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

Explanatory Information on the Guidelines for Accreditation of Organisations

18 April 2013

Version 1.4

TABLE OF CONTENTS

EXPLANATORY INFORMATION

Copies of the *Gene Technology Act 2000*, the *Gene Technology (Consequential Amendments) Act 2000*, the *Gene Technology (Licence Charges) Act 2000* and the *Gene Technology Regulations 2001* may be downloaded from the OGTR Website or Federal Register of Legislation Website.

IMPORTANT NOTE

These explanatory notes may be updated from time to time. Users should therefore assure themselves that they have access to the most recent version.

Definitions

Unless defined otherwise in this Explanatory Information 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.

accredited organisation	An organisation accredited by the Gene Technology Regulator under Section 92 of the Act.
corresponding State legislation	A law that the Minister has declared to be a corresponding State legislation.
dealing or deal with	In relation to a GMO, means the following: (a) conduct experiments with the GMO; (b) make, develop, produce or manufacture the GMO; (c) breed the GMO; (d) propagate the GMO; (e) use the GMO in the course of manufacture of a thing that is not the GMO; (f) grow, raise or culture the GMO; (g) import the GMO; (h) transport the GMO; (i) dispose of the GMO; and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i).
DIR	Dealing Involving Intentional Release.
DNIR	Dealing Not Involving Intentional Release.
GMO	Genetically Modified Organism.
Guidelines	Guidelines for the Accreditation of Organisations.
instrument of accreditation	A current written instrument issued by the Regulator accrediting an organisation pursuant to Section 92 (1) of the Act.
IBC	Institutional Biosafety Committee.
NLRD	Notifiable Low Risk Dealing.
OGTR	Office of the Gene Technology Regulator.

the Regulator	The Gene Technology Regulator**.**
relevant conviction	A conviction for an offence against a law of the Commonwealth, a State or a foreign country, relating to the health and safety of people or the environment, if: (a) the offence was committed within the period of 10 years immediately before the making of the application; and (b) the offence was punishable by a fine of $5000 or more, or by a term of imprisonment of one year or more.

PART 1 - INTRODUCTION

1.1 The Act and the Regulations, together with corresponding State legislation, provide the legislative foundation for Australia's nationally consistent scheme for the regulation of gene technology.

1.2 The objectives of the national 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 genetically modified organisms (GMOs).

1.3 The national laws prohibit dealings with GMOs, other than a limited range of permissible, authorised dealings. They establish a statutory officer, the Regulator, who is responsible for administering these laws. Part of that role includes responsibility for promoting compliance with the laws, and prosecuting non-compliance.

1.4 By encouraging good compliance practices by regulated organisations, particularly through the promotion and implementation of best practice techniques, the possibility of adverse environmental or human health outcomes associated with gene technology is reduced.

1.5 The Regulator strongly encourages all organisations conducting dealings with GMOs to obtain accreditation.

Institutional Biosafety Committees (IBCs)

1.6 Fundamentally, best practice is achieved when organisations regularly and routinely seek, and obtain assistance from, a properly constituted, resourced and maintained IBC, whose members are able to provide professional and unfettered advice on risks related to the gene technology work of the organisation.

1.7 IBCs assist organisations by advising on the identification and management of the risks associated with dealings with GMOs undertaken by the organisation, including the containment of GMOs and providing an interface with the OGTR.

1.8 Either having an IBC, or having access to one, is a pre-requisite to an organisation obtaining and maintaining accreditation.

1.9 IBCs are required to be consulted and used by organisations in certain situations regardless of whether an organisation is accredited. For example, the Regulations require that the dealing has been assessed by an IBC, even if the dealing is undertaken by an organisation which is not accredited.

1.10 IBCs therefore play an integral role in assisting compliance with Australia's national scheme laws. They are an important quality assurance system for regulated organisations.

1.11 It should be noted, however, that the role and responsibilities of IBCs and accreditation are limited in two important respects:

1.11.1 Firstly, IBCs are not intended to be responsible for the conduct of the organisations that they assist. Ultimately, the Regulator encourages organisations to make representations to the Regulator on their own behalf. IBCs are intended to provide relevant advice to assist with the identification and management of risks associated with GMOs without attracting liability for damages in the course of providing this advice.

