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

Explanatory Information

Certification of Physical Containment Facilities

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INDEX

Definitions

Unless defined otherwise in this document, words and phrases used in this document have the same meaning as in the *Gene Technology Act 2000* (the Act) and the Gene Technology Regulations 2001 (the Regulations).

Words in the singular include the plural and words in the plural include the singular. Where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning.

anteroom	An area or room between a pair of doors through which access is gained to the work area inside a facility. The anteroom must not be used for performing any dealings other than transport of GMOs.
dealings or deal with	In relation to a GMO, means the following: (a) conduct experiments with the GMO; (b) make, develop, produce or manufacture the GMO; (c) breed the GMO; (d) propagate the GMO; (e) use the GMO in the course of manufacture of a thing that is not the GMO; (f) grow, raise or culture the GMO; (g) import the GMO; (h) transport the GMO; (i) dispose of the GMO; and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (i).
DIR	Dealing involving intentional release of a GMO into the environment.
DNIR	Dealing not involving intentional release of a GMO into the environment.
environment	Includes: (a) ecosystems and their constituent parts; (b) natural and physical resources; and (c) the qualities and characteristics of locations, places and areas.
facility	The whole of the space that is to be certified by the Regulator to a specific level of containment.
GM	Genetically modified.
GMO	Genetically modified organism.
NLRD	Notifiable Low Risk Dealing.
PC	Physical Containment Level.

PART 1 – INTRODUCTION

Governing legislation

1.1 The Commonwealth Act and the Commonwealth Regulations, together with corresponding state legislation, provide the legislative foundation for Australia's national scheme laws for the regulation of gene technology.

1.2 The objectives of the national scheme laws are to protect the health and safety of people, and to protect the environment, by identifying risks posed by, or as a result of, gene technology, and by managing those risks by regulating certain dealings with GMOs.

1.3 The national scheme laws prohibit dealings with GMOs unless appropriately authorised. They establish a statutory officer, the Gene Technology Regulator (the Regulator), whose role is to administer these laws. Part of the Regulator's role includes responsibility for promoting compliance with the laws, and prosecuting non-compliance.

1.4 Under the provisions of the legislation, certain dealings with GMOs must be conducted within physical containment facilities.

1.5 Section 90 of the Act provides for the Regulator to "issue technical or procedural guidelines about the requirements for the certification of facilities to specified containment levels". Containment levels in these guidelines are referred to as 'physical containment levels' and are aligned as closely as possible to the physical containment levels described in AS/NZS 2243.3[1].

1.6 Section 84 of the Act provides for the Regulator to issue a written instrument certifying a facility to a specified containment level provided the facility meets the requirements specified in the guidelines issued under section 90.

1.7 Section 86 of the Act provides that the certification of a facility is subject to:

- any conditions imposed by the Regulator at the time of certification;
- any conditions imposed by the Regulator in varying the certification under section 87 after certification; and
- any conditions imposed by the Regulations.

Purpose of certification

1.8 The purpose of certification is to satisfy the Regulator that the containment facility has the capacity to:

- prevent release of GMOs into the environment;
- protect persons outside the facility from exposure to GMOs; and
- protect the safety of people working with GMOs inside the facility.

Certification and dealings with GMOs

1.9 A licence for a DNIR will usually require the dealing to be conducted in a facility certified by the Regulator against the relevant certification guidelines for the physical containment level and facility type necessary to contain the dealing.

1.10 Dealings that are NLRDs mentioned in Part 1 of Schedule 3 of the Regulations, as in force from 26 September 2011, must be undertaken in a facility certified by the Regulator to at least PC level 1.

[1] Australian/New Zealand Standard 2243.3 *Safety in laboratories Part 3: Microbiological aspects and containment facilities*.

1.11 Dealings that are NLRDs mentioned in 2.1 of Part 2 of Schedule 3 of the Regulations, as in force from 26 September 2011, must be undertaken in a facility certified by the Regulator to at least PC level 2.

1.12 Dealings that are NLRDs mentioned in 2.2 of Part 2 of Schedule 3 of the Regulations, as in force from 26 September 2011, must be undertaken in a facility certified by the Regulator to at least PC level 3.

1.13 Regulation 13(2)(c) also provides for NLRDs to be conducted in a facility that the Regulator has agreed in writing is a facility in which the dealing may be undertaken. The usual and anticipated place for the conduct of NLRDs is a certified facility. The certification process applies a suite of conditions related to the facility structure, fittings and equipment, as well as training requirements for persons authorised to enter and conduct dealings in the facility. These conditions, together with the provisions of regulation 13, provide assurance that the GMOs will not be released into the environment.

