The Legislative Assembly for the Australian Capital Territory

Explanatory Statement

Gene Technology Regulations 2004

Distributed by Authority of the Minister for Health
Simon Corbell MLA

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Acronyms used in this Explanatory Statement

AFFA	Agriculture Fisheries and Forestry Australia
ANZFA	Australia New Zealand Food Authority
AQIS	Australian Quarantine and Inspection Service
CSCG	Commonwealth State Consultative Group on Gene Technology
GMAC	Genetic Manipulation Advisory Committee
GMO	genetically modified organism
GM	genetically modified
GTR	Gene Technology Regulator [1](also referred to as "the Regulator")
GTTAC	Gene Technology Technical Advisory Committee
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
IGA	Intergovernmental Agreement on Gene Technology
IOGTR	Interim Office of the Gene Technology Regulator
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NRA	National Registration Authority for Agricultural and Veterinary Chemicals
OGTR	Office of the Gene Technology Regulator
RIS	Regulation Impact Statement
TGA	Therapeutic Goods Administration

[1] The full term is used in several places to distinguish the GTR from existing regulators

Explanatory Statement for the Gene Technology Regulations (ACT) 2004

Overview

The Regulations are a component of the national framework for the regulation of gene technology.

The *Gene Technology Regulations (ACT) 2004* will be an important component of the proposed national legislative scheme. The regulations will underpin the *Gene Technology Act (ACT) 2003* and will describe certain aspects of the operation of the legislation in detail. In particular, the regulations will contain many of the administrative details of the legislation and will determine the way the legislation will operate on a day-to-day basis.

The purpose of this Explanatory Statement is to:

- explain the overall intention of the regulations; and
- explain the effect of each of the regulations

The *Gene Technology Regulations 2004* mirror the Commonwealth *Gene Technology Regulations 2001*. A Regulatory Impact Statement was prepared by the Commonwealth as part of the development of the Commonwealth regulations. Consequently, in accordance with Section 36 (1) g of the *Legislation Act 2001* a separate RIS for the ACT regulations is not required.

Notes on Parts

Part 1 – Preliminary

This Part sets out the formal provisions of the regulations, including the name of the regulations, their commencement date, and also reference to the dictionary, where the definitions used in the regulations are located

1. Name of Regulations
Regulation 1 provides that the Regulations may be cited as the Gene Technology Regulations 2004

2. Commencement
This is a formal provision that states when the regulations will become operative.

3. Dictionary
This provision states the dictionary at the end of the regulations operates as a component of the regulations. The dictionary defines the words and phrases used in the regulations.

Note 1 provides direction to the dictionary at the end of the regulations for the definitions used in the regulations.

The dictionary in the regulations uses the same definitions as those provided in the Gene Technology Act (ACT) 2003. For example, terms such as “accredited organisation”, “notifiable low risk dealing” and “intentional release of a GMO into the environment” are used in both the Act and the regulations. This provision ensures that they have the same meaning, when used in either document.

The Schedules to these draft regulations (for example, the Schedules setting out the exempt dealings and notifiable low risk dealings) reference a number of scientific words or terms that may not be familiar to those who do not work in the area of biotechnology. For ease of reference, definitions of such terms have been included in the Schedules where they occur, rather than in this section of the regulations.

Note 2 provides that a definition provided in the dictionary applies to the entire regulations, unless a different intention is expressly stated.

3A. Numbering
This provisions’ purpose is to explain how formal consistency between the Commonwealth and ACT Regulations, is achieved.

The provision number and heading of a Commonwealth regulation not required in the ACT regulations will be cited in and form part of the ACT regulations. The body of the regulation will be omitted.

Numbering where the ACT regulations include a regulation not found in the Commonwealth regulations will be structured so as to retain formal consistency between the two instruments.

This provision permits referencing the Commonwealth regulations numbering, when referring to a provision other than a regulation in the ACT regulations, where the two instruments numbering differs. This provision is not reciprocated in the Commonwealth regulations.

3B. Notes
Notes found in the regulations do not form part of the instrument, but are merely explanatory.

3C. Offences against regulations- application of Criminal Code etc.
This provision lists the other legislation that applies where there is an offence made against the regulations. Legislation includes;

- Ch 2 of the Criminal Code (ACT) 2002, which defines relevant terms contained in the Code and explains relevant principles of criminal responsibility.

- The Legislation Act (ACT) 2001, which explains penalty units (numerical) as offence penalties (substantive meaning)

3A, 3B and 3C do not have equivalent provisions in the Commonwealth regulations.

Part 2 – Interpretation and general operation

A number of the central definitions in the Gene Technology Act (ACT) 2003, rely on further information being provided in the regulations. This provides for maximum flexibility, and will enable the legislation to respond to changes in the technology without the need to continually amend the primary legislation.

4. Techniques not constituting gene technology

This regulation states that somatic cell nuclear transfer (cloning) is not a technique that constitutes gene technology for the purposes of the legislation. This is because cloning does not involve the modification of genes or other genetic material, it simply involves the replication or duplication of genetic material.

As such, where cloning is used in work with plants or animals, it is not regulated under the legislation.

5. Organisms that are not genetically modified organisms

Regulation 5, supported by Schedule 1, excludes a number of organisms from the definition of 'genetically modified organism'.

The definition of 'genetically modified organism' in the GT Act was intentionally cast very broadly to ensure that the definition did not become outdated and ineffectual in response to rapidly changing technology.

As the definition is particularly broad it potentially encompasses things that were never intended to be regulated under this regulatory scheme. For example, organisms that naturally exchange genetic material.

The purpose of this Regulation is to remove from the scheme those types of organisms that are not intended to be regulated under the scheme. In summary, the organisms excluded from the scheme are organisms that:

- have been exempt or excluded from the voluntary Genetic Manipulation Advisory Committee (GMAC) system of controls on GMOs for many years (some since the late 1970s); and/or

- exchange genetic material in nature, and as such do not pose any unique biosafety risks to the environment or human health and safety; and/or

- are commonly used in biological research; and/or

- have a very long history of usage in Australia and overseas.

Following is a list of the organisms that are not considered to be GMOs for the purpose of this regulatory scheme (as detailed in Schedule 1), including some examples of such organisms and the rationale for prescribing them as not being GMOs for the purposes of the legislation.

- 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);

It is possible to effect changes to an organism by, for example, applying chemicals rather than by inserting or deleting a gene in the organism (gene technology). For example, wheat produced by treating cells of the wheat plant with a chemical that causes random mutations (heritable genetic changes) in the DNA of the cells. This technique has been used for many years to produce new varieties of plants. Organisms resulting from such technology are not considered to be GMOs for the purposes of the legislation because the process mimics natural mutation processes and the organisms have not had genes inserted or deleted by virtue of gene technology.

- a recombinant organism formed by integration into chromosomal or extrachromosomal DNA sequences of a genetic element that occurs naturally in the species concerned and moves sporadically between genome sites;

Certain species contain naturally occurring pieces of DNA that may spontaneously move within the DNA of that organism. When these pieces of DNA move, they may cause changes in the characteristics of that organism.

The modified organism that results is not considered a GMO because the process is one that occurs in nature.

- an organism that results from the fusion of 2 animal cells and is unable to form a viable whole animal;

For example, hybridomas created to produce monoclonal antibodies are cultured cells, growing in a petri dish, that have resulted from fusing an antibody-producing cell with another cell. The cell culture is used in the laboratory to produce a particular antibody that can be used in research. There is no possibility of the cells surviving outside the petri dish.

- an organism that results from protoplast fusion involving only non-pathogenic bacteria or non-pathogenic yeast;

For 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 These methods are standard techniques that have been used for many years by microbiologists to produce new bacteria or yeast that do not cause disease.

- a plant formed by embryo rescue, in vitro fertilisation, zygote implantation or protoplast fusion.

These methods are standard techniques that have been used for many years by plant breeders to produce new varieties of plants.

- an organism that results from an exchange of DNA if the donor species is also the host species and the vector DNA does not contain any heterologous DNA.

Certain organisms contain naturally occurring pieces of DNA that spontaneously move around within the DNA of that organism (without human intervention).For example, in nature, genetic exchange can occur between bacteria belonging to the same Salmonella species. Organisms that result from exchange of DNA within the same species (and where no genetic material from any other species is introduced) are not, therefore considered to be GMOs for the purposes of the regulatory scheme.

• 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 the 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.

Transfer of genes between different bacterial species occurs commonly in nature. Part 2 of Schedule 3 lists groups of species that are known to exchange genetic information under natural conditions. In order to be exempt, the exchange of DNA must only occur between members of any one group and the vector used must not contain DNA from species outside the same group.

TABLE A – EXAMPLES OF ORGANISMS THAT ARE NOT GMOS

Item	Regulation	Example
a	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)	A new variety of wheat that has been produced by bombarding cells of the wheat plant with a chemical that causes random mutations (heritable genetic changes) 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.
b	A recombinant organism formed by integration into chromosomal or extra chromosomal DNA sequences of a genetic element that: i. occurs naturally in the species concerned; and ii. moves sporadically between genome sites;	Some species contains 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.
c	An organism that: i. results from the fusion of 2 animal cells; and ii. is unable to form a viable whole animal;	One example, is 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, but there is no possibility that the cells would survive outside the petri dish.
d	An organism that results from protoplast fusion involving only non-pathogenic bacteria or non-pathogenic yeast;	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.
e	A plant formed by: i. embryo rescue; or ii. in vitro fertilisation; or iii. zygote implantation; or iv. protoplast fusion between sexually compatible species.	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

Part 3 – Dealings with GMOs

This Part provides further detail about the licensing process, notifiable low risk dealings and the process for obtaining accreditation and certification and provides additional detail about the system.

This Part sets out a range of matters, such as the timeframes for consideration of applications for licence, accreditation of organisations and certification of facilities. It also specifies which Commonwealth agencies the GTR must consult as part of the risk assessment process in relation to applications involving the intentional release of a GMO into the environment. It also clarifies the matters that the GTR must have regard to as part of the risk assessment process.