1.11.2 Secondly, accreditation does not automatically allow an organisation to conduct dealings with GMOs. If an accredited organisation wishes to work with GMOs it must ensure the correct approval or assessment is obtained before commencing this work. Further information about approval/assessment processes can be obtained from the OGTR website.

1.12 Information about the application process for accreditation and the technical and procedural requirements that must be addressed in an application, together with helpful hints to assist applicants to prepare their applications, is set out in Part 2 of this explanatory document.

What happens when an organisation becomes accredited?

1.13 Upon accreditation, the Regulator issues the organisation with an instrument of accreditation. The instrument shows that the organisation has met the requirements for accreditation.

1.14 The instrument will set out:

- the name of the accredited organisation; and
- any conditions of the accreditation.

1.15 Generally, a range of conditions will be imposed on the organisation at the time of accreditation. The organisation must comply with the conditions, on an ongoing basis, in order to maintain the accreditation. The conditions ensure that the standards of review and compliance initially attained by the organisation in the course of gaining accreditation are maintained by the organisation on an ongoing basis.

Note: Further information about conditions of accreditation and how organisations can maintain their accreditation can be found in Part 3 of this explanatory document.

PART 2 – HOW TO GET ACCREDITED

Introduction – the process and form

2.1 An organisation can apply for accreditation by making a written application to the Regulator. Application forms can be obtained from the OGTR or can be downloaded from the website: http://www.ogtr.gov.au

2.2 Applications must address a number of required technical and procedural matters. These matters are set out in the Guidelines and in the application form. Copies of the Guidelines can be downloaded from the OGTR website.

2.3 The Regulator considers the level of compliance with the technical and procedural requirements outlined in the Guidelines in determining whether to accredit an organisation.

2.4 The Regulator must decide whether or not to grant accreditation within 90 working days. If the Regulator requests further information in the course of consideration of the application, the 90 day time limit is suspended while the Regulator is waiting for information to be provided.

2.5 The application form requests information about the suitability of organisations to hold accreditation. It also makes provision for applications to be made in respect of organisations establishing at least one IBC of their own or arranging access to another organisation's IBC.

2.6 Because the accreditation application form covers all the matters required to be addressed, if the form is completed correctly, all relevant matters will be addressed.

Organisations must be suitable to be accredited

2.7 Suitability to hold accreditation is a mandatory, threshold test that all accredited organisations must satisfy. An organisation will not be accredited by the Regulator unless the Regulator is satisfied that the organisation is a suitable organisation.

2.8 In general terms, a suitable organisation is an organisation that is considered to be reasonably capable of conducting dealings with GMOs safely. Another way of describing a suitable organisation might be to describe them as 'fit and proper' to conduct dealings with GMOs.

2.9 Concepts of honesty, knowledge and ability are connoted by the expression 'suitable'.

2.10 Suitability is a broad assessment and the Regulator may have regard to any relevant information.

2.11 The range of matters to which the Regulator may have regard may extend beyond the organisation itself. For example, in considering the suitability of a wholly owned subsidiary company, the Regulator might, depending on the circumstances, investigate the reputation of the parent company and the closeness of the relationship between the organisation and its parent.

2.12 If an applicant previously had a GMO licence suspended or revoked by the Regulator, this would be relevant to the Regulator's assessment of whether the person is a suitable person. An organisation's conduct in connection with other regulation might also be relevant.

2.13 If an organisation has relevant convictions, those convictions must be set out in the application form.

2.14 A relevant conviction may prevent an organisation from obtaining accreditation.

2.15 An organisation must also list any revocation, suspension or cancellation of a licence or permit (however described) held by the organisation under a law of the Commonwealth, a State or a foreign country relating to the health and safety of people or the environment.

2.16 An organisation must include information about the revocation, suspension or cancellation of licences and permits issued by:

a) The Therapeutic Goods Administration
b) DAFF Biosecurity;
c) Food Standards Australia New Zealand;
d) National Industrial Chemical Notification and Assessment Scheme;
e) Australian Pesticides and Veterinary Medicines Authority; or
f) Department of Sustainability, Environment, Water, Population and Communities.

2.17 Other Commonwealth, State and Territory permit and licensing regimes could also be relevant.

2.18 The revocation, suspension or cancellation of an instrument like those described above may prevent an organisation from obtaining accreditation.

