

MONASH University



**SUMMARY OF THE REQUIREMENTS
OF THE GENE TECHNOLOGY
REGULATIONS (GTR)**

Definitions:

“Gene Technology”

Is defined as any technique for the modification of genes or other genetic material, but does not include sexual reproduction, homologous recombination or any other techniques

“Organism”

Is defined to mean a biological entity that is viable, capable of reproduction or capable of transferring genetic material.

“Genetically modified organism”

Is defined in the GT Act as:

- An organism that has been modified by gene technology
- organism that has inherited particular traits from an organism (parent) where those traits occurred in the parent organism because of gene technology.
- Anything declared by the Regulations to be a GMO does not include:
 - *Human beings, that have undergone somatic gene therapy*
 - *Somatic cell nuclear transfer (cloning) if the transfer does not involve genetically modified material.*
 - *Organisms that are not GMOs are mentioned in Box 1 of the Handbook (Part 1 of Schedule 1 of the GT Regulations, Refer to Appendix 1)*

NOTE: While cloning is not caught within the definition of gene technology, the GT Act does ban cloning of whole human beings (Refer to Chapter 12 of the Handbook on the Regulation of Gene Technology in Australia).

“DEALINGS”

dealings or deal with

has the same meaning as in the Act

“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;

and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (g)

Types of Dealings with GMOs:-

Exempt Dealings:

What types of Dealings are exempt?

A dealing with a GMO's is only an exempt dealing if it meets **all** of the following conditions:

- It is mentioned in Box 3 of the Handbook (Part 1 of Schedule 2 of the GT Regulations, see Appendix 1)
- It does **not** involve genetic modification, other than a modification described in Part 1 of Schedule 2 of the GT Regulations (Refer to Appendix 1).
- It is conducted in accordance with the OGTR Guidelines for Certification of Facilities /Physical Containment Requirements July 2002 and Australian/New Zealand Standard; AS/NZS 2243.3: 2002, Physical Containment Level1 (**PC1**)
- It does not involve intentional release of the GMO into the environment
- Exempt Dealings must be submitted to the Biosafety Committee for approval.
- Submissions should be made on the current OGTR Form and should include a covering letter describing the type and purpose of the Dealing. The original plus 10 copies should be submitted to the Secretary of the IBC
- An Annual Report (See Appendix 3 for Annual Report Form) on the progress of the dealing by the researcher must be submitted to the Biosafety Committee.

Notifiable Low Risk Dealings (NLRDs)

What are NLRDs?

These were formerly classed as **Category B** Proposals (GMAC Guidelines).

NLRDs are Notifiable Low Risk Dealings with GMOs that have been assessed over time as posing low risks provided certain risk management conditions are met.

NLRDs must be:

- Submitted to the IBC for assessment and approval
- notified to the regulator (by the IBC)
- conducted within a facility certified to be at least Physical Containment Level 2 (**PC2**) in accordance with the "Guidelines for Certification of PC2 Facilities/Physical Containment 2 Requirements, version 2.1- August 2003.
- appropriately supervised within an Accredited Organisation;
- transported in accordance with Guidelines for the Transport of GMOs, issued by the Regulator.
- GMOs must **not** be released into the environment.
- A detailed risk assessment must be provided
- Work may commence once the NLRD has been approved by the IBC and submitted to the OGTR
- The types of dealings with GMOs that qualify as NLRDs are set out in the Regulations, Part 1. Schedule 3 (Refer to Box 5 Appendix 1)

*NOTES:

- 1 For additional information please refer to Chapter 5 of the *Handbook on the Regulation of Gene Technology in Australia*
- 2 NLRD Submissions should be made on the appropriate OGTR Form, to the Secretary of the IBC. Ten copies, as well as the original application with **all** signatures **must** also be provided (to be submitted to the OGTR).
- 3 If research with NLRDs is discontinued but the researcher wishes to retain the GMOs in storage then an NLRD Storage form must be completed and submitted to the IBC for assessment. The IBC will then submit the form to the OGTR. The original (including all necessary signatures) and 10 copies should be submitted to the Secretary of the IBC.
- 4 The OGTR **will not accept copies** of signatures.

DEALINGS NOT INVOLVING INTENTIONAL RELEASE (DNIRs)

OR

Licensed Dealings

What types of Dealings need to be Licensed.

[These were formerly classed as **Category A** proposals (GMAC Guidelines)]

There are currently two types of licence:

1. A Licence for dealings involving the intentional release into the environment. (**DIRs**) (Currently **NOT** applicable to Monash University) and;
2. A Licence for dealings not involving the intentional release of a GMO into the environment (typically laboratory based research projects) (**DNIRs**)
 - All work must be undertaken in an OGTR Certified facility (**PC2 or PC3**).
 - Applicants must provide detailed Risk Assessments for each application (in accordance with the requirements of the Regulator)
 - Work must **NOT** commence on the **DNIR** until a **Licence** has been obtained from the OGTR (this may take up to 90 working days)
 - Even when a Licence has been granted by the OGTR work **MUST NOT** commence until the Facility to be used has been granted Certification by the OGTR (this may take up to 90 working days)

NOTES:

1: Fees may be introduced for Licensed Dealings after June 20th 2005.