Division 3.1 – Licensing system

6. Dealings exempt from licensing

Regulation 6, supported by Schedule 2, describes those dealings with GMOs that are exempt from the regulatory scheme. Unlike Regulation 5, that describes organisms that are not GMOs for the purposes of the legislation, this Regulation describes dealings with organisms that are GMOs (that is, they are organisms that have been modified by techniques of gene technology), but that are exempt from the scheme on the basis of negligible biosafety risk.

The exempt dealings with GMOs detailed in Schedule 2 are dealings with GMOs that have been assessed over many years by the Genetic Manipulation Advisory Committee (GMAC) as presenting negligible biosafety risks to public health and safety, including occupational health and safety, or to the environment.

As an additional precaution, the Regulation also provides that exempt dealings with GMOs:

- must not involve an intentional release of the GMO into the environment; and

- must be conducted in accordance the requirements of Australian Standard AS/NZS; 2243.3.1995 (Safety in laboratories: microbiology) for Physical Containment Level 1.

In addition, accredited organisations undertaking exempt dealings with GMOs are required to seek advice from their Institutional Biosafety Committee (to ensure that the work has not been mis-classified as exempt) and to keep a record of the exempt dealings. These requirements will be imposed by the Regulator as a condition of the accreditation of the organisation.

Subregulation (2) clarifies that a dealing with a GMO that is exempt does not include performing additional genetic modifications. That is, someone may deal with an exempt GMO (for example, use it, possess it etc), but they may

not undertake any further genetic modifications on the GMO. If they wish to do so, they must apply for a licence from the Regulator.

The note included in the Regulations clarifies that dealings with GMOs that are exempt under the GT Act are not exempt from any other Commonwealth or State legislation that may also have application.

Part 1 of Schedule 2 describes 6 kinds of exempt dealings:

- dealings with certain gene knock-out mice (where no advantage is conferred on the adult animal);

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

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 possible that an advantage may be conferred on the mouse as a result of the deletion of the gene then the work is not exempt.

- dealings with animals where naked recombinant nucleic acid has been introduced into the animal's somatic cells provided the introduced nucleic acid is not capable of giving rise to infectious agents;

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 if the genome has not been manipulated then the modified material will not be present in the genome of subsequent generations.

An example of this technique is using strands of 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).

- dealings with animals into which genetically modified somatic cells have been introduced unless the cells are capable of giving rise to recombinant infectious agents or contain viral sequences that could recombine with, or be complemented by, genomes of superinfecting viruses;

The risks posed by dealings with animals into which genetically modified somatic cells are introduced are minimal because the modification does not involve any changes to the animals genome (and, as such, the modified material will not be present in the genomes of subsequent generations). Recognising that there may be risks if the cells introduced into the animal are capable of giving rise to infectious agents or contain viral sequences, the exemption only applies where the cells are incapable of giving rise to infectious agents and do not contain viral sequences that could recombine with, or be complemented by, genomes of superinfecting viruses.

- certain dealings involving approved host/vector systems (Schedule 2, Part 2 identifies different types of approved host/vector systems) provided that

the donor DNA is not potentially harmful (for example, as the result of it being an oncogene or coding for toxins);

A host/vector system is a technique for introducing a foreign gene or sequence into an organism. For example, in order to undertake a study of the function of a particular gene, it may be desirable to propagate the gene a number of times and then study it in an organism. In a host/vector system, a transferring agent, for example a virus (the vector), is used to carry a strand of foreign DNA into an organism, for example cultured insect cells (the host).

The Regulations contain a restricted list of combinations of vectors and hosts that have been studied and are considered to offer a safe level of biological containment (approved host/vector systems). This means that it is very difficult for the foreign DNA to spread outside the host/vector system or the resulting GMO (the organism with foreign DNA in it), and unlikely that the GMO could survive outside a laboratory.

While the use of such host/vector systems minimises risks, the Regulations also require that other criteria are met in order for the work to be exempt. For example, in addition to using an approved host vector system, an exempt dealing must not use donor DNA that is an oncogene (a cancer causing gene), is derived from a microorganisms capable of causing disease in humans, animals or plants, or codes for toxin products (may be toxic to animals, plants or humans). If the donor DNA is potentially unsafe because of any of these factors, then the work is not exempt and must not proceed without approval from the Regulator.

• dealings involving shot-gun cloning of mammalian DNA in an approved host/vector system.

Shot-gun cloning is a type of dealing involving pieces of DNA. It is used in research to speed up the process of mapping large genetic sequences. Large genetic sequences can be determined quickly by shot-gun cloning by:

- breaking the long DNA sequences down into small pieces;

- putting small pieces of DNA into vectors;

- determining the sequence of the small bits of DNA; and

- using computer programs to reassemble all the small sequences into the large sequence.

These experiments are regarded as posing negligible risk because of:

(a) the confidence in the biological containment provided by the approved host/vector systems;

(b) the observation that interactions between mammalian DNA and many microbes have been occurring throughout evolution;

(c) the widespread and safe use of shot-gun cloning of mammalian DNA that has occurred in laboratories world-wide; and

(d) the understanding that DNA encoding a mammalian oncogene would only pose a possible hazard to researchers if the DNA was injected or introduced into the body (and would pose no hazard to the broader community).

The Australian/ New Zealand Standard AS/NZS 2243.3:1995 overrides the operation of s47(6) of the Legislation Act (ACT) 2001

7. Application for licence – prescribed information – Act s40(2)(a)

Regulation 7, supported by Schedule 4, prescribes information that must be contained in an application for a licence to undertake a dealing with a GMO. The Regulation sets out different information requirements depending on whether the proposed dealings with the GMO involve the intentional release of the GMO into the environment, or do not involve such release.

Schedule 4 sets out the minimum information to be provided by applicants in respect of applications for a licence to the Regulator. The Regulator may also request any additional information that is necessary to assist the Regulator's consideration of the application.

The Regulation requires that information provided to the Regulator in the course of applying for a licence must be as comprehensive as existing scientific knowledge permits at the time of application. The application must include all known information, supported by relevant data and references, about any impacts of the GMO on human health and safety and/or the environment.

Where comprehensive information is not supplied at the time of application, an applicant must identify all the gaps in the information which is supplied and provided with the application, to allow for an in-depth analysis of the risks posed by the absence of that information in the application.

This Regulation ensures that, as far as possible, in considering an application, the Regulator is provided with comprehensive information and that the absence of information is also taken into account by the Regulator when assessing the possible risks to the health and safety of people or the environment. The Regulator may always ask for more information if, he or she believes this is required by virtue of section 42 of the Act.

8. Time limit for deciding an application – Act s43(3)

Regulation 8 establishes the time frames within which the Regulator must issue, or refuse to issue, a licence authorising specified dealings with one or more specified GMOs.

The timeframes in which such decisions must be made are:

- 90 days after the day of receipt of an application that does not involve intentional release of a GMO into the environment; and

- 170 days after the day of receipt of an application that does involve intentional release of a GMO into the environment.

The Regulation also provides for circumstances under which the minimum time frames for considering the application will be suspended, and the permitted 90 days and 170 days will therefore be adjusted upward as necessary.

The time for considering the application will be suspended when the Regulator:

- is waiting for further information which has been requested in writing from the applicant; or

- has called for a public hearing; or

- is considering a request from the applicant that information provided by the applicant is confidential commercial information; or

- is seeking advice from the Gene Technology Ethics Committee (GTEC) on a relevant issue.

Saturdays, Sundays and public holidays in the Australian Capital Territory are not counted when calculating the proposed permitted time frames.

In considering an application for a licence for dealings involving the intentional release of a GMO into the environment, the Regulator must seek advice on risk assessment and risk management plans from the States, the Gene Technology Technical Advisory Committee (GTTAC), each Commonwealth agency and authority prescribed in Regulation 9, the Environment Minister and any local council that the Regulator considers appropriate. Subregulation 8(3) provides that the Regulator may specify a reasonable time within which such organisations must provide advice to the Regulator. The GT Act provides that the Regulator must give such organisations a minimum of 30 days to respond to a request for advice, however, the Regulator, may in a notice in writing specify a longer period of time.

If a body listed in the previous paragraph does not provide their advice within the specified time, then the Regulator may proceed with his/her consideration of the application, without such advice. It should be noted that the time for consideration of an application is not suspended while advice is being sought from such organisations.

The Regulator may also refer an issue raised in an application to GTEC for consideration. The Regulator may specify a time period within which such advice is required and for the duration of that period, the timeframe for consideration of the application is suspended. There is no minimum time limit prescribed in this instance.

9. Prescribed authorities – Act, s50(3)(c) and s52(5)(c)

Regulation 9 prescribes the Commonwealth authorities and agencies with whom it is intended that the Regulator must consult in particular situations.

The Commonwealth authorities and agencies prescribed are:

- the Australia New Zealand Food Authority;
- the Australian Quarantine and Inspection Service;
- the National Health and Medical Research Council;
- the National Industrial Chemical Notification and Assessment Scheme, National Occupational Health and Safety Commission;
- the National Registration Authority for Agricultural and Veterinary Chemicals; and
- the Therapeutic Goods Administration, Department of Health and Aged Care.

If the Regulator receives an application for a licence to undertake dealings involving intentional release of the GMO into the environment, the Regulator must consult these agencies on the application in order to inform the Regulator's preparation of a risk assessment and a risk management plan.

The Regulator must also consult these agencies again when the Regulator has prepared a risk assessment and risk management plan, which will, in effect be the draft decision in relation to the application.

This ensures that the Regulator will be fully advised of any issues and concerns which may exist from as broad a group of interested parties as is reasonably possible, in relation to GMOs and the risks associated with the proposed dealings. The list is not exhaustive and the Regulator may consult with other authorities and agencies as the Regulator considers desirable in deciding any application.

