Gene Technology Amendment Bill 2007

Explanatory Notes

General Outline

Title of the Bill

Gene Technology Amendment Bill 2007

Objective of the Gene Technology Act 2001

The object of the Gene Technology Act 2001 is 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 through regulating certain dealings with genetically modified organisms (GMOs). The Gene Technology Act 2001 is the Queensland Government's component of the nationally consistent regulatory scheme for gene technology.

Objectives of the Bill

The objectives of the Gene Technology Amendment Bill 2007 (the Bill) is to improve the operation of the Gene Technology Act 2001 without changing the underlying policy intent or overall legislative framework of the regulatory scheme.

Reasons for the Bill

The Queensland *Gene Technology Amendment Bill 2007* has been drafted to reflect changes to the Commonwealth gene technology legislation as a result of recent statutory reviews of the operation of the Commonwealth legislation and the intergovernmental *Gene Technology Agreement 2001* and the review of the operation of Queensland's legislation.

Amendments to the Queensland *Gene Technology Act 2001* are necessary to maintain national consistency as contemplated by Parliament in section 5 of the Act.

Under the intergovernmental *Gene Technology Agreement 2001*, all States and Territories have committed to maintaining corresponding legislation. On 27 October 2006, the Gene Technology Ministerial Council (GTMC), an intergovernmental body comprised of State, Territory and Australian Government Ministers, agreed to proposals to implement the recommendations of the Review.

The Commonwealth statutory review found that regulation of gene technology has worked well at the national level, and no major changes were required. It was concluded that the policy objectives remain valid and the scope of the Commonwealth Act should be maintained.

The statutory review also recommended a number of minor changes intended to improve the operation of the Commonwealth Act, which were subsequently incorporated in the *Gene Technology Amendment Act 2007* (Cth).

Section 194 of the Queensland *Gene Technology Act 2001* placed a statutory obligation on the Minister to cause a statutory independent review of the operation of the Act as soon as possible after 1 November 2005, the fourth anniversary of the commencement of the Act. The independent review of the Queensland Act was completed on 10 October 2006 and the report was tabled in Parliament on 30 October 2006.

The independent review concluded:

- differences between the Commonwealth Act and the Queensland Act are not material;
- there is no evidence to suggest that the Queensland Act should be different from the Commonwealth Act; and
- changes to the Commonwealth Act, as recommended by the Commonwealth review, should be adopted by Queensland.

This Bill proposes to implement the recommendations requiring legislative change, which include:

- introducing emergency powers, giving the Minister the ability to expedite the approval of a dealing with a GMO in an emergency (such as the recent use of the equine influenza vaccine to combine the current outbreak of this disease);
- improving the mechanism for providing advice to the Gene Technology Regulator (the Regulator) and the GTMC on ethics and community consultations;
- streamlining the process for the initial consideration of licences;

- reducing the regulatory burden for low risk dealings;
- providing clarification on the circumstances in which licence variations can be made;
- clarifying the circumstances under which the Regulator can direct a person to comply with the Act;
- providing the Regulator with the power to issue a licence to persons who find themselves inadvertently dealing with an unlicensed GMO, for the purpose of disposing of that organism.

Alternatives to the Bill

The objectives can only be achieved by amendment to the Queensland Act.

Both State and Commonwealth legislation are needed to achieve a nationally consistent scheme that provides full regulatory coverage for gene technology. The Queensland Act increases the coverage of the national scheme to include Queensland Government agencies and higher education institutions.

Administrative Cost

Administrative costs to the Queensland Government will not increase as a result of the proposed amendments.

Consistency with Fundamental Legislative Principles

The legislation is part of a national regulatory scheme, however, section 5 of the Act reflects Parliament's intention that this Act form a component of a nationally consistent scheme for the regulation of certain dealings with genetically modified organisms by the Commonwealth and the States.

Consultation

Extensive consultation with industry and the community was undertaken in the preparation of the Commonwealth gene technology amendment legislation. The Queensland Government conducted further consultation to determine appropriate amendments to the *Gene Technology Act 2001* (Qld) and the *Gene Technology Regulation 2002* (Qld).