2: DNIR submissions may be made electronically, on the appropriate OGTR Form, to the Secretary of the IBC. Ten copies as well as the original with the necessary signatures **must** also be provided (to be submitted to the OGTR).

Certification of Facilities

All NLRDs and DNIRs **MUST** be carried out in Facilities that have been Certified (PC2 or PC3) by the OGTR.

How to have Facilities Certified as PC2:

- Contact the Secretary of the IBC
- The secretary will then organize members of the IBC to inspect the facilities
- After inspection (using the OGTR Inspection report forms 12p) the IBC will apply to the OGTR on behalf of the “Accredited Organisation to have the Facilities Certified (12p Application for Certification).
- The OGTR then assesses the Application (approx 90 working days)
- The OGTR provides an “Instrument of Certification”
- **ALL** conditions on the “Instrument” must be adhered **at all** times by persons working in a Certified Facility whether or not they are “Dealing” with GMOs

NOTE:

1: Please see Appendix 2 For PC2 work Practices

2: To obtain **PC3** Certification, Facilities must be inspected by members of the Office of the Gene Technology Regulator (OGTR). This may be organized by the Secretary of the IBC.

What is the Difference Between Accreditation Of Organisations and Licensing dealings with GMO's?

An Organisation must become accredited by the OGTR before it can apply for a licence to deal with GMOs.

Accreditation means that The Regulator is satisfied:

- That the Organisation has access to a properly constituted & maintained IBC
- That the Organisation has quality assurance systems in place (overseen by the IBC)
- That the Organisation will be in Compliance with the “Act”

All Accredited Organisations will be independently monitored by visits from the Compliance Unit of the Regulator to ensure that they are operating in accordance with the conditions of the accreditation. Independent monitoring will include both announced and unannounced inspections of PC2 Laboratories by members of the Monitoring and Compliance Unit of the Office of the Gene Technology Regulator.

Accredited Organisations Affiliated with Monash University

Monash University (**Accred 058/2002**)

Macfarlane Burnet Institute for Medical Research and Public Health (**Var 079/2002**)

Prince Henry's Institute of Medical Research (**Accred 081/2003**)

Baker Medical Research Institute (**Accred 077/2002**)

Alfred Hospital

The level of the responsibility of the Accredited Organisation has increased under the Gene Technology Act.

It is **the Organisation** that is ultimately responsible for ensuring compliance with the Regulator's conditions of accreditation. It is the role of the Biosafety Committee to assist the organisation with compliance. It is the role of the Principal Researcher that **all** conditions, attached to a Licence issued by the OGTR, are adhered to and **all** conditions attached to an instrument of Certification are strictly adhered to.

More information

Application Forms. (Exempt, NLRDs, Licences, Certification)

<http://www.ogtr.gov.au/pubform/forms.htm>

Gene Technology Act 2000

scaleplus.law.gov.au/html/pasteact/3/3428/top.htm

Gene Technology Regulations 2001

scaleplus.law.gov.au/html/pastereg/3/1664/top.htm

Office of Gene Technology Regulator

Contact:

www.ogtr.gov.au

Free Call:

1800 181 030

email:

ogtr@health.gov.au

Monash University Biosafety Committee IBC #309

Contact: Mrs Solveiga Hall
Secretary, Biosafety Committee
Monash University

Telephone: 9905 4036

Email: solveiga.hall@adm.monash.edu.au

Research Grants and Ethics Branch, Clayton

Campus <http://www.monash.edu.au/resgrant/>

APPENDIX 1

(Part 1 of Schedule 1 of "The Regulations")

BOX 1 - ORGANISMS THAT ARE NOT GMOs

Item 1

A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species).

Example:

A new variety of wheat that has been produced by bombarding cells with ionising radiation or exposing them to chemical mutagens that cause mutations in the DNA of the cells. By chance, some of the mutations might lead to desirable changes in the characteristics of the wheat plants.

This technique has been used for many years to produce new varieties of plants.

Item 2

A recombinant organism formed through integration into chromosomal or extrachromosomal DNA sequences of a genetic element that:

- (a) occurs naturally in the species concerned; and
- (b) moves sporadically between genome sites.

Example:

Some species contain naturally occurring pieces of DNA that can spontaneously move around within the DNA of that organism. When these pieces of DNA move around they may cause changes in the characteristics of that organism, but the modified organism that results is not considered a GMO because the process is one that occurs in nature.

Item 3

An organism that:

- (a) results from the fusion of 2 animal cells; and
- (b) is unable to form a viable whole animal.

Example:

Hybridomas created to produce monoclonal antibodies. These are cultured cells, growing in a petri dish, that have resulted from fusing an antibody-producing cell with a cancer cell. The cell culture is used in the laboratory to produce a particular antibody that can be used in research.

Item 4

An organism that results from protoplast fusion involving only non-pathogenic bacteria or non-pathogenic yeast.

Example:

An organism that results when cells from two strains of yeast (that are known not to cause disease) are fused together after their cell walls have been removed.

Item 5

A plant formed by:

- (a) embryo rescue; or
- (b) *in vitro* fertilisation; or
- (c) zygote implantation; or
- (d) protoplast fusion.