Consultation with the agencies and authorities detailed in this Regulation is in addition to the requirements for public consultation on draft risk assessments and risk management plans prepared by the Regulator. The Act provides that before making a decision on an application, the Regulator must publish a notice in the Gazette, in a newspaper circulating generally in all States and on the Regulator's website, inviting public submissions on any risk assessment and risk management plan prepared by the Regulator.

10. Risk assessment – matters to be taken into account – Act s51(1)(d) and (2)(d)

Regulation 10 prescribes additional matters that the Regulator must take into consideration in preparing a risk assessment and a risk management plan.

Section 51(1)(d) and (2)(d) of the Act sets out a range of matters that the Regulator must take into account in preparing a risk assessment and risk management plan in relation to dealings with a GMO proposed to be authorised by a licence. These matters include:

- risks posed by the dealings including any risks to the health and safety of people or risks to the environment;

- any submissions made by the public in relation to such risks; and

- any advice provided by the States, the Gene Technology Technical Advisory Committee, Commonwealth agencies, the Environment Minister and local councils.

The Regulator must take previous assessments of dealings with GMOs in either Australia or overseas into account. The Regulator must also consider the potential of the GMO to be harmful to other organisms; to adversely affect any ecosystems; to transfer genetic material; to spread or persist in the environment; to have a selective advantage in the environment; or to be toxic, allergenic or pathogenic to other organisms.

In examining the potential of the GMO to have such effects, the Regulator will be looking at the possible impact of the GMO on all organisms including animals, plants and humans.

The Regulation also clarifies that the Regulator must consider potential long term and short term risks when preparing a risk assessment and risk management plan

11. Prescribed conditions of licence

This Regulation flags that the Regulations may, at a future time, include prescribed conditions of licence. At the commencement of these Regulations, no conditions are prescribed.

Division 3.2 – Notifiable low risk dealings

12. Notifiable low risk dealings – Act s74(1)

Regulation 12, supported by Schedule 3, details those dealings with GMOs that are notifiable low risk dealings. A dealing with a GMO is a notifiable low risk dealing if it is listed in Part 1 of Schedule 3 (provided that the dealing is not also mentioned in Part 2 of Schedule 3) and it does not involve intentional release of a GMO into the environment.

Notifiable low risk dealings with a GMO are ones that:

- do not involve the intentional release of a GMO into the environment; and

- are of minimal risk to the health and safety of people and the environment having regard to:

- whether the GMO is biologically contained so that it is not able to survive or reproduce without human intervention; and

- the potential properties of the GMO as a pathogen or pest and the toxicity of any proteins produced by the GMO.

- the Regulator has also considered whether any conditions are necessary to manage any risks associated with the properties of the GMO.

The conditions required to manage the minimal risks are detailed in Regulation 13.

The notifiable low risk dealings detailed in Schedule 3, have been developed following consideration by the Regulator of the matters detailed above. In addition, the dealings which have been identified as notifiable low risk dealings are based on GMAC Category B activities which have been assessed over time as presenting minimum biosafety risks.

It is important to note that even if a dealing with a GMO falls within Part 1 of Schedule 3, it will not be a notifiable low risk dealing if it also falls within Part 2 of Schedule 3. If the proposed dealing falls within Part 2 of Schedule 3, a licence must be obtained from the Regulator, before the dealing can be conducted

Following is a summary of the types of dealings with GMOs that are notifiable low risk dealings (subject to them not also falling within Part 2 of Schedule 3) and some examples of the types of dealings.

- 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.

For example, production of a laboratory mouse that has an altered form of one of its genes. Researchers can study the characteristics of the mouse to learn about the function of the gene that has been altered.

The dealings with whole animals described above are limited by Part 2 of Schedule 3. Dealings with whole animals that are higher risk (because of the type of genetic modification applied) are not notifiable low risk dealings. Part 2 of Schedule 3 describes such higher risk GMOs. For example, if a viral vector has been used to produce a transgenic animal that secretes or produces recombinant viral agents then the dealings with the GMO are not notifiable low risk dealings and must be licensed by the Regulator.

In relation to those dealings with whole animals that are low risk (and are not considered to be higher risk by virtue of characteristics described in Part 2 of Schedule 3), conditions must also be complied with to ensure that even the minimal risks can not be realised. For example, Regulation 13 requires that work with whole animals be conducted within a facility certified by the Regulator to be at least PC2 (or otherwise certified to a containment level that the Regulator considers suitable) and appropriate to contain the particular type of animal.

- 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;

In combination with Regulation 13 (requirements in relation to notifiable low risk dealings), the effect of this provision is that a person may deal with a genetically modified flowering plant provided the plant is contained within a PC2 facility and, if the plant is grown to flowering stage, additional precautions are undertaken. The additional precautions ensure that seed or pollen do not escape from the PC2 glasshouse.

• Any dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 1, 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;

For example, production of a genetically modified bacterium that is capable of producing insulin, where the wild-type unmodified bacterium occurs naturally in the human gut and does not cause disease.

Regulation 13 requires that such work must be carried out in laboratories certified to at least PC2 in accordance with procedures designed to prevent the transmission of the organisms outside of the laboratory. Further, in order to be a notifiable low risk dealing, both the hosts and the vectors used in these experiments must be non-pathogenic.

Dealings with these types of GMOs are also limited by Part 2 of Schedule 3. If the dealing, despite falling within this category, also involves, for example, high level expression of toxin genes, then the dealing will not be a notifiable low risk dealing and, if undertaken, must be licensed by the Regulator.

• Any dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 1, 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;

An example of the use of such technology is scientists studying the basis for pathogenicity in a bacterium such as Clostridium perfringens who wish to study the regulation of a gene which encodes an outer membrane protein believed to play a role in virulence. Because the assay for the presence of such a protein is complex and difficult, a strain is constructed in which this protein is replaced by a harmless protein, whose presence is easily detected. These are called reporter proteins and two examples are the enzyme ß-galactosidase and the coloured protein Green Fluorescent Protein (GFP). The loss of the outer membrane protein decreases the pathogenicity of the strain which is not otherwise affected by the addition of the reporter protein. Experiments such as these are important for investigating the biology of pathogenic microorganisms.

The risks posed by such dealings are minimal as the result of a number of factors. Firstly, the donor DNA used, must be fully characterised. This means that the physical makeup of the DNA has been researched and that an understanding has been obtained about the function of the genes in the DNA. Secondly the work must not involve any factors that may increase risk (these factors are outlined in Part 2 of Schedule 3). Thirdly, the work must be conducted in a laboratory that has been certified by the Regulator as being at least PC2 in order to ensure proper physical containment of the GMO.

• Any dealing involving a host/vector system mentioned in Part 2 of Schedule 1, 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.

For example, the use of rat cells to test genes which cause cancer or tumours when the rat cells containing the test gene are grown in petri dishes. There is no risk of the rat cells surviving outside the laboratory and the methods used to insert the genes are recognised as being safe.

Such dealings with GMOs may only be undertaken as notifiable low risk dealings if other risk factors are not also present. Part 2 of Schedule 3, describes such risk factors. If a dealing involves any of the risk factors identified at Part 2 of Schedule 3, then the dealing must not proceed as a notifiable low risk dealing and, if undertaken, must be licensed.

13. Requirements in relation to notifiable low risk dealings

Regulation 13 establishes the conditions and requirements that must be complied with by a person proposing to undertake, or who is undertaking, a notifiable low risk dealing.

If a person wishes to undertake a notifiable low risk dealing, they must first consider whether the proposed dealing with the GMO appears in Part 1 of Schedule 3. If they consider that the dealing falls within this Part (and does not also fall within Part 2 of Schedule 3), then the person must prepare detailed information about the proposed dealing with the GMO, in accordance with the Regulator's information requirements as set out in Part 3 of Schedule 3.

Regulation 13 also provides that an Institutional Biosafety Committee (IBC) must assess the information prepared by the person. The purpose of this is to ensure that the person has not incorrectly classified the dealing as a notifiable low risk dealing.

This Regulation further provides that, within 14 days of the IBC's assessment, the IBC must notify the Regulator of the proposed dealing, by giving the Regulator a copy of the information prepared by the person (in accordance with the Regulator's information requirements set out in Part 3 of Schedule 3), together with the IBC's assessment of the information and any other supporting information (also described in Part 3 of Schedule 3).

Once the IBC has written to the person and the project supervisor, advising them that the IBC has notified the Regulator, the notifiable low risk dealings with the GMO may commence. This Regulation further provides that once these preconditions have been met, the person undertaking the notifiable low risk dealing must also comply with certain conditions which assist to ensure that any risks associated with the dealing are not realised.

In summary, this Regulation prescribes that notifiable low risk dealings must:

- be conducted within a contained facility certified to at least PC2 and of appropriate design for containing the type of GMO proposed (or otherwise certified by the Regulator as being suitable for containing the particular GMO); and

- be properly supervised (for example by the accredited organisation within which the work is conducted) and a record of the details of the dealings retained; and

- only be transported in accordance with guidelines issued by the Regulator; and

- if the dealing involves organisms that may produce disease in humans, be conducted in accordance with vaccination requirements set out in the Australian Standard AS/NZA2243:3:1995 (Safety in laboratories: microbiology).

Subregulation 13(5) describes the transitional arrangements intended for notifiable low risk dealings. This Regulation provides that if GMAC has issued a notice in respect of the notifiable low risk dealing (and the notifiable low risk dealing is one that is included in Part 1 of Schedule 3 and not in Part 2 of Schedule 3), then the dealing may be conducted for up to 2 years provided that the conditions described in Subregulation 13(2) are complied with.

The Australian/ New Zealand Standard AS/NZS 2243.3:1995 overrides the operation of s47(6) of the Legislation Act (ACT) 2001

s88 of the Legislation Act (ACT) 2001 applies to Subregulation (5)

Subregulation (7) operates in accordance with standard ACT drafting practice of sunsetting provisions that are to operate for a fixed time. This provision states that subregulations (5) and (6) operation will expire 2 years from the day the regulations come into operation.