The Department has continued to liaise with members of the interdepartmental Gene Technology Contact Group.

Notes on Provisions

Short title

Clause 1 provides that the Act may be cited as the *Gene Technology Amendment Act 2007*.

Act amended

Clause 2 provides that the amending Act amends the *Gene Technology Act 2001*.

Amendment of s 31 (Simplified outline of Part 4)

Clause 3 inserts a new subsection into the simplified outline at the beginning of Part 4 of the Act. This makes it clear that a dealing stated in an emergency dealing determination is not prohibited under Part 4 which regulates the dealings with GMOS.

Replacement of s 32 (Person not to deal with a GMO without a licence with full knowledge or recklessness)

Clause 4 repeals existing section 32 and substitutes a new section 32 into the Act. The new section 32 is substantially the same as the existing section 32. It includes existing provisions that a person commits an offence if he or she deals with a GMO, knowing that it is a GMO and without a licence authorising the dealing, unless the dealing is a notifiable low risk dealing, it is an exempt dealing, or it has been placed on the GMO register. The person must either have known, or have been reckless about all of these things to have committed an offence.

It inserts an additional subsection providing that a person commits an offence if he or she deals with a GMO unless the dealing is stated in an emergency dealing determination and the person must know or be reckless as to this fact for an offence to be committed.

In addition, the subsection has been redrafted to clarify that an offence is only committed if the dealing with the GMO is not authorised by a licence.

Amendment to s 33 (Person not to deal with a GMO without a licence)

Clause 5 inserts a new subsection into section 33(1) of the Act. This amendment inserts an additional subsection providing that a person commits a strict liability offence if the person deals with a GMO, knowing that it is a GMO and the dealing is not stated in an emergency dealing determination.

Amendment of s 34 (Person must not breach conditions of a GMO licence with full intention and knowledge or recklessness)

Clause 6 repeals existing subsections 34(1) and (2) and substitutes new subsections 34(1) and (2).

Subsection 34(1) has been redrafted to clarify that in order to commit an offence a person's actions must contravene a licence and the person must know or be reckless as to that fact.

Subsection 34(2) has been redrafted to clarify that in order to commit an offence a person's actions must contravene a condition of a licence and the person must know or be reckless as to that fact.

Insertion of new ss 35A and 35B

Clause 7 inserts two new offence provisions into the Act.

Section 35A is similar to existing section 34 of the Act. It creates an offence for intentionally breaching the conditions of an emergency dealing determination. The penalty for an aggravated offence is 5 years imprisonment or 2933 penalty units (in Queensland a penalty unit is currently equivalent to $75. This equates to $219,975.00 for an individual and $1,099,875.00 for a body corporate.

If it is not an aggravated offence, the penalty will be 2 years imprisonment or 733 penalty units which equates to $54,975.00. An aggravated offence, dealt with in section 38, is an offence that causes significant damage, or is likely to cause significant damage, to human health and safety or to the environment.

The penalties are consistent with those contained in section 34.

Clause 35B creates a strict liability offence for breaching the conditions of an emergency dealing determination. It is similar to the existing section 35 of the Act. In order to have committed an offence under proposed new

section 35B, the person must have knowledge of the conditions to which the emergency dealing determination is subject, but need not know that he or she is breaching that condition. Penalties for an aggravated offence is 293 penalty units which equates to $21,975.00. If it is not an aggravated offence, the penalty will be 73 penalty units ($5,475.00).

The penalties are consistent with those contained in section 35.

Insertion of new s 40A

Clause 8 inserts a new section 40A which addresses the situation where a person finds herself or himself inadvertently in possession of a GMO without a licence. According to section 40A(1), the person in question does not need to apply for a licence in respect of inadvertent dealings with a GMO if they consent, although they can under section 40A(2). Therefore the Regulator may treat the person as having applied for a GMO licence without having received an application as long as that person agrees. This recognises that a person who inadvertently deals with GMOs may not be aware of the legislative framework for GMOs, and hence may not be equipped to apply for a licence under the Act. Section 40A(2) makes it clear that a person may apply for a licence under section 40 of the Act in relation to an inadvertent dealing.