Requirements in respect of IBCs

2.19 Applicant organisations are required to establish at least one IBC of their own, or access another organisation's IBC.

2.20 Accredited organisations are required to continue to have access to at least one IBC of their own, or another organisation's IBC.

2.21 An applicant organisation is able to obtain accreditation if it can demonstrate, in respect of the IBC, that:

- the membership of the IBC has the collective technical and scientific expertise to review and assess all the matters that are likely be put to it by the organisation;
- the members of the IBC are appropriately indemnified; and
- at least one of the members of the IBC is independent.

2.22 Depending on the range of activity it conducts and the expertise it requires, an organisation may choose to utilize more than one IBC. Applicants must address each of the criteria in the application form.

A. IBCs must have technical expertise to assess and review matters

2.23 In order to perform its functions satisfactorily, an IBC will ideally have, within its membership, a breadth of relevant expertise both to understand and analyse hazards and risks associated with the particular dealings and to provide expert commentary on those risks including, where relevant, any containment measures for GMOs involved in the dealings and the classification of the dealings with the GMO in accordance with the Regulations.

2.24 The scientific and technical skills that will be necessary to enable an IBC to satisfactorily perform its functions will vary, depending on the type of research being conducted.

2.25 For example, an IBC considering gene technology work on potentially pathogenic micro-organisms might reasonably include a microbiologist and a biological safety expert, and would need to have expertise in the physical containment of organisms and in the nature of the dealings or research being conducted.

2.26 An IBC overseeing tests of crop performance of GMOs might have a membership that includes, among other expertise, molecular biology, entomology, plant pathology, agronomy and ecology.

2.27 IBCs that oversee contained facilities that are certified to physical containment level 3, 4 or level 1 or 2 Large Scale facilities, will not ordinarily meet the criterion for technical expertise unless the IBC has expertise in physical containment of organisms. This comprises:

- understanding the building structural requirements, equipment and procedural requirements;
- relevant training or experience in the design and testing of biological safety facilities and equipment;
- relevant training or experience with proper procedures for the safety of persons and the containment of organisms; and
- knowledge of the biology and life cycles of organisms being used within the facilities.

2.28 To address this criterion in the application form, applicants are advised to:

- take stock of the scientific, technical and other professional skills of the membership of the IBC and the kinds of matters likely to be put to the IBC by the organisation; and
- document how those skills and experience will enable the IBC to efficiently and effectively assess and review the information that is likely to be put before it by the organisation.

2.29 It will be a condition of accreditation (and therefore an ongoing requirement) that an accredited organisation only use an IBC whose membership contains the requisite expertise. To account for requests for assessment of unanticipated risks and advice on dealings with GMOs, reliance on the advice of an expert (not a member of the IBC) to address specific, short-term skills deficit in the IBC will be recognised by the Regulator as compliance with that condition of accreditation.

B. IBC must have an independent member

2.30 The intention in requiring an independent member is to include someone who can exercise unfettered and independent judgement in relation to their participation in the IBC.

2.31 To address this criterion, an applicant must make a statement in the application form that at least one member of the IBC has no ongoing, substantive association (including personal, pecuniary or research interests) with matters likely to be considered by the IBC.

2.32 While it is not a requirement, the Regulator encourages members who satisfy the independence criterion to be free of any business or other relationship with the organisation that could materially interfere with the exercise of unfettered and independent judgement in contributing to decisions made by the IBC, including a relationship of employment.

C. IBC members must be appropriately indemnified

2.33 To address this criterion, an applicant must make a statement in the application form that all IBC members consider they are appropriately indemnified.

2.34 The statement can be made by the organisation itself, in terms as simple as 'the indemnity arrangements in place in respect of all IBC members, as regards the organisation, are satisfactory to them', or even 'All IBC members are appropriately indemnified'.

2.35 Alternatively, if the organisation prefers, it can provide written statements from each IBC member that the indemnity arrangements in place, as between the IBC member and the organisation, are satisfactory.

2.36 An indemnification arrangement is appropriate if it is in place and satisfactory to the IBC member covered by it. That is, indemnity arrangements are satisfactory if the IBC members consider that they are protected from legal liability for damages, as a result of their performing functions as an IBC member.