Division 3.3 – Certification and Accreditation

14. Time limit for deciding an application for certification within 90 days
This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

Commonwealth Explanatory Memorandum for Regulation 14 states;

Regulation 14 establishes the period during which the Regulator must consider and decide upon an application for certification of a facility. Applications may be made to the Regulator to have facilities certified to a certain containment level.

The Regulator must make a decision on the certification of a facility within 90 days after the application is received. For the purposes of determining the 90 day period, any time during which the Regulator is awaiting a response from an applicant in relation to a request for additional information, is not counted. Saturdays, Sundays and public holidays in the Australian Capital Territory are not counted as part of the 90 days.

15. Application for certification – failure to provide Act s.85 information

Regulation 15 enables the Regulator to refuse to certify a facility that is the subject of an application if the applicant, without reasonable explanation, has not complied with a request for further information within a permitted time.

A refusal to certify a facility is a reviewable decision under the Act.

16. Regulator to decide accreditation application within 90 days
This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

Commonwealth Explanatory Memorandum for Regulation 16 of the Commonwealth Regulations states;

Regulation 16 establishes the period during which the Regulator must consider and decide upon applications for the accreditation of an organisation under the GT Act.

Accreditation is intended to be a precondition for organisations wishing to undertake notifiable low risk dealings and dealings requiring a licence. It is intended that a key component of accreditation will be establishing to the Regulator's satisfaction, that an organisation has a properly constituted Institutional Biosafety Committee (IBC) or has access to such an IBC. As detailed in relation to Regulation 13, IBCs will play an important role in relation to notifiable low risk dealings by assisting applicants to ensure that a dealing is not inadvertently mis-categorised. The IBC is also required to provide supporting information in support of applications for licences made to the Regulator.

The Regulator must make a decision on the accreditation of an organisation within 90 days of receipt of the application. For the purposes of determining the 90 day period, any time during which the Regulator is awaiting a response from the applicant in relation to a request for additional information, is not counted. Saturdays, Sundays and public holidays in the Australian Capital Territory are not counted as part of the 90 days.

17. Application for accreditation – failure to provide s.93 information

Regulation 17 enables the Regulator to refuse to accredit an organisation, if the applicant, without reasonable explanation, fails to provide to the Regulator, within a permitted time period, the information which was requested by the Regulator.

Note 1 refers to division 12.2 in the Act, which provides that where an organisation is refused accreditation the decision is able to be reviewed.

Part 4 – Gene Technology Technical Advisory Committee

This Part sets out the conditions of appointment of members of the Gene Technology Technical Advisory Committee (GTTAC), including term of appointment and disclosure of interest provisions. The Part also sets out basic information about committee procedures, including voting conventions and reporting requirements.

Division 4.1 – Conditions of appointment

18. GTTAC members and advisers- terms of appointment

This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 18 of the Commonwealth Regulations states;

Regulation 18 provides for the appointment, by the Minister, of members and expert advisers to the Gene Technology Technical Advisory Committee (GTTAC) for a term of three years, or a lesser period if specified in the instrument of appointment. Members and expert advisers may be reappointed for a further term or terms.

The term of three years was chosen because it balances the interests of the committee, allowing for the development of expertise and corporate knowledge, with the interests of the committee in periodically incorporating new expertise and new ideas to assist it to continue to be relevant in its continually changing environment. It is anticipated that change of membership will be staggered to ensure that a complete turnover of members is avoided every three years. This will reduce the risk of a substantial periodic loss of corporate knowledge and expertise.

19. GTTAC members and advisers – resignation

This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 19 of the Commonwealth Regulations states;

Regulation 19 enables members and expert advisers of GTTAC to resign at any time by advising the Minister in writing of their resignation.

20. GTTAC members – disclosure of interests

This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 20 of the Commonwealth Regulations states;

Regulation 20 provides that before a person is appointed as a member of GTTAC, the person must have provided, to the Minister, a declaration setting out all direct or indirect interests, pecuniary or otherwise, and other possible conflicts of interests, of which he or she is aware and which may be of a kind likely to be considered at a meeting of GTTAC.

A member who has been appointed and, who then becomes aware of having a direct or indirect interest, including a possible conflict of interest, in a matter about to be discussed at a meeting of GTTAC, must without delay, disclose the interest at or before the meeting at which the matter may be discussed.

A member who discloses such an interest must not be present during any deliberations of GTTAC on the particular matter except to provide information as requested by GTTAC. This provision recognises that despite having an interest, the member may still have other valuable information to contribute to the Committee. The member must not, however, take part in any decision making process of the GTTAC about the matter. Further, the minutes of the meeting must record that the disclosure was made.

This Regulation is designed to ensure that the deliberations of members of GTTAC are not affected, or perceived to be affected, by the personal or other interests of one or more members.

21. GTTAC members and advisers – termination of appointment
This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 21 of the Commonwealth Regulations states;

Regulation 21 sets out the circumstances in which the Minister may terminate the appointment of a GTTAC member or expert adviser. Both members and expert advisers may have their appointment terminated for physical or mental incapacity, or for misbehaviour, which includes failure to disclose an interest.

The GT Act provides that the Chairperson is appointed by the Minister with the agreement of a majority of jurisdictions (jurisdiction is defined in the GT Act). The Regulation, therefore clarifies that the termination of appointment of the Chairperson must also be with the agreement of a majority of jurisdictions. The appointment of any member (other than the Chair) or expert adviser, may be terminated on the initiative of the Minister alone. This is consistent with the fact that the Minister may appoint other members of the Committee and expert advisers without the agreement of the majority of the jurisdictions.

The Minister must terminate the appointment of a member, if that member becomes bankrupt, enters into an arrangement with his creditors, or fails to fulfil his obligations as a member of GTTAC to provide advice on the request of the Regulator or the Ministerial Council. If a member fails to attend GTTAC for three consecutive attendance days without being granted leave of absence under Regulation 22, the Minister must terminate their appointment. The Minister does not have discretion in these matters and must terminate the appointments if these events occur. The termination of appointment of members of GTTAC is subject to section 27A of the Administrative Appeals Tribunal Act 1975 and the Code of Practice which was set up to facilitate the review of any reviewable decision in circumstances where a person's interests are affected by a notice of termination of appointment.

22. GTTAC members – leave of absence
This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 22 of the Commonwealth Regulations states;

Regulation 22 provides that leave of absence may be granted to the Chairperson of GTTAC by the Minister. The Chairperson may grant leave of absence to any other members.

Leave of absence which is properly granted in accordance with this Regulation is intended to ensure that the Chairperson and any member who takes official leave will not be in breach of the conditions of their appointment and risk the possibility of their appointment being terminated for absence.

23. Expert Advisers – disclosure of interests
This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 23 of the Commonwealth Regulations states;

Regulation 23 ensures that before a person may be appointed as an expert adviser to GTTAC, the person must have provided to the Minister, a declaration, setting out all direct or indirect interests, pecuniary or otherwise, and possible conflicts of interests, of which he or she is aware and which may be of a kind likely to be considered at a meeting of GTTAC.

An expert adviser, who then becomes aware of having a direct or indirect interest, including a possible conflict of interest, in a matter about to be discussed at a meeting of GTTAC, must without delay, disclose the interest at or before the meeting at which the matter may be discussed.

A disclosure made by an expert adviser must be recorded in the minutes of the meeting. This ensures that the deliberations of GTTAC are not affected by the personal interests of any expert advisers.

Division 4.2 Committee procedures

24. Committee procedures generally
This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 24 of the Commonwealth Regulations states;

Regulation 24 provides additional detail about how GTTAC must perform its functions.

Under the Regulations, GTTAC must act in accordance with these Regulations, and as informally and as quickly as due and proper consideration of the issues before the Committee permits.

GTTAC may also obtain further information in any way that it considers appropriate. In obtaining information, the Committee must observe any directions given in a request from the Regulator or the Ministerial Council. For example, the Ministerial Council may consider it important that consultation be undertaken in a particular way or with a particularly broad group of stakeholders. In such a circumstance, the Ministerial Council would include in their request for advice from the Committee, a requirement that such consultation be undertaken.

25. Committee meetings
This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 25 of the Commonwealth Regulations states;

Regulation 25 provides some basic parameters to GTTAC in terms of how, when and how often it must meet. It authorises the Chairperson of GTTAC to direct the Committee to hold meetings. Notices of meetings must be sent to GTTAC by the Chairperson in writing and specify the time, place and matters for consideration. The Chairperson may organise meetings by video conference or teleconference if the Chairperson thinks fit.

In order to impose some discipline on the Committee (in terms of number of face-to-face meetings) and to enable accountability (including in terms of resources allocated to support the work of the Committee), it is intended that at the beginning of each year the Chairperson and the Regulator will agree on the maximum number of face-to-face meetings that will be held that year. Work proposals and work plans will be prepared based on the proposed meeting timetable. This will enable members to plan their calendars so as to be available for meetings and minimise the need for a member to apply for leave or be absent. The Committee may not meet face-to-face more times than is agreed (or at all if there is no agreement).

If the agreed number of face-to-face meetings is not adequate to enable the Committee to properly consider the issues before it, the Chair and the Regulator may agree that additional meetings be held (beyond those agreed in the workplan). The Chair may also direct the Committee to hold meetings and resolve issues by teleconference or videoconference or to meet out of session. 'Out of session' is defined in the Regulations as a meeting in which members take part in the meeting by means of correspondence, electronic mail, telephone or any other method that does not involve simultaneous meeting and voting by GTTAC.

This Regulation will ensure that the Regulator's responsibility for managing the Office of Gene Technology Regulator is balanced with the activities of GTTAC.

26. Presiding member
This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 26 of the Commonwealth Regulations states;

Regulation 26 ensures that the Chairperson must preside at all GTTAC meetings, or appoint another member to preside. A member who is appointed to act as presiding Chairperson must be appointed in writing and must not be

a member of any of the other committees established under the provisions of the GT Act. This is intended to ensure total independence of the Chairperson and prevent the possibility of cross interests of members improperly affecting the deliberations of the Committee. It is, intended that, when the Chairperson is present at a meeting of GTTAC, the Chairperson will, in usual circumstances, be the presiding member.