Amendment of s 42 (Regulator may require applicant to give further information)

Clause 9 is a technical amendment inserting a new subsection in section 42 to remove any doubt as to when the Regulator may request further information in relation to an application. It provides that the Regulator may request further information at any time before the application is decided, whether before or after she has commenced consideration of the application.

Amendment of s 43 (Regulator must consider applications except in certain circumstances)

Clause 10 is a technical amendment to section 43(2) of the Act to expressly allow the Regulator to cease (in addition to not commence) considering an application if one of the circumstances listed in section 43(2) exists. An additional circumstance is inserted in section 43(2)(f) providing that where the Regulator is not a suitable person to hold a licence (having regard to the matters listed in section 58 of the Act such as whether the applicant has any relevant convictions to licence revocations, and the capacity of the person

to meet the conditions of the licence), Regulator is not required to consider the application.

Insertion of new s 46A and Replacement of s 49 (Dealings that may pose significant risks to the health and safety of people or the environment)

Clauses 11 and 12 inserts new sections 46A and 49 into the Act. These sections make it clear that if the Regulator is satisfied that the:

- licence applied for will only authorise the disposal of the GMO; and
- applicant has come into possession of the GMO inadvertently;

the normal process for the initial consideration of licence to which Division 3 (dealings not involving intentional release of a GMO into the environment) and Division 4 (dealings involving intentional release of a GMO into the environment) will not apply.

An example of a situation in which the new sections 46A and 49 could apply is where a particular GMO has been licensed for use in a certain restricted area and remnants of the GMO become lodged in transporting or handling equipment. In this situation, the GMO crop could conceivably become mixed with non-genetically modified seeds. Thus, a farmer could purchase what he or she believes to be non-genetically modified seeds but subsequently discovers GMOs growing amongst his or her crop. A farmer in this situation could apply to the Regulator under section 40 for a licence to dispose of the GMO. If the Regulator was satisfied that the farmer had come into possession of the GMO inadvertently, and the licence sought was only for the purposes of disposal of the GMO, then sections 46A and 49 would apply, meaning that the Regulator could issue a licence for disposal without having to observe the usual process for the initial consideration of licences in Divisions 3 or 4.

Clause 12 repeals the existing section 49 of the Act. Pursuant to this section, the Regulator is required to assess whether a proposed dealing may pose a significant risk before developing a Risk Assessment and Risk Management Plan. This has proved problematic, as it can be difficult for the Regulator to make a judgment on the risk of a GMO prior to the development of the comprehensive Risk Assessment and Risk Management Plan.

Amendment of s 50 (Regulator must prepare risk assessment and risk management plan)

Clause 13(1) repeals section 50(2) as a consequence of the amendment to section 49.

Clause 13(2) amends section 50(3) of the Act to provide that if an application is for a limited and controlled release application (a field trial), the Regulator does not have to seek advice from the States, the Gene Technology Technical Advisory Committee, prescribed agencies the Commonwealth Environment Minister, or local councils on the preparation of the Risk Assessment and Risk Management Plan.

Insertion of new s 50A

Clause 14 inserts a new section 50A into the Act to create a new category of licence application, to be known as "limited and controlled release" applications.

Clause 14(1) inserts a new subsection 50A(1) which provides that a licence application will be classed as a limited and controlled release if the Regulator is satisfied that:

- the principal purpose of the licence sought is to enable experiments to be conducted;
- the release of the GMO under the licence would be limited and that controls would be in place to limit the dissemination of the organism; and
- it is appropriate for section 50(3) of the Act not to apply to the licence (i.e. it is appropriate that the Regulator does not have to seek advice from the States, the Gene Technology Technical Advisory Committee, prescribed agencies the Commonwealth Environment Minister, or local councils on the preparation of the Risk Assessment and Risk Management Plan).