1.14 Sometimes, dealings authorised by DIRs may also be required to be conducted in certified facilities.

1.15 Guidance on the types of dealings that can be conducted in the various PC levels and facility types is contained in the *Guide to Physical Containment Levels and Facility Types*, available from the OGTR website <www.ogtr.gov.au> or from the OGTR.

Contents of the certification guidelines

1.16 The certification guidelines contain the requirements that the Regulator takes into account when certifying different types of facilities to specified containment levels.

Limits to coverage of the certification guidelines

1.17 The certification guidelines only include requirements that contribute to achieving the objectives of the Act with respect to dealings with GMOs that require containment in physical containment facilities. They do not provide comprehensive coverage of laboratory design and construction.

1.18 It is anticipated that facility management and staff will be operating their facilities and conducting their work practices in accordance with relevant work health and safety legislation. In addition, it is assumed that people working with micro-organisms in certified facilities will use good microbiological practices and that the construction of facilities will meet the requirements of relevant jurisdictional authorities.

1.19 For guidance on whether there is a need to comply with any other regulatory requirements, certification holders should refer to all other relevant legislation applicable in the jurisdiction in which the facility is located.

1.20 For further guidance on the comprehensive details of laboratory design and construction, biological safety, laboratory safety, and broader occupational health and safety issues, certification holders may like to refer to AS/NZS 2982.1[2] and AS/NZS 2243.3.

Relationship between the certification guidelines and AS/NZS 2243.3

1.21 It is considered that AS/NZS 2243.3 is a national benchmark for the control and containment of micro-organisms, for good laboratory work practices, for guidance on work health and safety issues affecting laboratory personnel, and for guidance in the design of containment facilities for micro-organisms.

[2] Australian New Zealand Standard 2982.1 - *Laboratory design and construction Part 1: General requirements.*

1.22 The guidelines for each facility type and PC level contain the minimum set of requirements that the Regulator considers fulfil the objectives of the Act with respect to the physical containment of GMO dealings.

1.23 Therefore, many of the physical requirements detailed in AS/NZS 2243.3 have not been included in the Regulator's certification guidelines, along with requirements for facility construction in AS/NZS 2982.1 that is referenced by AS/NZS 2243.3.

1.24 Where a certification requirement is included in the certification guidelines and also in AS/NZS 2243.3, the requirements in the certification guidelines are intended to harmonize as closely as possible with AS/NZS 2243.3. However, they have been drafted in a style that enables enforcement under the Act, and provisions have been included for the purposes of administration of the certification process under the Act.

1.25 AS/NZS 2243.3 is specifically intended for work with micro-organisms in laboratories. The Regulator also issues guidelines for facility types not covered by AS/NZS 2243.3, particularly for the containment of GMOs that are not micro-organisms.

1.26 It is not intended that compliance with the requirements of the Regulator's certification guidelines would imply that a facility is compliant with AS/NZS 2243.3.

1.27 Likewise, compliance with the requirements of AS/NZS 2243.3 does not circumvent the need to apply to the Regulator for certification. However, any documentation or evidence of compliance with requirements of AS/NZS 2243.3 that relate to a requirement in the certification guidelines for a relevant facility type and PC level may be considered as part of the process of evaluating an application for certification. Applicants who have such documentation or evidence are welcome to discuss their application with the OGTR before submitting it.

Compliance with other regulatory agencies

1.28 Where a containment facility is jointly regulated by another regulatory agency (for example, DAFF Biosecurity) there is potential for confusion about compliance with multiple regulatory requirements and a conflict of requirements.

1.29 As far as is practicable, the requirements in the certification guidelines aim to harmonize with those of other agencies. However, different legislative requirements make it necessary for each agency to approve the facility to meet the objectives of their respective governing legislation.

1.30 Differing administration of the regulatory agencies may also result in different floor areas, rooms or buildings being approved rather than an exact, one to one, corresponding approval.

1.31 In the event of any real or apparent conflict of requirements, applicants are welcome to contact the OGTR to discuss the situation prior to making the application. Alternatively, the application can include information about the conflict and any proposal to manage any risks associated with such a conflict.