2.37 IBC members and organisations are encouraged to obtain their own separate legal advice in coming to arrangements between them.

2.38 IBCs provide advice and assistance to organisations on matters that were historically not regulated, but are now regulated under the Act.

2.39 To address this, indemnity requirements benefiting IBC members are a requirement in the Guidelines. The requirement for indemnity arrangements provides comfort to IBC members so that they continue to provide a valuable service to organisations.

2.40 Implementing prescribed, standard indemnity arrangements between IBC members and organisations has been considered on a number of occasions. However, because the indemnity requirement is included to provide comfort to IBC members via what is essentially a private arrangement between an IBC member and an organisation, the Guidelines do not prescribe particular indemnity arrangements. If an IBC member is satisfied, the objective of the indemnity requirement is achieved.

2.41 Indemnities can therefore take many different forms, depending on a range of matters, including the nature and extent of the activities they are made in contemplation of, and people's attitudes towards them. These arrangements provide flexibility to IBC members and organisations to settle arrangements that are satisfactory to them by not prescribing any particular indemnity arrangement (or a minimum requirement).

Requirements for use of other organisations' IBCs

2.42 For a variety of reasons, some organisations are not able to establish their own IBCs. For example many small institutions are not able to fund IBCs and many collaborative research arrangements exist where there is limited or no access to internal IBCs. It is still possible for these organisations to become accredited.

2.43 Organisations that have established arrangements to use an IBC belonging to another organisation can seek accreditation from the Regulator.

2.44 An applicant is able to obtain accreditation if they can demonstrate, in respect of the IBC of the other organisation, that:

- the other organisation has consented, in writing (on page 21 of the application form), to its IBC being accessed and used by the organisation seeking accreditation;
- the organisation that maintains the IBC has declared that:
  - the members of its IBC are appropriately indemnified, as regards the organisation seeking accreditation; and
  - the membership of the IBC includes at least one independent member.
  - the membership of the IBC has the collective technical and scientific expertise to review and assess all the matters that are likely be put to it by the organisation seeking accreditation.

2.45 Applicants must address each of the criteria in the application form.

2.46 In all other respects, the information requirements are equivalent to those for applications in respect of IBCs created by the organisation. Applicants should refer back to earlier information in this explanatory document about skills and experience and indemnification requirements.

Helpful Hints – Applications for Accreditation

2.47 If the Regulator requests further information from you in the course of considering an application, please provide the information promptly. Failure to do so may slow the consideration of your application, or even result in its refusal.

2.48 Generally, the Regulator must make a decision on an application for accreditation within 90 working days.

2.49 But if the Regulator requests further information from you, the 90 day time frame will be suspended until the information is provided.

2.50 If the Regulator stipulates a timeframe within which any requested information must be provided, and the information is not provided within that time and without reasonable excuse, the Regulator may refuse the application.

2.51 Organisations should not be discouraged from highlighting aspects of applications that are not fully compliant with the Guidelines, particularly if they also have proposals for how full compliance, or equivalent compliance, might be achieved by the organisation in a reasonable period following accreditation. The Regulator is empowered to grant accreditation subject to conditions. In appropriate circumstances, the Regulator may consider imposing conditions at the time of accreditation allowing an organisation to work towards reaching full compliance.

2.52 Decisions by the Regulator to refuse an application for accreditation, to impose conditions, or to vary, suspend or cancel accreditation are "reviewable decisions" under the Act. This means that an applicant may seek review of the decision by the Administrative Appeals Tribunal (AAT).

2.53 The AAT undertakes merit reviews of administrative decisions. The AAT may:

- stay the operation or implementation of a decision until the AAT hearing;
- affirm the decision made by the decision maker;
- vary the decision;
- set aside the decision;
- substitute its own decision; or
- remit the matter to the original decision maker with directions or recommendations for re-making the decision.

PART 3 – HOW TO STAY ACCREDITED

Introduction

3.1 Upon accreditation, the Regulator issues an instrument of accreditation to the organisation. The instrument denotes that the organisation has met the requirements for accreditation.

3.2 The instrument sets out:

- the name of the accredited organisation; and
- any conditions of accreditation.