Example:

A new variety of plant formed by one of the methods listed. These methods are standard techniques that have been used for many years by plant breeders to produce new varieties with desirable characteristics.

Item 6

An organism that results from exchange of DNA if:

- (a) the donor species is also the host species; and
- (b) the vector DNA does not contain any heterologous DNA.

Example:

For example, the transfer of naturally occurring plasmids within a single species where the plasmid does not contain any DNA from other species.

Item 7

An organism that results from an exchange of DNA between the donor species and the host species if:

- (a) such exchange can occur by naturally occurring processes; and
- (b) the donor species and the host species are both mentioned in the same group in Part 2 of this Schedule; and
- (c) the vector used in the exchange does not contain heterologous DNA from any organism other than an organism that is involved in the exchange.

Example:

Certain species naturally exchange DNA. Part 2 of Schedule 1 of the Regulations (as replicated in Box 2) describes such species. If the work involves exchange of DNA between such species (where such exchange can occur naturally) the resulting organism is not a GMO

(Part 2 Schedule 1 of "The Regulations")

BOX 2 - SPECIES KNOWN TO EXCHANGE DNA BY A KNOWN PHYSIOLOGICAL PROCESS

Group 1

Alcaligenes
Campylobacter coli
Campylobacter fetus
Campylobacter jejuni
Citrobacter (including levinea)
Enterobacter
Erwinia
Escherichia
Klebsiella
Pseudomonas aeruginosa
Pseudomonas fluorescens
Pseudomonas mendocina
Pseudomonas putida
Rhizobium
Salmonella (including arizona)
Serratia marcescens
Shigella
Yersinia enterocolitica

Group 2

Bacillus amyloliquefaciens
Bacillus atterimus
Bacillus globigii
Bacillus licheniformis
Bacillus nato
Bacillus niger
Bacillus pumilus
Bacillus subtilis

Group 3

Streptomyces aureofaciens
Streptomyces coelicor
Streptomyces rimosus

Group 4

Streptomyces cyaneus
Streptomyces griseus
Streptomyces venezuela

Group 5

Streptococcus mutans DNA and Streptococcus lactis DNA - in a one-way transfer into
Streptococcus sanguis

Group 6

Streptococcus faecalis
Streptococcus mutans
Streptococcus pneumoniae
Streptococcus pyogenes
Streptococcus sanguis

Group 7

Bacillus cereus
Bacillus thuringiensis

(Part 1 Schedule 2 of “The Regulations”)

BOX 3 – DEALINGS EXEMPT FROM LICENSING

Item 1

Any dealing with gene-knockout mice (that is, mice whose genetic modification involves deletion or inactivation of a specific gene), if no advantage is conferred on the adult animal:

- (a) by the deletion or inactivation of the gene concerned; or
- (b) for mice that also carry a selectable marker gene – by the selectable marker gene.

Examples:

Gene knock-out mice are mice that have genes removed from the genome (or ‘knocked out’ of their DNA) so that the effects of the loss of the gene may be studied.

Guidance Notes:

- An important limitation on this exemption is that in order to be exempt, the removal of genes from the mouse must not be able to give rise to an advantage in the modified adult mouse over wild type unmodified mice. If it is likely that an advantage would be conferred on the mouse as a result of the deletion of the gene, then the work is not exempt.

Item 2

Any dealing with a whole animal, if:

- (a) naked recombinant nucleic acid has been introduced into its somatic cells; and
- (b) the introduced nucleic acid is incapable of giving rise to infectious agents.

Examples;

The introduction of naked recombinant nucleic acid into an animal’s somatic cells does not involve manipulation of the animal’s genome. The significance of this is that because the genome has not been manipulated and the introduction is only through somatic cells, then the modified material will not be present in the genome of subsequent generations.

An example of this technique is using DNA as vaccines to vaccinate animals against disease.

This is a technique that has the potential to be safer than current non-GMO vaccines which use live, weakened strains of an organism (eg the polio vaccine).

Guidance notes:

In order to satisfy as exempt under this item, 4 important criteria must be met:

- the work must involve whole animals;
- the whole animal must be a GMO only because naked recombinant nucleic acid has been introduced into the animal’s somatic cells. If any other type of modification has been made to the animal (and such modification is not also exempt) then the work is not exempt;
- the introduced nucleic acid must be incapable of giving rise to infectious agents; and
- the work must not involve intentional release of the GM animal into the environment.

Item 3

Any dealing with an animal into which genetically modified somatic cells have been introduced, unless the cells:

- (a) are capable of giving rise to recombinant infectious agents; or

(b) contain viral sequences that could recombine with, or be complemented by, genomes of introduced superinfecting viruses.

Guidance Notes:

This exemption only applies if:

- the modification does not involve any changes to the germ cells of the animal and hence any changes are not capable of being passed on to the next generation;
- the somatic cells that have been introduced are incapable of giving rise to infectious agents and do not contain viral sequences that could recombine with, or be complemented by, genomes of introduced superinfecting viruses;
- the dealings with the GMO do not involve the intentional release of a GMO into the environment.

Gene therapy of an animal where the genetically modified somatic cells contain whole viral genomes is therefore not exempt.