If there are occasions when the Chairperson will be temporarily absent from a meeting, those members who are present at the meeting must choose a member who is present to preside over the meeting for the duration of the Chair's absence. This provision is intended to ensure that the business of GTTAC will not be hindered or stopped by the temporary non-availability of the appointed Chairperson.

27. Quorum

This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 27 of the Commonwealth Regulations states;

Regulation 27 establishes the quorum for a meeting of the GTTAC. The GT Act provides that the Minister is to appoint up to 20 members to GTTAC. A quorum will exist if half of those members who have been appointed are present at the meeting.

28. Voting

This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 28 of the Commonwealth Regulations states;

Regulation 28 describes the requirements for a valid vote of GTTAC. A decision of GTTAC will be carried by a majority of the members present and voting for the motion. If the Chairperson nominates a member to preside, or if a member has been appointed to preside at the meeting in the temporary absence of the Chairperson, that member has a deliberative vote and a casting vote in the event of a vote being tied (otherwise, the Chairperson has a deliberative vote and a casting vote in the event of a vote being tied).

29. Records and reports

This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 29 of the Commonwealth Regulations states;

Regulation 29 sets out the procedures for the maintenance of records of proceedings and resolutions. A record of all proceedings must be kept by GTTAC and a copy of every resolution passed by GTTAC must be provided to the Regulator.

The Regulator must keep copies of all resolutions of the Committee and make them available to the public, for example, by posting them on the Regulator's website or by including them in quarterly reports to be issued by the Regulator in accordance with the GT Act. Information that the Regulator considers is confidential commercial information is intended to be excluded from public access.

The Regulation seeks to ensure that the activities of GTTAC are made known to the Regulator and all decisions of GTTAC are available to the public, while safeguarding legitimate confidential commercial information. It also ensures that GTTAC must report on its activities to the Regulator, thus enabling the Regulator to provide comprehensive periodic reports.

Division 4.3 Subcommittees

30. Operation of subcommittees

This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 30 of the Commonwealth Regulations states;

Regulation 30 establishes the procedures and rules for the operation of subcommittees of GTTAC established under section 105 of the GT Act.

This Regulation establishes:

a) the procedures under which a subcommittee must operate;

b) the arrangements for the conduct of a subcommittee meeting;

c) the requirement that the Chairperson must preside at a meeting (or if absent appoint a member to preside); and

d) the procedures for voting at a subcommittee meeting.

The procedures for subcommittees reflect, as far as possible, the procedures for GTTAC. In this regard:

- A subcommittee must act in accordance with these Regulations, as informally and as quickly as due and proper consideration of the issues put before it permits. The subcommittee may obtain further information in any way that it considers appropriate. The scope of the information which may be sought will be limited by any directions issued by the Regulator or Ministerial Council. It is intended that such directions will specify the extent to which or the manner in which such information may be obtained.

This Regulation ensures that any subcommittee functions properly in accordance with the provisions of the GT Act and these Regulations, efficiently and consistently with GTTAC procedures while safeguarding the interests of applicants, the GTTAC and the subcommittee.

- The Chairperson of the subcommittee may direct the subcommittee to hold meetings. As is the case for GTTAC, it is intended that the Chair of the subcommittee will agree with the Regulator, at the beginning of the year, a maximum number of face-to-face meetings to be held that year. Details of such meetings will be notified to the subcommittee by the Chairperson in writing and will specify the time, place and matters for consideration. Meetings may be conducted by means of video conference or teleconference if the Chairperson considers such forums to be appropriate and efficient. Any such meetings held by videoconference and teleconference may discuss and resolve issues as if such meetings were held as face-to-face meetings. The Chairperson may also arrange meetings out of session. 'Out of session' is defined in the Regulations as a meeting in which members take part in the meeting by means of correspondence, electronic mail, telephone of any other method that does not involve simultaneous meeting and voting of the members.

- The Chairperson must preside at all subcommittee meetings or appoint a member to preside. A member who is appointed to act as presiding Chairperson must be appointed in writing and must not be a member of any other committees established under the provisions of the GT Act. This ensures the independence of the position of the Chairperson of the subcommittees and prevents the possibility of cross interests from other committees improperly affecting the deliberations of the other committee concerned. If there are occasions when the Chairperson will be temporarily absent from a meeting, those members who are present at the meeting must choose a member who is present to preside over the meeting for the duration of the Chairperson's absence. This ensures that the business of the subcommittee will not be hindered or stopped by the temporary non-availability of the Chairperson.

- A decision of the subcommittee will be carried by a majority of the members present and voting for the motion. If the Chairperson has nominated a member to preside, or if a member has been appointed to preside over the meeting in the temporary absence of the Chairperson, that member has a deliberative vote and a casting vote in the event of a vote being tied (otherwise the Chairperson has a deliberative vote and a casting vote in the event of a vote being tied).

- A quorum exists if half of the members of the subcommittee are present

- The subcommittees must keep records of their proceedings and must give a copy of each resolution passed by them to GTTAC. This is intended to ensure that GTTAC is kept up to date on the activities and resolutions of the subcommittees (if any).

Part 5 – Gene Technology Community Consultative Committee

Part 5 of the Regulations prescribes those issues which apply to the Gene Technology Community Consultative Committee (GTCCC).

Regulations 31, 32 and 33 mirror as far as possible, in respect of GTCCC, the conditions which apply to the GTTAC and establish the conditions of appointment to GTCCC, committee procedures and function and operation of any subcommittees which may be established. The Act does not provide for the appointment of expert advisers to GTCCC.

31. GTCCC – conditions of appointment

This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 31 of the Commonwealth Regulations states;

Regulation 31 operates as follows:

- Members of GTCCC are appointed by the Minister, for a term of three years or a lesser period if specified in the instrument of appointment. Members may be reappointed for a further term or terms. The term of three years was chosen because it balances the interests of the committee, allowing for the development of expertise and corporate knowledge, with the interests of the committee in periodically incorporating new expertise and new ideas to assist the committee to continue to be relevant in its continually changing environment. It is anticipated that change of membership will be staggered to ensure that a complete turnover of members is avoided every three years. This reduces the risk of a substantial periodic loss of corporate knowledge and expertise.

- Members of the GTCCC may resign at any time by advising the Minister in writing of their resignation.

- Before a person may be appointed as a member of GTCCC, the person must have provided to the Minister, a declaration, setting out all direct or indirect interests, pecuniary or otherwise, and other possible conflicts of interests, of which he or she is aware and which may be of a kind likely to be considered at a meeting of GTCCC. A member after appointment, who then becomes aware of having a direct or indirect interest, including a possible conflict of interest, in a matter about to be discussed at a meeting of GTCCC, must without delay, disclose the interest at or before the meeting at which the matter may be discussed. A member who discloses such an interest must not be present during any deliberations of GTCCC on the particular matter except to provide information as requested by GTCCC. This provision recognises that despite having an interest, the member may still have other valuable information to contribute to the Committee. That member, however, must not take part in any decision making process of GTCCC about the matter. Further, the minutes of the meeting must record that the disclosure was made. These

requirements ensure that the deliberations of GTCCC are not affected, or perceived to be affected, by personal interests of one or more members.

• The Minister may terminate the appointment of a member of the GTCCC. A member may have their appointment terminated for misbehaviour, which includes failure to disclose an interest, or for physical or mental incapacity. The GT Act provides that the Chairperson is appointed by the Minister with the agreement of a majority of jurisdictions (jurisdiction is defined in the GT Act). This Regulation, therefore clarifies that the termination of appointment of the Chairperson must also be with the agreement of a majority of jurisdictions. The appointment of any member other than the Chairperson, may be terminated on the initiative of the Minister alone. The Minister must terminate the appointment of a member if that member becomes bankrupt, enters into an arrangement with his creditors, or fails to fulfil his or her obligations as a member of the GTCCC to provide advice on the request of the Regulator or the Ministerial Council. If a member fails to attend the GTCCC for three consecutive attendance days without being granted leave of absence under Regulation 22, the Minister must terminate their appointment. The Minister does not have discretion in these matters and must terminate the appointments if these events occur.

• The termination of appointment of members of GTCCC is subject to section 27A of the Administrative Appeals Tribunal Act 1975 and the Code of Practice which was set up to facilitate the review of any reviewable decision in circumstances where a person's interests are affected by a notice of termination of appointment.

• Leave of absence may be granted to the Chairperson of the GTCCC by the Minister. The Chairperson may grant leave to any other member. Leave of absence which is properly granted in accordance with this Regulation ensures that the Chairperson and any member who takes official leave will not be in breach of the conditions of their appointment and risk the possibility of their appointment being terminated for absence.

32. GTCCC – Consultative Committee procedures

This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 32 of the Commonwealth Regulations states;

Regulation 32 establishes the committee procedures of GTCCC consistently, as far as possible, with the procedure for operation of GTTAC as set out in Regulations 24-29 inclusive.

The intended operation of Regulation 32 is as follows:

• GTCCC must act in accordance with these Regulations and, as informally and as quickly as due and proper consideration of the issues before the committee permits. GTCCC may obtain further information in any way that it considers appropriate. In obtaining information, the Committee must

observe any directions given in a request from the Regulator or the Ministerial Council. For example, the Ministerial Council may consider it important that consultation be undertaken in a particular way or with a particularly broad group of stakeholders. In such a circumstance, the Ministerial Council would include in their request for advice from the Committee, a requirement that such consultation be undertaken.