Compliance with other legislation

1.32 Where there is a conflict between the requirements of the certification guidelines and other general legislative requirements, for example the requirements of State legislation in the State in which you are operating, the matter should be discussed with the OGTR.

PART 2 – HOW TO GET A FACILITY CERTIFIED

Applying for certification

2.1 Under section 83 of the Act a person may apply, in writing, to the Regulator for certification of a facility. Application proformas can be obtained from the OGTR or downloaded from the OGTR website.

Choosing the physical containment level and facility type

2.2 The certification guidelines establish four levels of containment, listed here in ascending order of the stringency of containment requirements, reflecting the level of risk:

- Physical Containment Level 1 (PC 1)
- Physical Containment Level 2 (PC 2)
- Physical Containment Level 3 (PC 3)
- Physical Containment Level 4 (PC 4)

2.3 These levels are intended to align as closely as possible with the Physical Containment Levels described in Section 3 of AS/NZS 2243.3.

2.4 There are also several types of facilities intended to contain different types of organisms and dealings (micro-organisms, plants, animals, etc.).

2.5 Applicants will be required to indicate on the application form the PC level and the type of facility to be certified.

2.6 The *Guide to Physical Containment Levels and Facility Types* provides details of the PC levels in relation to the regulation of gene technology and describes the types of dealings that can be conducted in each facility type. This guide is available from the OGTR website <www.ogtr.gov.au> or from the OGTR.

Confidential commercial information

2.7 The Act provides that a person may apply to the Regulator for a declaration that specified information is confidential commercial information (CCI) for the purposes of the Act.

2.8 The Act sets out the matters about which the Regulator must be satisfied before declaring that certain information is confidential commercial information.

2.9 The applicant must satisfy the Regulator that the information specified in the application is:

- a trade secret; or
- any other information that has a commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed; or
- other information that concerns the lawful commercial or financial affairs of a person, organisation or undertaking, and if it were disclosed, could unreasonably affect the person, organisation or undertaking.

2.10 The Regulator may refuse to declare that the information is confidential commercial information if the Regulator is satisfied that the public interest in disclosure outweighs the prejudice that the disclosure would cause to any person.

2.11 Details of facilities that have been certified are not included on the public Record of GMO Dealings and GM Products.

2.12 Each piece of information (for which the organisation seeks protection) must be detailed in an application for a declaration of CCI and the criteria detailed in the Act must be met for each piece of information. An application for the declaration of CCI may be obtained from the OGTR or downloaded from the OGTR website.

Requirements to be met before the application for certification can be approved

2.13 A facility may be certified if the Regulator is satisfied it meets the containment requirements set out in the certification guidelines. The specific requirements for the certification of each facility type at each different PC level are set out in individual guidelines.

2.14 All facilities must be inspected to assess compliance with the requirements for certification and to assess the ability to comply with the usual conditions that will be applied to the certification.

2.15 Staff from the OGTR will usually conduct the inspection of the following facilities for the Regulator, prior to certification:

- PC 2 Large Scale facilities; and
- all PC 3 and PC 4 facilities.

2.16 Inspection of all other facilities must be inspected by a person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skill enabling that person to assess compliance with the requirements for certification of a physical containment facility. The applicant is responsible for choosing an appropriate person to do the inspection. The inspection could be conducted by, for example, an IBC member, a contractor, an independent expert, an employee, or anyone else considered by the organisation to be appropriate. The OGTR does not provide any endorsement of any individuals or organisations to conduct inspections, and keeps no details of appropriate persons or organisations.

2.17 Inspection checklists are not mandatory for all facility types. They must be submitted with applications for PC 2 Large Scale facilities and all PC 3 and PC 4 facilities.

2.18 For all others, checklists may be used if convenient. Proforma checklists for each PC level/facility type are available from the OGTR or can be downloaded from the OGTR website.

2.19 Applicants may choose to use a different format for inspection reports for the facilities that require submission with the application, but the inspection report must address each of the requirements for certification of the relevant PC level/facility type.

Floor plans

2.20 Floor plans or diagrams of the layout of the facility must be submitted with all applications for certification. A formal floor plan is preferred. If a formal floor plan is not able to be provided, an alternative plan must show sufficient details to enable the OGTR to evaluate whether the facility has the required physical barriers. At the minimum, the floor plan should show allocated room numbers (if room numbers exist) and all doorways and doors in the facility.

2.21 If certification of a whole building, or the majority of the building, is being sought, the entire floor plan will be required. If certification is sought for one or more rooms within a larger area, the plan or sketch must show the boundary of the facility (doors and walls) as well as any adjoining corridors and their doors.