Item 4

Any dealing involving a host/vector system mentioned in Part 2 of this Schedule and producing no more than 10 litres of GMO culture, if:

(a) the donor DNA:

(i) is not derived from micro-organisms capable of causing disease in human beings, other animals, plants or fungi, or is fully characterised and will not increase the virulence or host range of the host or vector; and

(ii) is not an oncogene; and

(iii) does not code for a toxin for vertebrates with an LD50 of less than 100µg/kg; and

(iv) does not code for a toxin for vertebrates with an LD50 of 100µg/kg or more, if the intention is to express the toxin at high levels; and

(v) is not uncharacterised DNA from a micro-organism that produces toxins with an LD50 of 100 µg/kg or less; or

(b) the donor DNA includes a viral sequence or viral sequences, but:

(i) is missing at least 1 gene essential for viral multiplication that is not available in the cell into which the DNA is introduced and that will not become available through subsequent breeding; and

(ii) is incapable of complementing a defect in the host/vector system.

Guidance Notes:

This exemption only applies if:

- the dealing does not involve the production of more than 10 litres of GMO culture (if the production of more than 10 litres of culture is envisaged then such work must be licensed by the Regulator); and
- the dealing involves a host/vector system mentioned in Part 2 of Schedule 2 AND the conditions relating to the donor DNA (as detailed above are met). For example the donor DNA must not be an oncogene, must not code for dangerous toxins etc. If the donor DNA is any of these things then the work will not be exempt; and
- the dealing does not involve any other type of genetic modification.

Item 5

Any dealing involving shot-gun cloning of mammalian DNA in a host/vector system mentioned in Part 2 of Schedule 2.

Examples:

The formation of libraries of mammalian DNA fragments cloned into approved host/vector systems as has occurred extensively in major genome sequencing projects such as the Human Genome.

Guidance Notes:

This exemption only applies if the dealing involves shot-gun cloning of mammalian DNA in a host/vector system mentioned in Part 2 of Schedule 2.

IMPORTANT NOTE

Please note that the Regulator will be issuing further Guidelines for work with toxins, work with hazardous fragments of DNA and work involving GM viruses for gene transfer into animal and human cells. These will be available as an Appendix to the *Handbook on the Regulation of Gene Technology in Australia* and also from the OGTR and the OGTR website.

(Part 2 of Schedule 2 of "The Regulations")

BOX 4: HOST/VECTOR SYSTEMS FOR EXEMPT DEALINGS

Item	Class	Host	Vector
1	Bacteria	<i>Escherichia coli</i> K12 or <i>E. coli</i> B-any derivative that does not contain: (a) conjugative or generalized transducing phages; or (b) genes able to complement the conjugation defect in a nonconjugative plasmid	1. Non-conjugative plasmids 2. Bacteriophage (a) lambda (b) lambdoid (c) Fd or F1 (eg M13)
2		<i>Bacillus subtilis</i> or <i>B. licheniformis</i> -an asporogenic strain with a reversion frequency of less than 10 ⁻⁷	Plasmids and phages whose host range does not include <i>B. cereus</i> , <i>B. anthracis</i> or any other pathogenic strain of bacillus
3		<i>Pseudomonas putida</i> -strain KT 2440	Certified plasmids: pKT 262, pKT 263, pKT 264
4		<i>Streptomyces</i> -specified species: (a) <i>S. coelicolor</i> (b) <i>S. lividans</i> (c) <i>S. parvulus</i> (d) <i>S. griseus</i>	1. Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives 2. Actinophage phi C31 and derivatives
	Fungi	<i>Neurospora crassa</i> -laboratory strains <i>Pichia pastoris</i> <i>Saccharomyces cerevisiae</i> <i>Schizosaccharomyces pombe</i> <i>Kluyveromyces lactis</i> <i>Trichoderma reesei</i>	All vectors All vectors All vectors All vectors All vectors All vectors
	Slime moulds	<i>Dictyostelium</i> species	<i>Dictyostelium</i> shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2
	Tissue culture	Mammalian (including human) cells and cells of aquatic organisms Avian cells Plant cell cultures Insect cell cultures, such as <i>Spodoptera frugiperda</i> , if the recombinants are also inclusionnegative (eg polyhedrin minus)	Non-viral vectors or defective viral vectors (including retrovirus or retroviral-helper combinations that cannot infect human cells) Avipoxvirus vectors (attenuated vaccine strains) Non-tumorigenic disarmed Ti plasmid vectors in <i>Agrobacterium tumefaciens</i> or non-pathogenic viral vectors Baculovirus (<i>Autographa californica</i> nuclear polyhedrosis virus), polyhedrin minus
5		Any host mentioned, or of a kind mentioned, in any of items 1 to 4	Any non-biological vector (for example, electrocorporation or particle bombardment)

BOX 5: Notifiable low risk dealings with GMOs

The following kinds of dealings are notifiable low risk dealings:

Item a

- (a) any dealing involving whole animals (including non-vertebrates) that:
- (i) involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism; and
 - (ii) does not involve gene-knockout mice.