• The Chairperson of GTCCC may direct GTCCC to hold meetings. Notices of meetings must be sent to GTCCC by the Chairperson, in writing and specify the time, place and matters for consideration. The Chairperson may organise meetings by video conference or teleconference if the Chairperson thinks fit. In order to impose some discipline on the Committee (in terms of number of face-to-face meetings) and to enable accountability (including in terms of resources allocated to support the work of the Committee), it is intended that at the beginning of each year the Chairperson and the Regulator will agree on the maximum number of face-to-face meetings that will be held that year. Work proposals and work plans will be prepared based on the proposed meeting timetable. This enables members to plan their calendars so as to be available for meetings and minimise the need for a member to apply for leave or be absent. The Committee may not meet face-to-face more times than is agreed (or at all if there is no agreement). If the agreed number of face-to-face meetings is not adequate to enable the Committee to properly consider the issues before it, the Chair and the Regulator may agree that additional meetings be held (beyond those agreed in the workplan).

• The Chair may also direct the Committee to hold meetings and resolve issues by teleconference or videoconference or to meet out of session. ‘Out of session’ is defined in the Regulations as a meeting in which members take part in the meeting by means of correspondence, electronic mail, telephone or any other method that does not involve simultaneous meeting and voting by GTCCC.

• This Regulation ensures that the Regulator’s responsibility for managing the Office of the Gene Technology Regulator is balanced with the activities of the GTCCC.

• The Chairperson must preside at all GTCCC meetings or appoint another member to preside. Any member who is so appointed to act as presiding Chairperson must be appointed in writing and must not be a member of any of the other Committees established under the provisions of the GT Act. This ensures total independence of the Chairperson and prevents the possibility of cross interests of members improperly affecting the deliberations of the Committee. It is intended that when the Chairperson is present at a meeting of GTCCC, the Chairperson will, in usual circumstances, be the presiding member. If there are occasions when the Chairperson will be temporarily absent from a meeting, those members who are present at the meeting must choose a member who is present to preside over the meeting for the duration of the Chair’s absence. This provision ensures that the business of the GTCCC will not be hindered or stopped by the temporary non-availability of the appointed Chairperson.

• A quorum for a meeting of GTCCC exists if half of the members who have been appointed are present at the meeting. The GT Act provides that the Minister shall appoint up to 12 members to the GTCCC and one of those members shall be appointed as the Chairperson.

• A decision of GTCCC is carried by a majority of the members present and voting for the motion. If the Chairperson nominates a member to preside, or if a member has been appointed to preside at the meeting in the temporary absence of the Chairperson, that member has a deliberative vote and a casting vote in the event of a vote being tied (otherwise the Chairperson has a deliberative vote and a casting vote in the event of a vote being tied).

• A record of all proceedings must be kept by GTCCC and a copy of every resolution passed by the GTCCC must be provided to the Regulator. The Regulator must keep copies of all resolutions of the Committee and make them available to the public, for example by posting them on the Regulator's website or by including them in quarterly reports to be issued by the Regulator in accordance with the GT Act. Resolutions which contain information that the Regulator considers is confidential commercial information is intended to be excluded from public access. This ensures that the activities of the GTCCC are made known to the Regulator and all decisions of the GTCCC are available to the public while safeguarding information that is legitimately confidential commercial information. It also ensures that the GTCCC must report on its activities to the Regulator, thus enabling the Regulator to provide comprehensive periodic reporting.

33. GTCCC – operation of subcommittees

This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 33 of the Commonwealth Regulations states;

Regulation 33 establishes the procedures and rules for the operation of subcommittees of the GTCCC which may be set up under the Act.

This Regulation establishes:

a) the procedures under which a subcommittee must operate;

b) the arrangements for the conduct of a subcommittee meeting;

c) the requirement that the Chairperson must preside at a meeting (or if absent, appoint a member to preside); and

d) the procedures for voting at a subcommittee meeting.

The procedures for subcommittees reflect as far as possible, the procedures for GTCCC. In this regard:

• A subcommittee must act in accordance with these Regulations, as informally and as quickly as due and proper consideration of the issues put

before it permits. The subcommittee may obtain further information in any way that it considers appropriate. The scope of the information which may be sought will be limited by any directions issued by the Regulator or Ministerial Council. It is intended that such directions will specify the extent to which, or the manner in which, such information may be obtained.

This Regulation ensures that the subcommittee functions properly in accordance with the provisions of the GT Act and these Regulations, efficiently and consistently with GTCCC procedures while safeguarding the interests of the GTCCC and the subcommittee.

- The Chairperson of the subcommittee may direct the subcommittee to hold meetings. As is the case for GTCCC, it is intended that the Chair of the subcommittee will agree with the Regulator, at the beginning of the year, a maximum number of face-to-face meetings to be held that year. Details of such meetings will be notified to the subcommittee by the Chairperson in writing and will specify the time, place and matters for consideration. Meetings may be conducted by means of video conference or teleconference if the Chairperson considers such forums to be appropriate and efficient. Any such meetings held by videoconference and teleconference may discuss and resolve issues as if such meetings were held as face-to-face meetings. The Chairperson may also arrange meetings out of session. ‘Out of session’ is defined in the Regulations as a meeting in which members take part in the meeting by means of correspondence, electronic mail, telephone of any other method that does not involve simultaneous meeting and voting of the members.

- The Chairperson must preside at all subcommittee meetings or appoint another member to preside. A member who is appointed to act as presiding Chairperson must be appointed in writing and must not be a member of any other committees established under the provisions of the GT Act. This ensures the independence of the position of the Chairperson of the subcommittees and prevents the possibility of cross interests from other subcommittees from improperly affecting the deliberations of other subcommittees. If there are occasions when the Chairperson will be temporarily absent from a meeting, those members who are present at the meeting must choose a member who is present to preside over the meeting for the duration of the Chairperson’s absence. This ensures that the business of the subcommittee will not be hindered or stopped by the temporary non-availability of the Chairperson.

- A decision of the subcommittee will be carried by a majority of the members present and voting for the motion. If the Chairperson has nominated another member to preside, or if a member has been appointed to preside over the meeting in the temporary absence of the Chairperson, that member has a deliberative vote and a casting vote in the event of a vote being tied (otherwise the Chairperson has a deliberative vote and a casting vote in the event of a vote being tied).

- A quorum exists if half of the members of the subcommittee are present.

• The subcommittees must keep records of their proceedings and must give a copy of each resolution passed by them to the GTCCC. This is intended to ensure that the GTCCC is kept up to date on the activities and resolutions of the subcommittees (if any).

Part 6 – Gene Technology Ethics Committee

Part 6 of the Regulations prescribes those issues which relate to the Gene Technology Ethics Committee (GTEC). This part provides for the conditions of appointment and committee procedures for the Gene Technology Ethics Committee (GTEC).

34. GTEC – Conditions of appointment

This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 34 of the Commonwealth Regulations states;

Regulation 34 operates as follows:

• Members and expert advisers to the GTEC are appointed by the Minister, for a term of three years or a lesser period if specified in the instrument of appointment. Members and expert advisers may be reappointed for a further term or terms. The term of three years was chosen because it balances the interests of the committee in allowing for the development of expertise and corporate knowledge, with the interests of the committee in periodically incorporating new expertise and new ideas through new members and advisers, to assist the Committee to continue to be relevant in the continually changing environment. It is anticipated that change of membership will be staggered to ensure that a complete turnover of members or expert advisers is avoided every three years. This will reduce the risk of a substantial periodic loss of corporate knowledge and expertise.

• Members and expert advisers of GTEC may resign at any time by advising the Minister in writing of their resignation.

• Before a person may be appointed as a member of GTEC, the person must have provided to the Minister, a declaration, setting out all direct or indirect interests, pecuniary or otherwise, and other possible conflicts of interests, of which he or she is aware and which may be of a kind likely to be considered at a meeting of GTEC. A member after appointment, who then becomes aware of having a direct or indirect interest, including possible conflict of interest, in a matter about to be discussed at a meeting of GTEC, must without delay, disclose the interest at or before the meeting at which the matter may be discussed.

• A member who discloses such an interest must not be present during any deliberations of GTEC on the particular matter except to provide

information as requested by GTEC. This provision recognises that despite having an interest, the member may still have other valuable information to contribute to the Committee. That member must not, however, take part in any decision making process of GTEC about the matter. Further, the minutes of the meeting must record that the disclosure was made. These requirements will assist to ensure that the deliberations of members of GTEC are not affected, or perceived to be affected, by the personal or other interests of one or more members.

• Before a person may be appointed as an expert adviser to the GTEC, the person must have provided to the Minister, a declaration, setting out all direct or indirect interests, pecuniary or otherwise, and other possible conflicts of interests, of which he or she is aware and which may be of a kind likely to be considered at a meeting of the GTEC. An expert adviser, who then becomes aware of having a direct or indirect interest, including a possible conflict of interest, in a matter about to be discussed at a meeting of the GTEC, must, without delay, disclose the interest at or before the meeting at which the matter may be discussed. A disclosure made by an expert adviser must be recorded in the minutes of the meeting. This ensures that the deliberations of the GTEC are not improperly affected by the personal interests of any expert adviser to the GTEC.

• The Minister may terminate the appointment of a GTEC member or expert adviser. Both members and expert advisers may have their appointment terminated for misbehaviour, which includes failure to disclose an interest, or for physical or mental incapacity. The GT Act provides that the Chairperson is appointed by the Minister with the agreement of a majority of jurisdictions (jurisdiction is defined in the GT Act). The Regulation, therefore clarifies that the termination of appointment of the Chairperson must also be with the agreement of a majority of jurisdictions. The appointment of any member or expert adviser, other than the Chairperson, may be terminated on the initiative of the Minister alone. The Minister must terminate the appointment of a member if that member becomes bankrupt, enters into an arrangement with his creditors, or fails to fulfil his obligations as a member of GTEC to provide advice on the request of the Regulator or the Ministerial Council. If a member fails to attend GTEC for three consecutive attendance days without being granted leave of absence, under Regulation 22, the Minister must terminate their appointment. The Minister does not have discretion in these matters and must terminate the appointments if these events occur.