2.22 If there are any lifts, stairs or ramps between levels (inside the building), or openings into the facility or adjoining areas/corridors, they must be indicated as they may have a significant bearing on the approval of the application.

2.23 When applying for certification of facilities that require anterooms or airlocks the anteroom(s)/airlocks(s) must be clearly indicated. In relevant PC 2 facilities, if an adjoining corridor or another certified or non-certified room is proposed to perform the function of an anteroom, the floor plan must show all doors, lifts, stairs or ramps, and any other relevant details that may compromise the functioning of the corridor or room as an anteroom.

Supporting information must also be supplied to indicate any risks that might arise from using the adjoining corridor or other room as the anteroom. If there is any doubt about this, it is recommended you contact the OGTR to discuss your proposal prior to submitting the application.

What to do if the requirements cannot be met or do not apply to the facility

2.24 There may be circumstances where a specific requirement or proposed usual condition for a PC level/facility type may not be applicable. Where facility design or proposed work practices can be shown to provide the necessary containment or risk management for the dealings to be conducted in that facility, a request for an exemption from the requirement or condition in question may be made on the application form. Applicants are welcome to discuss the proposal with the OGTR prior to completing the application.

2.25 A request for exemption from a particular requirement or condition must be supported with information explaining the reason for the request and the proposed risk management strategy that will apply in place of the requirement for which the exemption is requested. If the Regulator approves the request, conditions may be imposed on the certification relating to the exemption. Such conditions might, for example, restrict the types of dealings that can be conducted in the facility, or include the imposition of additional physical containment and/or procedural requirements.

Certification conditions

2.26 As in the case of the certification requirements, there may be some conditions that are not necessary or appropriate to the particular facility or proposed dealings. Applicants are able to provide information on the application form explaining how the necessary containment or risk management for the dealings to be conducted in that facility will be provided to manage any risks posed by non-compliance with the condition.

2.27 This information will be taken into account in evaluating the application and in determining the conditions that will be imposed on the certification, if approved.

2.28 Applicants are welcome to discuss any questions they have about certification conditions with the OGTR.

Assessment of applications for certification of facilities

2.29 The Regulations require that applications for certification are decided within 90 working days of receipt of the application, unless the period is extended because the Regulator has sought additional information from the applicant.

2.30 When applications for certification of PC 1 Large Scale facilities, PC 2 Large Scale facilities, PC 3 facilities or PC 4 facilities are made, the Regulator usually requires inspection by staff from the OGTR. These inspections are conducted prior to a decision on the certification application.

Notification of decision

2.31 If the application is approved, the Regulator will issue a certification instrument that includes details of the facility, the period for which the facility is certified and the conditions of the certification.

2.32 If the application is not approved, the Regulator will write to the applicant detailing the terms of the decision, the reasons for the decision and a statement setting out the applicant's review rights with respect to the decision.

PART 3 – HOW TO MAINTAIN A CERTIFICATION

Compliance with conditions of certification

3.1 Conditions are imposed on facilities by the Regulator at the time of certification, pursuant to section 86 of the Act. The condition clauses that can be expected, in most cases, to be included in the certification instrument are attached to the relevant guidelines.

3.2 The conditions of certification must be complied with at all times during the period for which the facility is certified. In all cases it is the responsibility of the holder of the certification to ensure compliance with the conditions of certification.

3.3 Prior to any significant structural changes that will affect the containment of GMOs in the facility, the applicant must either:

- request a suspension of the certification, in writing, from the Regulator; or
- for PC 1 or PC 2 facilities, request a variation to the conditions of certification in writing, from the Regulator, to allow dealings to continue in a part of the facility unaffected by the structural changes. Such a variation may, for example, temporarily partition the facility to provide containment for GMOs at one end while the other end is being modified.

3.4 Before a suspension of the certification can be lifted, or the variation reversed, the facility must be inspected by a person qualified to assess the facility's compliance with the conditions of certification. Dealings with GMOs must not recommence in a facility that has its certification suspended until the Regulator has lifted the suspension by notice in writing.

3.5 In the case of a variation, as described in the example above, dealings must not be conducted in a part of the facility that has been excluded from the facility by variation, until the Regulator approves a further variation to allow the resumption of dealings in that part of the facility.