Guidance Notes:

Dealings with GMOs only fall within this category of NLRDs if:

- the dealings involve whole animals that are GMOs because of modification of the genome of the oocyte or zygote or early embryo;
- they do not also fall within Part 2 of Schedule 3 (as set out in Box 6). For example, the dealings with the GMO will not be NLRDs if the dealings involve a viral vector to produce a transgenic animal that secretes or produces recombinant viral agents.

Gene-knock out mice do not fall within this category of NLRD because they will either:

- be exempt (if no advantage is conferred on the adult animal); or
- require licensing by the Regulator if an advantage is conferred on the adult animal.

Item b

- (b) any dealing involving a genetically modified flowering plant, if:
- (i) the dealing does not involve the plant being grown to flowering stage; or
 - (ii) for a dealing that does involve the plant being grown to flowering stage:
 - (A) the plant is male sterile and is unable to set seed; or
 - (B) if the plant is male sterile and can set seed – all vents and drains in the facility are screened with mesh or filters that block the escape of viable pollen and seed; or
 - (C) before flowering, all inflorescences are wholly enclosed in bags designed to prevent escape of viable pollen and seed; or
 - (D) if the plant can be wind-pollinated – all vents and drains in the facility are screened with mesh or filters that block the escape of viable pollen and seed; or
 - (E) if the plant can be vector-pollinated only – all vents and drains in the facility are screened with mesh or filters that block the escape of viable seed and exclude pollen vectors from the facility.

Examples:

As an example, if work involves canola being grown to flowering stage, then provided the plant is not male sterile and can set seed and can be vector pollinated only, the work will only be a NLRD if either inflorescences are bagged as per condition (C) or all vents and drains are screened to prevent seed escaping and exclude pollen vectors as per condition (E).

If *Arabidopsis thaliana* is being grown, while it is predominantly self-pollinating, there is a finite possibility of it being wind pollinated therefore either conditions (C) or (D) must be met to prevent pollen and seed escaping. Plants that are non-flowering including gymnosperms (such as conifers), ferns, fungi, mosses and lichens are not NLRDs and a licence must be held in order to undertake the work.

Guidance notes:

Dealings with GMOs only fall within this category of NLRDs if:

- the dealings involve a GM flowering plant; and
 - the dealings do not involve the plant being grown to flowering stage OR if the plant is grown to flowering stage, the appropriate precaution for the particular type of flowering plant is adopted (as detailed at A-D). It is important that observance of the appropriate requirement detailed at A-D is in addition to the general requirements that the work be conducted in a PC2 facility; and
 - the dealings do not also fall within Part 2 of Schedule 3 (as set out in Box 6). For example, the dealings with the GMO will not be NLRDs if the dealings involve:
 - cloning or transfer of fragments of a viral or viroid genome that is capable, in the host vector system to be used, of giving rise to infectious agents that are capable of infecting cells of human, animal, plant or fungal origin;
 - recombination between whole viral genomes, viroids, or complementing fragments of such genomes (if one or more fragments contain virulence or pathogenic determinants).
 - the use of a viral vector (except a vector that is used in the dealing as part of a host/vector system mentioned in Part 2 of Schedule 2) containing one or more inserted sequences, that codes for a product known to play a role in the regulation of cellular growth or to be toxic to mammalian cells; or
 - the production of dangerous toxins, for example, if it produces toxins of low toxicity in large quantities or if the gene encodes a highly toxic toxin; and
 - the dealings do not involve an intentional release of a GMO into the environment. That is, this category of NLRD does not apply to field trials of GM plants.
- Please note that there is an error in (b)(ii)(A). A plant that is male sterile cannot produce viable pollen

Item c

(c) any dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 2, if:

- (i) the host is incapable of causing disease in human beings, animals, plants or fungi; and
- (ii) the vector is incapable of causing disease in human beings, animals, plants or fungi.

Guidance notes:

Dealings with GMOs only fall within this category of NLRDs if:

- the dealings involve a host and vector that are not mentioned in Part 2 of Schedule 1 (refer Box 4); and
- both the host and the vector are incapable of causing disease in human beings, animals, plants or fungi; and
- the dealings do not also fall within Part 2 of Schedule 3 (as set out in Box 6). For example, the dealings with the GMO will not be NLRDs if the dealings involve:
 - the use of a viral vector (except a vector that is used in the dealing as part of a host/vector system mentioned in Part 2 of Schedule 2) containing one or more inserted sequences, that codes for a product known to play a role in the regulation of cellular growth or to be toxic to mammalian cells; or
 - the production of dangerous toxins, for example, if it produces toxins of low toxicity in large quantities or if the gene encodes a highly toxic toxin; and
- the dealings do not involve the intentional release of the GMO into the environment.

Item d

(d) any dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 2, if, although the host or vector is capable of causing disease in human beings, animals, plants or fungi, the donor DNA is fully characterised and will not increase the virulence of the host or vector.