• The termination of appointment of members and expert advisers of GTEC is subject to section 27A of the Administrative Appeals Tribunal Act 1975 and the Code of Practice which were set up to facilitate the review of any reviewable decision in circumstances where a persons interests are affected by a notice of termination (see Regulation 38).

• Leave of absence may be granted to the Chairperson of GTEC by the Minister. The Chairperson may grant leave to any other member. Leave of absence which is properly granted in accordance with this Regulation ensures that the Chairperson and any member who takes official leave will not be in

breach of the conditions of their appointment and the risk the possibility of their appointment being terminated for absence.

35. GTEC – Committee procedures

This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 35 of the Commonwealth Regulations states;

Regulation 35 establishes the committee procedures for GTEC consistently, as far as possible, with the procedures for GTTAC as set out in Regulations 24-29 inclusive.

Regulation 35 operates as follows:

- The GTEC must act in accordance with these Regulations, as informally and as quickly as due and proper consideration of the issues before the Committee permits. The GTEC may obtain further information in any way that it considers appropriate. In obtaining information, the Committee must observe any directions given in a request from the Regulator or the Ministerial Council. For example, the Ministerial Council may consider it important that consultation be undertaken in a particular way or with a particularly broad group of stakeholders. In such a circumstance, the Ministerial Council would include in their request for advice from the Committee, a requirement that such consultation be undertaken.

- The Chairperson of GTEC may direct GTEC to hold meetings. Notices of meetings must be sent to GTEC by the Chairperson, in writing and specify the time, place and matters for consideration. The Chairperson may organise meetings by video conference or teleconference if the Chairperson thinks fit. In order to impose some discipline on the Committee (in terms of number of face-to-face meetings) and to enable accountability (including in terms of resources allocated to support the work of the Committee), it is intended that at the beginning of each year the Chairperson and the Regulator will agree on the maximum number of face-to-face meetings that will be held that year. Work proposals and work plans will be prepared based on the proposed meeting timetable. This enables members to plan their calendars so as to be available for meetings and minimise the need for a member to apply for leave or be absent. The Committee may not meet face-to-face more times than is agreed (or at all if there is no agreement). If the agreed number of face-to-face meetings is not adequate to enable the Committee to properly consider the issues before it, the Chair and the Regulator may agree that additional meetings be held (beyond those agreed in the workplan). The Chair may also direct the Committee to hold meetings and resolve issues by teleconference or videoconference or to meet out of session. ‘Out of session’ is defined in the Regulations as a meeting in which members take part in the meeting by means of correspondence, electronic mail, telephone or any other method that does not involve simultaneous meeting and voting by GTEC.

• This Regulation ensures that the Regulator's responsibility for managing the budget of the Office of the Gene Technology Regulator is balanced with the activities of the GTEC.

• The Chairperson must preside at all GTEC meetings or appoint another member to preside. Any member who is so appointed to act as presiding Chairperson must be appointed in writing and must not be a member of any of the other committees established under the provisions of the GT Act. This ensures total independence of the Chairperson and prevents the possibility of cross interests of members improperly affecting the deliberations of the Committee. It is, intended that, when the Chairperson is present at a meeting of GTEC, the Chairperson will, in usual circumstances, be the presiding member. If there are occasions when the Chairperson will be temporarily absent from a meeting, those members who are present at the meeting must choose a member who is present to preside over the meeting for the duration of the Chair's absence. This provision ensures that the business of the GTEC will not be hindered or stopped by the temporary non-availability of the appointed Chairperson.

• A quorum for a meeting of GTEC exists if half of those members who have been appointed are present at the meeting. The GT Act provides that the Minister shall appoint up to 12 members to the GTEC.

• A decision of GTEC will be carried by a majority of the members present and voting for the motion. If the Chairperson nominates a member to preside or a member has been appointed to preside over the meeting in the temporary absence of the Chairperson, that member has a deliberative vote and a casting vote in the event of a vote being tied (otherwise the Chairperson has a deliberative vote and a casting vote in the event of a vote being tied).

• A record of all proceedings must be kept by the GTEC and a copy of every resolution passed by the GTEC must be provided to the Regulator. The Regulator must keep copies of all resolutions of the Committee and make them available to the public, for example, by posting them on the Regulator's website or by including them in the quarterly reports to be issued by the Regulator in accordance with the GT Act. Resolutions which contain information that the Regulator considers is confidential commercial information will be excluded from public access. This ensures that the activities of GTEC are made known to the Regulator and all decisions of GTEC are available to the public while safeguarding confidential commercial information. It also ensures that GTEC must report on its activities to the Regulator thus enabling the Regulator to provide comprehensive periodic reporting.

36. GTEC – operation of subcommittees

This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 36 of the Commonwealth Regulations states;

Regulation 36 establishes the procedures and rules for the operation of subcommittees of GTEC which may be set up under section 116 of the GT Act.

This Regulation establishes:

a) the procedures under which a subcommittee must operate;

b) the arrangements for the conduct of a subcommittee meeting;

c) the requirement that the Chairperson must preside at a meeting (or if absent, appoint a member to preside); and

d) the procedures for voting at a subcommittee meeting.

The procedures for subcommittees are intended to reflect as far as possible, the procedures for GTEC. In this regard:

• A subcommittee must act in accordance with these Regulations, as informally and as quickly as due and proper consideration of the issues put before it permits. The subcommittee may obtain further information in any way that it considers appropriate. The scope of the information which may be sought will be limited by any directions issued by the Regulator or Ministerial Council. It is intended that such directions will specify the extent to which or the manner in which such information may be obtained.

This Regulation ensures that the subcommittee functions properly in accordance with the provisions of the GT Act and these Regulations, efficiently and consistently with GTEC procedures while safeguarding the interests of applicants, the GTEC and the subcommittee.

• The Chairperson of the subcommittee may direct the subcommittee to hold meetings. As is the case for GTEC, it is intended that the Chair of the subcommittee will agree with the Regulator, at the beginning of the year, a maximum number of face-to-face meetings to be held that year. Details of such meetings will be notified to the subcommittee by the Chairperson in writing and will specify the time, place and matters for consideration. Meetings may be conducted by means of video conference or teleconference if the Chairperson considers such forums to be appropriate and efficient. Any such meetings held by videoconference and teleconference may discuss and resolve issues as if such meetings were held as face-to-face meetings. The Chairperson may also arrange meetings out of session. ‘Out of session’ is defined in the Regulations as a meeting in which members take part in the meeting by means of correspondence, electronic mail, telephone of any other method that does not involve simultaneous meeting and voting of the members.

• The Chairperson must preside at all subcommittee meetings or appoint another member to preside. A member who is appointed to act as presiding Chairperson must be appointed in writing and must not be a member of any other committees established under the provisions of the GT Act. This

ensures the independence of the position of the Chairperson of the subcommittees and prevents the possibility of cross interests from other subcommittees improperly affecting the deliberations of other subcommittees. If there are occasions when the Chairperson will be temporarily absent from a meeting, those members who are present at the meeting must choose a member who is present to preside over the meeting for the duration of the Chairperson's absence. This ensures that the business of the subcommittee will not be hindered or stopped by the temporary non-availability of the Chairperson.

- A decision of the subcommittee will be carried by a majority of the members present and voting for the motion. If the Chairperson has nominated a member to preside, or if a member has been appointed to preside over the meeting in the temporary absence of the Chairperson, that member has a deliberative vote and a casting vote in the event of a vote being tied (otherwise the Chairperson has a deliberative vote and a casting vote in the event of a vote being tied).

- A quorum exists if half of the members of the subcommittee are present.

- The subcommittees must keep records of their proceedings and must give a copy of each resolution passed by them to the GTEC. This ensures that the GTEC is kept up to date on the activities and resolutions of the subcommittees (if any).

Part 7– Miscellaneous

37. Reviewable state decisions
This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 37 of the Commonwealth Regulations states;

This Regulation anticipates that at some time in the future a list of reviewable State decisions (under section 19 of the GT Act) may be included against this Regulation. However, at the commencement of these Regulations, no such decisions are recorded. This is because at the time of commencement of these Regulations, no State or Territory will have a corresponding State law in place (prescribing that decisions made by the Regulator in performance of a function or power conferred under a corresponding State law are reviewable State decisions).

38. Review of decisions
This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 38 of the Commonwealth Regulations states;

This is a technical provision which clarifies that if the Minister terminates the appointment of a member, or expert adviser, to a committee, the Minister must give the person a notice of the decision. Information must also be provided about the person's right to have the decision reviewed by the Administrative Appeals Tribunal (AAT). If the member or adviser is dissatisfied with the decision, they may then apply to the AAT to have the decision reviewed by the AAT.

39. Record of GMO and GM Product dealings

Regulation 39 sets out the information that must appear on the Record of GMO and GM Product Dealings (the Record) about notifiable low risk dealings that are notified to the Regulator and GM products. This information is in addition to the information that must be included on the Record in relation to each licence issued by the Regulator, as required by section 138 of the Act.

This Regulation provides that the Record must contain the following information about all notifiable low risk dealings that are notified to the Regulator:

• the name of the organisation proposing to undertake the notifiable low risk dealing;

• the kind of notifiable low risk dealing proposed, by reference to the descriptions in Part 1 of Schedule 3; and

• the identifying name given to the proposed undertaking by the organisation (that is, the project title of which the dealing is a part); and

• the date of the notification of the dealing to the Regulator.

This Regulation also sets out the information that is required to be placed on the Record in respect of GM products notified to the Regulator by other regulators such as the Australia New Zealand Food Authority (ANZFA), the National Registration Authority, the Therapeutic Goods Administration and the National Industrial Chemicals Notification and Assessment Scheme.

In respect of such GM products, the Record must include:

• the name of the organisation producing the GM product;

• a description of the GM product by reference to the relevant legislation under which the GM product was approved (for example, whether it is a therapeutic good approved under the Therapeutic Goods Act 1989);

• a description of the GM product by reference to its common name as a product, or type or class of product (for example, vegetable oil);

• information about the GM product including:

- the common name and the scientific name of the parent organism involved;

- details of the introduced trait in the GM product; and

- the identity of the introduced gene responsible for conferring the introduced trait.