3.3 A range of conditions will generally be imposed on an organisation at the time of accreditation. Organisations must comply with any conditions imposed, on an ongoing basis, in order to maintain the accreditation.

3.4 Conditions imposed at the time of accreditation are designed to ensure that compliance with the standards of review is maintained by the organisation on an ongoing basis. They also establish minimum standards for the organisation and the relevant IBC on a range of matters affecting the IBC and its use by the organisation.

3.5 As a result, accredited organisations will be required to:

- develop and implement processes and procedures to address conflicts of interest;
- keep satisfactory records; and
- prepare and submit annual reports and other notices to the Regulator.

3.6 Depending on the circumstances, the Regulator may also impose other conditions at the time of accreditation.

3.7 The usual conditions are outlined in the Guidelines; some of the usual conditions are also explained in more detail below.

Usual conditions of accreditation

A. Continuing requirements to address conflicts of interest

3.8 There may be occasions where a proposal submitted by an organisation arises from the recommendations of an IBC where one or more of the members of the IBC have a close involvement in the matter being considered. This may give rise to a conflict of interest, or a perception of a conflict of interest.

3.9 For the purposes of the Guidelines, a 'conflict of interest' in a matter includes:

- a direct financial interest;
- any indirect interest, for example a financial benefit accruing to a close relative or partner of the member;
- a non-financial interest, for example a person may have an interest in a matter as a result of an affiliation or membership of an interest group or organisation;
- any interest that could be viewed as a possible conflict of interest; or
- any combination of the above interests.

3.10 It is the Regulator's policy to impose conditions at the time of accreditation requiring accredited organisations to have effective mechanisms in place to address conflicts of interest on the part of IBC members. In most cases, these conditions will:

- require IBC members to declare conflicts of interest, whether direct or indirect, pecuniary or otherwise, perceived or real;
- require declared conflicts to be recorded in the minutes of IBC meetings along with any measures taken to address the conflict; and
- enable IBCs to decide for themselves whether, in a particular instance, a conflict of interest is so significant that an IBC member be absented from further participation in a matter before the IBC.

3.11 The Guidelines contain draft conditions of accreditation dealing with conflicts of interest. The draft clauses are likely to form the basis of any conditions actually imposed.

B. Continuing requirements to keep records and submit reports to the Regulator

3.12 Good records, good record keeping practices and good reporting practices are all important tools in the proper management of dealings with GMOs. For example, in the event of a breach of containment, proper records and reporting may be essential to ensuring that the causes and impacts of the breach can be identified and redressed.

3.13 It is the Regulator's policy to require accredited organisations to maintain a minimum standard of good record keeping and reporting practices. In most cases, these conditions will require:

- records of meetings of IBCs to be kept for a minimum of 3 years from the date of each meeting;
- records of meetings to record all conflicts of interest declared to the IBC;
- records of inspections of certified facilities to be kept for a minimum of 5 years from the date of the inspection;
- records of assessment of NLRDs to be kept for a minimum of 8 years after the date of assessment by the IBC;
- annual reports to be submitted to the Regulator; and
- notice to be given, in writing, to the Regulator within 30 days if the accredited organisation:
  - wishes to access or establish an IBC other than the IBC(s) identified in their application;
  - disbands or ceases to use an IBC;
  - changes its primary contact or the contact details for the primary contact;
  - changes its IBC contact or the contact details for its IBC contact (where the IBC is the accredited organisation's own IBC);
  - changes the its CEO (or equivalent) or the contact details for the CEO (or equivalent);

- changes its IBC chair or the contact details for its IBC chair (where the IBC is the accredited organisation's own IBC);
- changes its name or ownership;
- is convicted of an offence against a law of the Commonwealth, a State or a foreign country relating to the health and safety of people or the environment and punishable by a fine of $5000 or more; or
- has had a licence or permit (however described), held by the organisation under a law of the Commonwealth, a State or a foreign country relating to the health and safety of people or the environment, revoked, suspended or cancelled.

3.14 All records must be available for inspection by the Regulator upon request.

3.15 It is the Regulator's policy that accreditation conditions, in respect of annual reports, will require them to:

- report for the period 1 July to 30 June in the following year (the reporting period);
- be submitted by 30 September each year; and
- list all NLRDs assessed by an IBC in the reporting period.