Guidance notes:

Dealings with GMOs only fall within this category of NLRDs if:

- the dealings involve a host and vector that are not mentioned in Part 2 of Schedule 2 (refer Box 4); and
- the donor DNA is fully characterised; and
- the donor DNA will not increase the virulence of the host or vector; and
- the dealings do not also fall within Part 2 of Schedule 3 (as set out in Box 6). For example, the dealings with the GMO will not be NLRDs if the dealings involve:
 - the introduction into a microorganism of genes that determine pathogenicity; or
 - cloning or transfer of fragments of a viral or viroid genome that is capable, in the host/vector system to be used, of giving rise to infectious agents that are capable of infecting cells of human, animal, plant or fungal origin; or
 - recombination between whole viral genomes, viroids, or complementing fragments of such genomes (if one or more fragments contain virulence or pathogenic determinants).
- the use of a viral vector (except a vector that is used in the dealing as part of a host/vector system mentioned in Part 2 of Schedule 2) containing one or more inserted sequences, that codes for a product known to play a role in the regulation of cellular growth or to be toxic to mammalian cells; or
- the production of dangerous toxins, for example if it produces toxins of low toxicity in large quantities or if the gene encodes a highly toxic toxin; and
- the dealings do not involve an intentional release of a GMO into the environment

Item e

(e) any dealing involving a host/vector system mentioned in Part 2 Schedule 2, if the gene inserted:

- (i) is a pathogenic determinant; or
- (ii) is uncharacterised DNA from a micro-organism that is capable of causing disease in human beings, animals, plants or fungi; or
- (iii) is an oncogene

Guidance notes:

Dealings with GMOs only fall within this category of NLRDs if:

- the dealings involve a host/vector system mentioned in Part 2 of Schedule 2 (refer Box 4); and
- the gene inserted is a pathogenic determinant, is uncharacterised DNA from a microorganism that is capable of causing disease in human beings, animals, plants or fungi or is an oncogene; and
- the dealings do not also fall within Part 2 of Schedule 3 (as set out in Box 6). For example, the dealings with the GMO will not be NLRDs if the dealings involve:
 - cloning or transfer of fragments of a viral or viroid genome that is capable, in the host/vector system to be used, of giving rise to infectious agents that are capable of infecting cells of human, animal, plant or fungal origin; or
 - recombination between whole viral genomes, viroids, or complementing fragments of such genomes (if one or more fragments contain virulence or pathogenic determinants); or
 - the use of a viral vector (except a vector that is used in the dealing as part of a host/vector system mentioned in Part 2 of Schedule 2) containing one or more inserted sequences, that codes for a product known to play a role in the regulation of cellular growth or to be toxic to mammalian cells; or
 - the production of dangerous toxins, for example if it produces toxins of low toxicity in large quantities or if the gene encodes a highly toxic toxin; or
 - the cloning of uncharacterised DNA from toxin producing microorganisms; and
- the dealing does not involve an intentional release of a GMO into the environment.



(Part 2 Schedule 3 of "The Regulations")

**BOX 6: DEALINGS (HIGHER RISK) THAT ARE NOT NOTIFIABLE
LOW RISK DEALINGS**

A dealing of any of the following kinds, or involving a dealing of the following kinds, is not a notifiable low risk dealing:

- (a) a dealing involving cloning of DNA encoding a toxin for vertebrates having an LD50 of less than 100 µg/kg;
- (b) a dealing involving high level expression of toxin genes, even if the LD50 is greater than 100 µg/kg;
- (c) a dealing involving cloning of uncharacterized DNA from toxin-producing microorganisms;
- (d) a dealing involving a viral vector (except a vector that is used in the dealing as part of a host/vector system mentioned in Part 2 of Schedule 2), containing one or more inserted sequences, that codes for a product known to play a role in the regulation of cellular growth or to be toxic to mammalian cells;
- (e) a dealing involving, as host or vector, a micro-organism that is capable of causing disease in humans, animals, plants or fungi, unless:
 - (i) the host/vector system is a system mentioned in Part 2 of Schedule 2; or
 - (ii) the dealing involves only the cloning of DNA that is fully characterised and is known not to increase the virulence of the host and vector;
- (f) a dealing involving the introduction into a micro-organism, other than a host mentioned in Part 2 of Schedule 2, of genes that determine pathogenicity;
- (g) a dealing involving the introduction into a micro-organism, other than a host mentioned in Part 2 of Schedule 2, of genes whose expressed products have a heightened risk of inducing an autoimmune response;
- (h) a dealing involving cloning or transfer of fragments of a viral or viroid genome that are capable, in the host/vector system to be used, of giving rise to infectious agents that are capable of infecting cells of human, animal, plant or fungal origin;
- (i) a dealing involving recombination between whole viral genomes, viroids or complementing fragments of such genomes (if one or more fragments contain virulence or pathogenic determinants);
- (j) a dealing involving use of a viral vector to produce a transgenic animal, plant or fungus that secretes or produces infectious recombinant viral agents;
- (k) a dealing involving the production of more than 10 litres of GMO culture;
- (l) a dealing that is inconsistent with a policy principle issued by the Ministerial Council.