• the date on which the decision of the other regulator (for example, ANZFA) enabling supply of the GM product in Australia, takes effect; and

• details of any conditions attaching to the decision from the other regulator (for example, labelling conditions in the case of food products).

The Record will be made publicly available (including on the Regulator's website) and will be a comprehensive listing of all GMOs and GM products approved in Australia.

40. Inspector identity card

This provision is included for the purpose of formal consistency with the Commonwealth legislation. The Gene Technology Act 2003 defers to the Commonwealth Act in relation to this section.

The Commonwealth Explanatory Memorandum for Regulation 40 of the Commonwealth Regulations states;

Regulation 40 prescribes additional information that must be included on identity cards carried by inspectors. The additional information on the card (photograph of the investigator's face, date of issue and expiry date) enables the cardholder's identity and authority to act as an Inspector to be readily ascertained and verified by someone to whom it is shown.

Part 8– Transitional

41. Existing facilities – certification

Regulation 41 is a transitional provision which enables some facilities, that have been approved by the GMAC in the period leading up to the commencement of the Act, to be automatically certified for the purposes of the Act upon commencement of the Act. This enables existing, operational facilities, that already meet certain containment requirements, to continue to operate (for a limited period of time) without having to obtain certification immediately upon commencement of the Act.

This Regulation "deems" certain facilities to be certified under section 84 of the Act, if prior to the commencement of Part 7 of the Act, the GMAC has issued a notice that the facility provides a particular containment level.

The 'deemed' certification will be:

• to the level of containment described in the GMAC notice; and

• effective for up to 2 years from the commencement of the Regulations in the case of facilities certified to PC2,excluding PC2 Large Scale facilities-defined in Subregulation (3), and, for up to one year from commencement of the Regulations for all other facilities; and

- subject to sections 86 (b) and (c), 87 and 88 of the GT Act. This is intended to ensure that the Regulator can vary, suspend or cancel a 'deemed' certification by notice in writing.

The different time frames for review of deemed certification ensure that different contained facilities are reviewed at rates that reflect the nature of the dealings conducted within them and the level of risk or potential risk posed to public health and environmental safety.

42. Existing organisations – accreditation

Regulation 42 provides that organisations currently undertaking dealings with GMOs that receive a notice from the GMAC that they are an accredited organisation, will be "deemed" to be accredited for the purposes of section 92 of the GT Act, upon commencement of the Act. This Regulation enables organisations that already meet certain criteria for accreditation (including because they already have an Institutional Biosafety Committee or have access to another organisation's Institutional Biosafety Committee), to continue to operate without having to obtain accreditation from the Regulator following commencement of the Act.

This Regulation also places a number of conditions and limitations on the "deemed" accreditation. Firstly, the "deemed" accreditation is only effective for up to two years (subject to being suspended or cancelled by the Regulator). During the two year transitional period, all organisations must reapply for accreditation in accordance with criteria set down by the Regulator in Guidelines for Accreditation.

This Regulation also provides that the Regulator is able to vary, suspend, cancel or impose other conditions in respect of a 'deemed' accreditation, under sections 94(b) and (c), 95 and 96 of the Act.

In accordance with the standard ACT drafting practice of sunsetting provisions that are only to operate for a fixed period, s88 of the Legislation Act (ACT) 2001 applies to this regulation. In effect this Regulation expires 2 years from the day the Regulations come into operation.

Schedule 1 – Organisms that are not genetically modified organisms

Part 1.1 Organisms

This Part provides a description of the organisms that are not deemed to be GMOs under the Act. Dealings with these organisms do not require licensing by the GTR.

Part 1.2 Species known to exchange DNA by a known physiological process

This Part provides a description of the organisms that are know to exchange DNA by a known physiological process. Dealings with these organisms do not require licensing by the GTR.

Schedule 2 - Dealings exempt from Licensing

Part 2.1 – Exempt dealings

This Part sets out the dealings with certain GMOs that are exempt under the *Gene Technology Act 2002*. Dealings with GMOs that are exempt do not require licensing by the GTR.

The exemptions apply to a limited number of dealings with GMOs that:

- have been assessed over time as presenting no significant biosafety risks to public health and safety (including occupational health and safety) or the environment; and
- are undertaken within contained facilities (that is, they do not involve intentional release of a GMO into the environment).

Part 2.2 – Host/vector systems for exempt dealings

This Part of the Schedule must be read in conjunction with Part 2.1 of the Schedule which describes each of the dealings that are exempt from the regulatory system.

A number of these exemptions, rely on the dealings utilising certain host/vector systems. The relevant host/vector systems are described in this part of the Schedule.

Part 2.3 – Definitions

This Part sets out some of the words and terms that are used in Part 2.1 of the Schedule (Exempt dealings). The terms that have been defined are terms that may have different definitions in everyday usage to those used in biotechnology.

For example, the word “characterised” has a common dictionary meaning but the meaning in relation to DNA is quite different. As such, the meaning that is to be used by a reader when reading the Schedule has been spelt out in this Part.

Schedule 3 – Notifiable low risk dealings in relation to a GMO

Part 3.1 – Dealings that are notifiable low risk dealings

This Part of the Schedule sets out those dealings that are “notifiable low risk dealings”. The only dealings that have been included on the list of notifiable low risk dealings are those that:

- have been assessed over time as presenting minimal biosafety risks where such risks can be properly managed through containment of the GMO in a laboratory certified to Physical Containment Level 2. For example, some of the factors considered in assessing a GMO to be of low risk (with the low risk able to be managed through containment measures) include the extent to which the GMO is ‘biologically contained’ (because it has a reduced ability to survive or reproduce

without human intervention) and the properties of the GMO including the inability of the GMO to be a pathogen or pest or produce toxic proteins; and

- do not involve the intentional release of a GMO into the environment.

Part 3.2 – Dealings (higher risk) that are not notifiable low risk dealings

This Part of the Schedule must be read in conjunction with Part 3.1 of the Schedule which describes each of the dealings that are notifiable low risk dealings.

A number of the dealings mentioned in Part 3.1 are notifiable low risk dealings provided they are not **also** dealings that fall within the list of dealings mentioned in this Part of the Schedule. If the dealings fall within Part 3.1 of the Schedule but also fall within Part 3.2 of the Schedule, then the dealing is not a notifiable low risk dealing and the proponent must apply to the GTR for a licence to deal with the GMO in the manner proposed.

Part 3.3 – Prescribed information – notification of proposed notifiable low risk dealing

As mentioned in the explanation of regulation 13, the requirements which must be satisfied before work with a notifiable low risk dealing may proceed include:

- the applicant must prepare information about the proposed dealing;
- the applicant must submit the information to the IBC for consideration; and
- the IBC must consider the proposal and submit the applicant's information and the IBC's assessment to the GTR.

This Part of the Schedule sets out all of the information that must be provided, by way of notification, to the GTR.

For example, the GTR must be provided with:

- general information (including their contact details, a description of the
- project, the premises where the dealing is proposed to be undertaken and the
- date of commencement of the dealings);
- information about the genetics of the GMO (including information about the biological system intended to be used);
- risk assessment information (including details of the possible risks posed by the dealings with the GMO); and
- risk management information (including how the GMO will be physically contained. This is important because it is a requirement that all

notifiable low risk dealings must be undertaken in facilities certified to a minimum of Physical Containment Level 2);

Once the IBC has considered the proposal, they must prepare a report, to be provided to the GTR, in accordance with this Schedule of the regulations. For example, the IBC must:

- confirm that the information to be given to the GTR has been checked by the IBC and found to be accurate;
- confirm that the IBC considers that the personnel proposed to undertake the dealing have adequate training and experience; and
- provide an evaluation of the proposal.

It should be noted that the regulations set out the minimum information requirements to be provided by people proposing to undertake notifiable low risk dealings. If the GTR is dissatisfied with the information that he/she receives by way of notification or seeks any further information or clarification of matters, the GTR may seek such information from the applicant or the IBC.

Schedule 4 – Prescribed information – application for a licence

The Schedule sets out very comprehensive data requirements to ensure that the GTR has all of the information before him/her that is necessary to make a comprehensive assessment of the proposal. The GTR may also request any additional information from the applicant at any time.

Part 4.1 – Dealings not involving an intentional release of a GMO into the environment (Division 5.3 of the Act)
This Part sets out the information that an applicant must provide to the GTR in support of an application for a licence to undertake dealings not involving an intentional release of a GMO into the environment.

Part 4.2 – Dealings involving an intentional release of a GMO into the environment (Division 5.4 of the Act)
This Part sets out the information that an applicant must provide to the GTR in support of an application for a licence to undertake dealings involving an intentional release of a GMO into the environment.

The Part sets out:

- information that must be provided by all applicants. For example, all applicants must provide:
  - general information including the name and contact details of the applicant and a description of the GMO proposed to be dealt with;
  - risk assessment information including:
    - information about the parent organism. For example, details of whether the parent organism is capable of

causing disease or other ill-health in humans, plants or animals and, if so, the possible effects;

- information about the GMO. For example, details of the genetic modification that has been made, including detail of the steps undertaken in its construction;
- information about the dealings with the GMO. For example, description of the proposed dealing, or dealings, with the GMO, or GMOs, including a description of the proposed intentional release into the environment;
- information on the interaction between the GMO and the environment. For example, details of whether the GMO is likely to be able to establish in the open environment outside the release site(s); and
- information about any risks the GMO may pose to public health and safety.

➢ risk management information including;

- information about previous assessments or approvals. For example, if the GMO has been previously released either within or outside Australia, information about any beneficial or adverse consequences of the release including references and reports of assessments; and
- information about the suitability of the applicant. For example, details of qualifications, experience and role of personnel involved with the release of the GMO.

- additional information may be required of an applicant depending on the particular type of GMO proposed to be used.