easily cleaned and decontaminated;
- access to the concrete bay is restricted to a person or class of persons mentioned in an IBC's record of assessment as having the appropriate training and experience to deal with the GMOs;
- all seeds have been removed from the GM plant material prior to placing in the concrete bay;
- the concrete bay is protected from entry by animals that would be able to distribute any undecomposed GM plant material beyond the concrete bay;
- the concrete bays containing composting GM plant material are monitored every month for volunteer GM plant growth;
- any volunteer GM plants are removed and destroyed;
- monitoring continues until six months has passed, after the last addition of GM plant material to the bay, without the emergence of any volunteer GM plants.

3.1.16 Decontamination of GM plant material that does not contain any GM micro-organisms may be effected by shredding the GM plant material provided:

- all seeds have been removed from the GM plant material prior to shredding it;
- shredding has been validated as effective in rendering the GM plant material non-viable.

3.1.17 Decontamination may only occur by any other method if approved in writing by the Regulator.

Prohibited decontamination

3.1.18 Decontamination of GMOs must not be performed using:

- decontamination equipment that is defective;
- any heat based decontamination equipment for which the results of each month's monitoring tests for the previous 12 months and the results of each year's calibration are not available to the Regulator;
- chemical decontamination agents that are past their expiry date; or
- any method that has not been validated as effective for the decontamination of the GMOs.

3.2 Requirements for the Disposal of PC3 & PC4 GMOs

- Part 3.2 applies to GMOs that require containment in a PC3 or PC4 facility certified by the Regulator.

3.2.1 Prior to disposal, the GMOs to which Part 3.2 applies must be decontaminated inside a relevant facility certified by the Regulator, unless otherwise permitted, in writing, by the Regulator.

3.2.2 Requirements for the decontamination of the GMOs to which Part 3.2 applies will be those applied by the licence or other authority issued by the Regulator that permits the conduct of the dealing and/or by the guidelines for certification of the relevant facility, issued by the Regulator.

Standards referenced in this document

List of the Australian/New Zealand standards referenced in this document

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

AS/NZS 2243.3:2010 Safety in laboratories
Part 3: Microbiological safety and containment