APPENDIX 2

CERTIFIED PC2 LABORATORY

Work Practices

- 19^{*} All requirements for a PC2 Laboratory Facility specified in the Certification Instrument issued by the Regulator must be complied with at all times, even if the work being performed in the facility involves organisms that are not GMOs.
- 20 Access to the facility must be restricted to authorised persons and/or authorised classes of persons.
- 21^{*} Windows must remain closed while laboratory procedures are in progress unless they are fitted with intact flyscreens.
- 22 All facility personnel must be trained in the requirements of the OGTR PC2 Laboratory Facility guidelines. Only trained personnel are to clean contaminated equipment and surfaces, or handle hazardous waste.
- 23^{*} Facility personnel must indicate to the certification holder that they fully understand their training in the OGTR requirements by signing a record of their training after completion. A record of those trained must be kept and made available if requested.
- 24 Any procedures that generate aerosols containing GMOs must be performed in a biological safety cabinet or other equipment designed to contain aerosols specifically approved in writing by the Regulator.
- 25 Any unintentional release of GMOs from the facility must be reported to the Regulator as soon as practicable.
- 26 Work benches, surfaces and equipment where laboratory procedures have taken place must be decontaminated immediately after any spills and when laboratory procedures using GMOs are completed.
- 27 All work surfaces and equipment, in relevant areas of the facility, must be decontaminated before maintenance is carried out.
- 28 GMOs, organisms infected with GMOs, equipment or protective clothing contaminated with GMOs, and liquid and solid wastes containing GMOs, must be decontaminated by pressure steam sterilisation (autoclaving), chemical treatment, incineration or any other method approved in writing by the Regulator. Chemical disinfectant treatment must be in accordance with Appendix E of AS/NZS 2243.3:2002. Incineration must be in a high temperature, high efficiency, EPA-approved incineration facility.
- 29 Where a pressure steam steriliser (autoclave) is used for decontamination:

- (a) Provision must be made to allow for the penetration of steam into the container during autoclaving.
 - (b) The coldest part of the load must be exposed to a minimum temperature of 121 ° C for at least 15 minutes.
 - (c) Measures must be taken to ensure that loads that have been processed can be differentiated from loads that have not (e.g. by use of autoclave tape).
 - (d) The temperature of each cycle must be monitored by use of one of the following means: a thermocouple and recorder; a maximum thermometer; a chemical indicator (e.g. thermalog strips, Brownes tubes); spore strips; or readings from the autoclave panel.
 - (e) The effectiveness of decontamination by the pressure steam steriliser (autoclave) used by the facility must be tested monthly with biological indicators. A notice must be posted on, or adjacent to, the autoclave indicating the result and the date of the latest test.
- 30 * All GMOs, and waste resulting from a GMO dealing, being transported out of the facility must be transported in accordance with the "Guidelines for the Transport of GMOs".
- 31 * Animals and plants not used in the work being performed in the facility must be regarded as waste on removal from the facility and decontaminated by pressure steam sterilisation (autoclaving), incineration or any other method approved in writing by the Regulator.
- 32 * GMOs or organisms infected with GMOs may be stored outside the facility in a storage unit (freezer, fridge, controlled temperature room or other controlled temperature container). The storage unit must be locked when not in use, unless access is restricted to the room or area where the storage unit is located, and have a biohazard symbol posted on it.
- 33 * GMOs or organisms infected with GMOs being stored outside the facility must be double-contained. The primary container must be sealed and unbreakable. The primary container must be stored in an unbreakable secondary container and clearly labelled. In the case of a small storage unit such as a fridge, freezer or liquid nitrogen container, the secondary container may be the storage unit.
- 34 * Transport of material between the facility and the storage unit must be in accordance with the "Guidelines for the Transport of GMOs". Gloves must be worn while transferring primary containers between the storage unit and the secondary container used for transport. Any spills that occur during storage outside the facility or when transferring to the storage unit, must be reported to the Regulator as soon as practicable. The spilt material and the area must be decontaminated.
- 35 All cultures must be clearly identified.

- 36 All cultures of fungi and other spore-dispersing organisms must be sealed during storage.
- 37 Eating, drinking, smoking, shaving and applying cosmetics are prohibited in the facility. Food or drink intended for human consumption must not be brought into or stored in the facility.
- 38 Long hair must be tied back or covered with a hair net to avoid contamination.
- 39 Mouth pipetting is prohibited in the facility.
- 40 Only reading/writing material and computers essential to procedures performed within the facility are permitted on work benches where procedures are performed. Reading and writing material must not be used inside a biological safety cabinet. Where possible dedicated reading/writing areas should be provided and used.
- 41 Persons who have been performing procedures in the facility must wash or decontaminate their hands immediately before leaving the facility or before using any dedicated facility reading/writing areas.
- 42^{*} The facility and equipment in the facility must be maintained so that the facility meets the containment requirements of these Guidelines.
- 43 Strategies must be in place to ensure that the facility is free of pests. A record of the program and dates of specific activities must be kept and made available if requested