Clause 14(2) inserts a new subsection 50A(2) which provides that in determining whether the principal purpose of the licence is to conduct experiments (or, in other words, in determining whether subsection 50A(1) applies to a licence), the Regulator must have regard to whether the applicant proposes to test hypotheses; to gain scientific or technical knowledge; or to gain data for regulatory purposes or for product development or marketing. An undertaking to conduct any of these forms of research would help establish that a licence is for the purposes of conducting experiments. However, the Regulator still needs to consider

whether conducting experiments is the principal purpose of the licence. Paragraph 50A(2)(b) makes clear that the Regulator may also consider any other matters that he or she considers to be relevant.

Clause 14(3) provides guidance on the meaning of the term 'controls' referred to in subsection 50A(1). It provides that controls can relate to the dissemination and persistence of the GMO, the disposal of the GMO, the studies that can be conducted on the GMO, the restricted geographic area in which dealings may be conducted, and compliance with a code of practice or technical and procedural guideline.

Clause 14(3) provides guidance on the meaning of the term 'limits' referred to in subsection 50A(1). It provides that limits can include limits on the scope, scale, location and duration of dealings with a GMO, as well as the persons who are permitted to conduct dealings with the GMO.

Amendment of s 51 (Matters Regulator must take into account in preparing risk assessment and risk management plan)

Clause 15 makes consequential amendments to the Act by omitting references to section 49 in section 51(1)(a) and repealing sections 51(1)(b) and 51(2)(b) which relate to actions required by the current section 49.

Amendment of s 52 (Public Notification of risk assessment and risk management plan)

Clause 16(1) makes a consequential amendment to section 52(1) by omitting references to section 49 which relates to action required by the current section 49.

Clause 16(2) inserts a new paragraph (ba) into section 52(2) of the Act. The new paragraph provides that if the Regulator is satisfied that dealings with a GMO pose a significant risk, then the Regulator should make a statement to that effect in the notice published under section 52(1) (i.e. public notification of risk assessment and risk management plans in the gazette, newspaper and Regulator's website).

Clause 16(3) provides for a longer consultation process on the risk assessment and risk management plan where the Regulator considers that the GMO poses a significant risk to the health and safety of the people or the environment. The clause proposes two new subsections into section 52(2)(d) of the Act. Section 52(2)(d)(i) allows for a time period of at least 50 days for submissions if the Regulator is satisfied that the dealings may pose a significant risk. For all other dealings section 52(2)(d)(ii) allows for at least a thirty day time period for submissions.

Amendment of s 56 (Regulator must not issue the licence unless satisfied as to risk management)

Clause 17 inserts reference to section 47 in both sections 56(2)(a) and (b). Therefore the Regulator is required to have regard to the risk assessment and risk management plans prepared under section 47 for dealings not involving intentional release, for the purposes of being satisfied that any risks posed by the dealings proposed to be licensed are able to be managed in such a way as to protect the health and safety of people and the environment. The note to section 56 of the Act makes it clear that paragraphs 56(2)(a), (b) and (c) do not apply to inadvertent dealings applications.

Amendment of s 57 (Other circumstances in which Regulator must not issue the licence)

Clause 18 inserts a new subsection into section 57 of the Act. The new subsection makes it clear that section 57(2), which requires the Regulator to be satisfied that an applicant is a suitable person before issuing a licence, does not apply to inadvertent dealings applications.

Amendment of s 60 (Period of licence)

Clause 19 inserts a new subsection into section 60 of the Act. The new subsection provides that a licence issued for an inadvertent dealing cannot be valid for a period longer than 12 months. This is a maximum period and the Regulator may specify a shorter period as the licence for an inadvertent dealing will only be for the purposes of the disposal of a GMO.

Amendment of s 67 (Protection of persons who give information)

Clause 20 includes in section 67 reference to section 72D(2)(h). This amendment ensures that the same protection is afforded to persons who provide information under the new section 72D(1)(h) (obligations to inform the Regulator in relation to emergency dealing determinations) from certain civil liability.

Amendment of s 71 (Variation of licence)

Clause 21(1) repeals the current section 71(1) and inserts a revised section 71(1) and a new section 71(1A) into the Act. Section 71(1) clarifies that the Regulator has the power to vary a licence either unilaterally, or after

receiving an application from a licence holder. Section 71(1A) provides that the licence holder's application for a variation must be in writing and include any information prescribed by the regulations or required by the Regulator in writing.