3.6 For PC 3 & PC 4 facilities an inspection by officers of the OGTR or an independent expert must be conducted after the completion of work on the facility prior to lifting of a suspension.

Behavioural requirements

3.7 A clause has been included in the conditions of certification to provide for the Regulator to require the certification holder to exclude a person, or a class of person, from a facility, if the person, or class of person:

- has behaved, or is behaving, in a manner that has caused, or that may cause, GMOs to escape from a facility; or
- has behaved, or is behaving, in a manner that has exposed, or exposes, other persons in a facility to a GMO in circumstances where the exposure causes, or is capable of causing, a threat to the health and safety of those other persons.

3.8 Exclusion of a person, or class of person, from a facility is a measure to ensure that the ongoing containment capacity of the facility or the safety of others in the facility is not compromised by the behaviours of persons in the facility..

3.9 However, for the purposes of determining whether or not a person, or class of person, has behaved in a manner that compromises containment or the safety of others in a facility, the Regulator may give consideration to the particulars of any behaviour that has compromised, or may compromise, the containment capacity of the facility or the safety of its occupants. This consideration may be given whether or not the specific behaviour in question is covered in the 'Behavioural Requirements' attached to the conditions.

3.10

This is because the Regulator accepts and recognises that:

- researchers typically behave in a responsible manner that generally will not compromise the capacity of a facility to contain GMOs or the safety of others in the facility; behaviour that differs from that recommended in the training will not always be a hazard to others or the environment, or lead to a loss of the containment of the GMOs; and, conversely,
- behaviour that threatens the containment of the GMOs or the safety of others will not always be able to be listed in a finite set of behaviours.

3.11 Exclusion of a person, or class of person, may not necessarily affect the ongoing authority of an organisation or a licence holder to continue to conduct dealings authorised under the Act. The dealings may continue to be conducted by other persons authorised to enter the facility. For example, in the case of a licence, if a person covered by the licence is excluded it would be appropriate for an organisation to nominate another person covered by the licence.

3.12 In cases where behaviour leads to concerns for the effective containment of the GMOs, ongoing admission of a person to a facility may be restricted, subject to conditions imposed by the Regulator.

3.13 The Regulator will usually not require the certification holder to exclude, or impose conditions of entry on, a person, or class of person, without giving the certification holder notice and an opportunity to comment on why the person, or class or person, should not be excluded, or have conditions imposed on their entry, unless the immediate exclusion of the person, or class of person, is necessary to protect the health and safety of people or to protect the environment.

3.14 It is also a condition of the certification that the certification holder ensure that access to a facility is confined to persons who are trained in a specific set of behaviours appropriate to the facility itself and the dealings being conducted in that facility.

3.15 It is a matter for the certification holder to determine whether or not the person already has adequate training in the behaviours as they apply to that facility. For example, a person covered by a licence may have already had the relevant training by the licence holder pursuant to a condition in the licence. If satisfied that this training meets the certification obligation, the certification holder may accept a signed and dated statement, stating that they have the relevant training, from a person as a record that the training has been undertaken. Where the relevant training has not occurred, the person must undergo training before being admitted into the facility to undertake dealings. The certification holder or other suitably qualified person may provide the relevant training.

Variation of certification conditions requested by the certification holder

3.16 A certification holder may request a variation to the certification in writing (letter, e-mail or fax).

3.17 A common reason for seeking a variation is when facilities are renovated, as discussed above. Other common reasons include when rooms are to be added or removed from suites of rooms covered by a single certification, when there is a change to the name of a certified facility, or when there is a change in the nature of the dealings that may result in different work practices.

3.18 Certification holders are welcome to contact the OGTR to discuss what is required before applying for a variation. Alternatively, the written application for the variation can include information about the proposed changes affecting compliance with the conditions.

3.19 In cases where renovations are undertaken or changes have been made to the room configurations to be covered by the certification, it is most likely the OGTR will need to see

revised floor plans. A new inspection report checklist may be requested for PC 2 Large Scale facilities, PC 3 facilities and PC 4 facilities. For other PC 1 and PC 2 facilities, only written confirmation that the facility complies with the conditions of certification is required.

Variation of certification conditions initiated by the Regulator

3.20 The Act provides that the Regulator may vary the certification at any time by notice in writing given to the certification holder. The variation may entail imposing additional conditions or removing or varying conditions that were previously imposed by the Regulator.