CERTIFIED PC2 ANIMAL FACILITY

Work practices

- 21 * All requirements for a PC2 Animal Containment Facility specified in the Certification Instrument issued by the Regulator must be complied with at all times, even if the work being performed in the facility involves organisms that are not GMOs.
- 22 Access to the facility must be restricted to authorised persons and/or authorised classes of persons.
- 23 Facility doors must be closed while work is being undertaken in the facility and must remain locked when the animals are not under supervision.
- 24 Windows must be closed and locked while GM animals or animals containing GMOs are in the facility.
- 25 All facility personnel must be trained in the requirements of the OGTR PC2 Animal Containment Facility guidelines. Only trained personnel are to clean contaminated equipment and surfaces, or handle hazardous waste.
- 26 * Facility personnel must indicate to the certification holder that they fully understand their training in the OGTR requirements by signing a record of their training after completion. A record of those trained must be kept and made available if requested.
- 27 Any procedures that generate aerosols containing GMOs must be performed in a biological safety cabinet or other equipment designed to contain aerosols specifically approved in writing by the Regulator. Bedding material and waste from infected animal cages or pens must be handled in a manner that minimises the creation of aerosols.
- 28 * Any unintentional release of GMOs from the facility must be reported to the Regulator as soon as practicable.
- 29 Work benches, surfaces and equipment where procedures have taken place must be decontaminated immediately after any spills containing viable GMOs and when procedures using GMOs are completed.
- 30 All work surfaces and equipment, in relevant areas of the facility, must be decontaminated before maintenance is carried out.
- 31 Equipment or protective clothing, pens, cages, bedding or wastes contaminated with GM microorganisms must be decontaminated by pressure steam sterilisation (autoclaving), chemical treatment, incineration or any other method approved in writing by the Regulator. Chemical disinfectant treatment must be in accord with Appendix E of AS/NZS 2243.3:2002. Incineration must be in a high temperature, high efficiency, EPA-approved incineration facility.
- 32 Carcasses of animals infected with GM microorganisms or GM animals infected with infectious agents must be decontaminated by pressure steam sterilisation

(autoclaving), incineration or any other method approved in writing by the Regulator.

- 33 Where a pressure steam steriliser (autoclave) is used for decontamination:
- (a) Provision must be made to allow for the penetration of steam into the container during autoclaving.
 - (b) The coldest part of the load must be exposed to a minimum temperature of 121 C for at least 15 minutes.
 - (c) Measures must be taken to ensure that loads that have been processed can be differentiated from loads that have not (e.g. autoclave tape).
 - (d) The temperature of each cycle must be monitored by use of one of the following means: a thermocouple and recorder; a maximum thermometer; a chemical indicator (e.g. thermalog strips, Brownes tubes); spore strips; or readings from the autoclave panel.
 - (e) The effectiveness of decontamination by the pressure steam steriliser (autoclave) used by the facility must be tested monthly with biological indicators. A notice must be posted on, or adjacent to, the autoclave indicating the result and the date of the latest test.
- 34 * All GMOs, and waste resulting from a GMO dealing, being transported out of the facility must be transported in accordance with the "Guidelines for the Transport of GMOs".
- 35 * Animals and plants not used in the work being performed in the facility, that are potentially infected with infectious agents, must be regarded as waste on removal from the facility and decontaminated by pressure steam sterilisation (autoclaving), incineration, or any other method approved in writing by the Regulator.
- 36 Viable animals must not be removed from the facility unless they are to be transported to a containment facility certified by the Regulator to equivalent or higher containment level. Animals must be transported in accordance with the "Guidelines for the Transport of GMOs".
- 37 * All animal cages or containers must be labelled to enable identification of the animals being contained and to indicate the number of animals in the containers.
- 38 Large animals must be clearly marked so they can be readily identified (e.g. with a tattoo, permanent tag, microchip or permanent brand).
- 39 Eating, drinking, smoking, shaving and applying cosmetics are prohibited in the facility. Food or drink intended for human consumption must not be brought into or stored in the facility.
- 40 * Long hair must be tied back or covered with a hair net, to avoid contamination, when the work of the facility involves animals inoculated with infectious agents.

- 41 * Cuts and abrasions on the skin of facility personnel must be covered while working in the facility.
- 42 Only reading/writing material and computers essential to procedures performed within the facility are permitted on work benches where procedures are performed. Reading and writing material must not be used inside a biological safety cabinet. Where possible, dedicated reading/writing areas should be provided and used.
- 43 Persons who have been performing procedures in the facility must wash or decontaminate their hands immediately before leaving the facility or before using any dedicated facility reading/writing areas.
- 44 * The facility and equipment in the facility must be maintained so that the facility meets the containment requirements of these Guidelines.
- 45 Strategies must be in place to ensure that the facility is free of pests. A record of the program and dates of specific activities must be kept and made available if requested.

Appendix 3:

EXEMPT DEALING ANNUAL REPORT MONASH UNIVERSITY IBC (309)

Dealing Title:.....

.....

IBC No.....

Principal Researcher/s:.....

Department/Institution:.....

	YES	NO
Is the Dealing ongoing?	<input type="checkbox"/>	<input type="checkbox"/>

If No, Date Completed:.....

Have there been changes in procedures?	<input type="checkbox"/>	<input type="checkbox"/>
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	<input type="checkbox"/>	<input type="checkbox"/>
Do these change the classification of the Dealing		

Which Classification (please circle)	NLRD	DNIR
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List changes:.....

.....

Have there been changes in facilities used?	<input type="checkbox"/>	<input type="checkbox"/>
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List changes:.....

Signature:..... Date:.....

Appendix 4: DECISION TREE FOR “APPROVALS” FOR DEALINGS WITH GMOs