3.16 The Regulator circulates a form for annual reporting by accredited organisations. In most cases, accredited organisations can satisfy annual reporting conditions of accreditation by filling out the form correctly and submitting it on time.

3.17 Accredited organisations should take special note that if they hold GMO licences, those licences may impose additional annual, or other, reporting obligations on them.

Monitoring and non-compliance with accreditation conditions

3.18 Accredited organisations are monitored by the Regulator to ensure that they are operating in accordance with any conditions of accreditation imposed on them. The Regulator also monitors, audits and inspects dealings with GMOs, to ensure that any conditions particular to certain dealings with GMOs are being observed.

3.19 The OGTR has programs for both routine (announced) and on-the-spot (unannounced) monitoring visits to accredited organisations to assess compliance with their conditions of accreditation. During monitoring visits, monitoring and compliance officers may ask to look at records, standard operating procedures and other documents held and used by the organisation.

3.20 Accredited organisations are encouraged to contact the OGTR if they find that they have not complied with their conditions of accreditation.

3.21 Where conditions of accreditation have not been met, the Regulator has recourse to the OGTR's Monitoring Section and Compliance and Investigation Section protocols and the Compliance and Enforcement policy. Further information can be obtained from the OGTR website.

Variation of accreditation

3.22 To allow accreditations to adjust to changing circumstances, instruments of accreditation are able to be varied. The Regulator may impose additional conditions, remove or vary conditions previously imposed, either on the initiative of the Regulator or in response to a request.

3.23 If you consider that variations to your conditions of accreditation are necessary or desirable, you are welcome to contact the OGTR to discuss how changes to your accreditation might be made.

3.24 If circumstances arise such that the Regulator considers a variation of your accreditation is desirable, the Regulator will consult you in connection with the proposed variation before any variation decision is made.

PART 4 –QUESTIONS AND ANSWERS

4.1 Who is authorised to complete an accreditation application form?

The accreditation application form can be completed by anyone authorised to act on behalf of the organisation to complete the form.

4.2 Who is authorised to sign the declaration of the organisation submitting the accreditation application?

The CEO (or equivalent) or a person with the authority to sign on behalf of the organisation, is authorised to sign the application form.

4.3 What is the role of the organisation's primary contact officer?

The organisation's primary contact officer is the first point of contact for all matters that the OGTR would like to discuss. This role will involve receiving written correspondence and telephone enquiries from the OGTR.

4.4 Who should be the primary contact of the IBC?

The OGTR does not dictate who should take on the role of primary contact for the IBC. The IBC is required to make its own decision regarding who is the most suitable person. The committee should be aware, however, that the OGTR will be contacting the primary contact for matters relating to the IBC, applications and notifications

4.5 How long does an accreditation last?

Accreditations are issued without an expiry date; however, the Regulator can choose to issue an accreditation with an expiry date. If an accreditation has an expiry date, the date will be set out in the instrument of accreditation.

4.6 Is there an application fee for accreditation?

There is no application fee at the time of issue of these explanatory notes.

4.7 How long does it take to assess an application?

Accreditations must be decided within 90 working days of the application being received by the Regulator, plus any time spent waiting for responses to requests for additional information from the applicant.

4.8 What are the functions of an IBC?

The function of an IBC is to provide assistance to an accredited organisation in relation to the gene technology dealings that the organisation undertakes. Specifically this involves:

- **For Licensed dealings**
  - confirming that for applications for licensed dealings the information provided to the Regulator is complete;
  - confirming that personnel are adequately trained to undertake the dealing; and
  - evaluating the proposed project.

- **For NLRDs**
  - assessing the proposal for an NLRD;
  - making a record of its assessment, in a form approved by the Regulator;
  - assessing that the persons or classes of persons undertaking the dealing have the appropriate training and experience to undertake the dealing;
  - assessing that the facilities or classes of facilities in which the dealing is proposed to be undertaken is of the appropriate physical containment level and type for the dealing; and
  - giving a copy of the record of assessment to the person or accredited organisation that submitted the proposal to the committee.

4.9 Does the OGTR have specific terms of reference for IBCs?

Currently the OGTR does not have any specific model terms of reference for IBCs. In general an organisation setting out an IBC's terms of reference could include the scope of its responsibilities, relationship to non-affiliated researchers, accountability and mechanisms of reporting.