3.21 Before the Regulator can initiate the variation of a certification, the Regulator must give written notice of the proposed variation to the certification holder. The notice may request relevant information from the certification holder and may invite a written submission from the certification holder. If a written submission is invited the Regulator's notice must specify a time period within which the certification holder may make the submission. The Regulator must consider any written submissions made.

3.22 The requirement that the Regulator provide prior notice of the variation to the certification holder may be waived where the Regulator considers that the action is necessary to avoid an imminent risk of death, serious illness and/or serious injury to any person/s or serious damage to the environment.

Suspension or cancellation of certification

3.23 A certification can be either suspended or cancelled. Both can be initiated by the certification holder or the Regulator. When a certification holder requests the cancellation of a certification, the OGTR refers to the certification as being "surrendered".

3.24 Suspension does not override the expiry date on the certification instrument. If a certification is due to expire while under suspension an application can be made, by letter, e-mail or fax, to extend the period of the certification while under suspension. However, any future lifting of the suspension may be conditional on the facility complying with any new requirements if the certification guidelines have been updated after the certification was suspended. Any certification holders in this position would need to contact the OGTR to discuss their situation.

3.25 The Act provides that the Regulator may, by notice in writing, suspend or cancel the certification of a facility if the Regulator believes on reasonable grounds that a condition of the certification has been breached.

3.26 When the Regulator initiates the suspension or cancellation of a certification, the Regulator must give written notice of the proposed suspension or cancellation to the certification holder.

3.27 The notice may request relevant information from the certification holder and may invite a written submission from the certification holder, within a designated timeframe. The Regulator must consider any written submissions made.

3.28 The requirement for the Regulator to provide prior notice of the suspension or cancellation may be waived where the Regulator considers that the action is necessary to avoid an imminent risk of death, serious illness and/or serious injury to any person/s or serious damage to the environment.

3.29 After the cancellation/surrender of a certification, no NLRDs or DNIRs can be conducted in the facility. Any stickers issued by the Regulator must be removed after cancellation/surrender.

3.30 In the case of the suspension of a certification, NLRDs and DNIRs may only resume in the facility after the Regulator has lifted the suspension. While the certification is suspended, any stickers or labels issued by the Regulator must be either covered or removed.

Applications to modify certifications

3.31 The OGTR requires certain information to process any applications to modify certifications (i.e. variation, suspension, lift of suspension, surrender and transfer). A guidance note has been issued to indicate what information will assist efficient processing of an application request: *Guidance Note for the submission of Applications to modify Certifications (i.e. Variation, Suspension, Lift of Suspension, Surrender and Transfer)* Version 1.1 – Issued 23 January 2012. This guidance note is available from the OGTR or can be downloaded from the OGTR website.

Review of the Regulator's decision

3.32 Decisions by the Regulator to: refuse to certify a facility; specify a condition of a certification; vary a certification; or suspend or cancel a certification, are "reviewable decisions" under the Act.

3.33 If the original decision was not made by the Regulator in person, but by a delegate of the Regulator, an applicant may apply in writing to the Regulator for an internal review of the decision. An application for internal review must be made within 30 days after the day on which the decision first came to the notice of the applicant, or within such period (if any) as the Regulator, either before or after the end of that period, allows.

3.34 For decisions made by the Regulator personally, including decisions made on internal reviews, applicants may make an application to the Administrative Appeals Tribunal.

PART 4 – OTHER INFORMATION

US National Institutes of Health Grants

4.1 Several Australian organisations are conducting research funded by the US National Institutes of Health (NIH). The NIH requires all grant recipients conducting recombinant DNA research within the United States or its territories to comply with the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

4.2 For research in countries outside the US and its territories, section I-C-1-b-(3) of the NIH Guidelines March 2013 states:

> If the host country has established rules for the conduct of recombinant or synthetic nucleic acid molecule research, then the research must be in compliance with those rules. If the host country does not have such rules, the proposed research must be reviewed and approved by an NIH-approved Institutional Biosafety Committee or equivalent review body and accepted in writing by an appropriate national governmental authority of the host country. The safety practices that are employed abroad must be reasonably consistent with the NIH Guidelines.

4.3 The Gene Technology legislation in Australia qualifies as a system of rules for the conduct of gene technology research and should satisfy the clause above in respect of avoiding the need to have proposed research approved by an NIH-approved Institutional Biosafety Committee (IBC). Australian IBCs would need to satisfy themselves as to the consistency with NIH Guidelines in respect of safety measures employed in the conduct of any proposed dealings with GMOs that are brought before them.