The terms of reference could generally contain such information as:

- Composition of its membership
- Appointment of members
- Working procedures
- Conflict of interest procedures
- Financial affiliations
- Inspection of certified facilities
- Recording of decisions
- Monitoring of the organisation's research
- Complaints mechanisms
- Procedures for suspension or discontinuation of research
- Annual reporting requirements to OGTR
- Record keeping requirements

4.10 What is the role of the IBC Chair?

A member of the IBC should be appointed Chair of the IBC. The Chair of the IBC shall convene meetings of the IBC and provide leadership and direction to the conduct of the business of the IBC. Arrangements should be in place for another member to act as the Chair if the need arises.

4.11 What expertise must the IBC have?

IBCs must have the collective expertise to competently assess and provide advice on the identification and management of the risks associated with dealings with GMOs undertaken by the organisation and to advise on the containment of GMOs. The composition of individual IBCs will therefore depend on the dealings with GMOs and the nature of the work being undertaken by the organisation.

4.12 Can an organisation utilise more than one IBC?

An organisation may choose to utilise more than one IBC because external IBCs may have more extensive experience in certain aspects of an organisation's dealings. This expertise can be sought and utilised through any number of internal and external IBCs.

At the time of application, the organisation must notify the OGTR if additional IBCs are to be accessed, using the relevant part of the accreditation application form.

4.13 If an organisation wishes to access an additional IBC or cease to access an existing IBC, what action is required?

If an organisation wishes to add/remove an IBC to/from their accreditation, the OGTR requires notification of this change. The organisation should send formal correspondence, including relevant pages of the accreditation application form, to the OGTR requesting that the IBC is added or removed, as appropriate. The OGTR will then amend their records in accordance with the advice.

4.14 How many meetings per year is the IBC expected to hold?

The OGTR does not prescribe internal operating procedures for IBCs. The committee should come to an agreement on how many meetings are needed to ensure that all OGTR requirements, in relation to dealings with GMOs and inspections of certified facilities, are met.

4.15 What is the minimum number of members required to attend IBC meetings?

The committee can agree on how many members are required at a meeting to make a decision. These rules, however, must ensure that the purpose of the IBC to provide oversight of the organisation's activities in relation to GMOs and a robust scientific assessment of licence applications, are achieved. The IBC should have sufficient expertise at the meetings to assess the applications and ensure that all risks associated with dealings are considered.

4.16 What constitutes a conflict of interest?

A 'conflict of interest' in a matter may include:

- a direct financial interest;
- any indirect interest, for example a financial benefit accruing to a close relative or partner of the member;
- a non-financial interest, for example a person may have an interest in a matter as a result of an affiliation or membership of an interest group or organisation;
- any interest that could be viewed as a possible conflict of interest; or
- any combination of the above interests.

IBC members must declare any such conflict of interest whether direct or indirect, pecuniary or otherwise, and perceived or real.

4.17 Do conflict of interest procedures need to be formal?

Procedures for conflict of interest need to be established and formalised in relevant documents. Organisations must have documents and procedures in place that define conflict of interest and require members of the IBC to declare any conflict of interest. Any conflicts of interest must be recorded in the minutes of the relevant IBC meeting along with any measures taken to address the conflicts of interest.

4.18 Where can I get a copy of the Gene Technology Act 2000?

A copy of the *Gene Technology Act 2000* can be downloaded from the OGTR Website or the Federal Register of Legislation website.

If an organisation decides to change its name, what action is required?
If an accredited organisation chooses to change its name the OGTR needs to be informed. This is because the organisation's records need to be updated. The organisation should send correspondence to the OGTR via email or in a letter explaining the change and confirming whether a legal entity change is also occurring. The action taken by the OGTR depends on whether the organisation's legal entity has also changed. Action taken may be a simple administrative name change, accreditation of the new legal entity and subsequent surrender of the old legal entity or a variation of the accreditation. The OGTR will inform the organisation, in writing, when the process has been completed.

4.19 What are the requirements for an organisation in regards to NLRDs?

The requirements for organisations undertaking NLRDs can be found under Regulation 13 of the Gene Technology Regulations 2001.