Clause 21(2) makes a consequential amendment to section 71(2) of the Act.

Clause 21(3) inserts two new subsections into section 71 of the Act. Section 71(2A) which provides that the Regulator must not vary a licence if the original application was for a limited and controlled release unless the licence as varied is also for a limited and controlled release. In other words, the object of this section is to prevent a variation turning a licence for a limited and controlled release into a licence permitting intentional release of a GMO into the environment.

Section 71(2B) provides that the Regulator must not vary a licence if the licence, as varied, would pose new risks which were not covered in the original risk assessment and risk management plans.

Clause 21(4) makes a consequential amendment to subsection 71(4) of the Act.

Clause 21(5) inserts a new subsection into the Act. The new section 71(5) provides that the Regulator must consult with any appropriate local government before varying a licence. This subsection differs from the subsection of the Commonwealth Act. The Commonwealth Act refers to "local council" rather than "local government".

Clause 21(6) inserts a new subsection into the Act. The new section 71(6) provides that the Regulations may impose additional limitations on the Regulator's power to vary the licence.

Clause 21(7) inserts a new section 71(7) which provides that the Regulations may set a time limit in which the Regulator must vary a licence.

Clause 21(8) makes it clear that the terms 'controls' and 'limits' have the same meaning in subsection 71(2A) as in the proposed section 50A of the Act.

Amendment of s 72 (Regulator to notify of proposed suspension, cancellation and variation)

Clause 22 adds a new subsection to section 72 of the Act. Section 72(7) provides that section 72 of the Act, which requires the Regulator to notify a

licence holder of proposed suspension, cancellation or variation, does not apply where the proposed variation is of minor significance or complexity.

Renumbering of s 72A (GMO licence – annual charge)

Clause 23 is a consequential amendment that renumbers the current section 72A as section 72AA.

Insertion of new Part 5A

Clause 24 inserts a new Part in the Act. The new Part 5A is entitled "Emergency dealing determination".

The proposed section 72A provides a simplified outline for the Part. It provides that the Part creates a system whereby the Minister may make a determination relating to dealings in an emergency.

Section 72B(1) gives the Minister the power to make an emergency dealing determination in respect of dealings with a GMO, by gazette notice. The gazette notice will authorise the stated dealings with the GMO. Authorising an emergency dealing determination by notice published in the Government Gazette by the Minister will ensure national consistency is maintained as contemplated by section 5 of the Act as it is not subject to disallowance. Section 72B(e) of the Commonwealth Act requires the relevant Commonwealth Minister to consult with the States about making the proposed emergency dealing determination.

Section 72B(2) gives the Minister the power to make an emergency dealing determination only if the relevant Commonwealth Minister has made or proposes to make an emergency dealing determination. Section 72B of the Commonwealth Act sets out the conditions under which the relevant Commonwealth Minister is permitted to make an emergency dealing determination. It states that the Minister must:

- have received advice from the Commonwealth Chief Medical Officer; the Commonwealth Chief Veterinary Officer, the Commonwealth Chief Plant Protection Officer or a person specified in the regulations, that there is an actual or imminent threat to the health and safety of people or the environment and that the dealings proposed to be specified in the emergency dealing determination would, or would be likely to, adequately address the threat;
- be satisfied that there is an actual or imminent threat to the health and safety of people or the environment, that the dealings proposed to be

covered by the emergency dealing determination would, or would be likely to, adequately address the threat; and

- be satisfied that the risks posed by the proposed dealings can be managed safely, and have received advice from the Regulator to that effect.

In addition, States must have been consulted about the proposed emergency dealing determination.

Section 72B(3) of the Commonwealth Act gives examples of situations in which it may be appropriate to issue an emergency dealing determination. These include:

— where there is a threat of disease;

— where there is a threat from an animal or plant (such as a pest or alien invasive species); or

— where there is a threat from industrial spillage.

This Part of the Commonwealth Act was recently invoked for release of the genetically modified equine influenza vaccine to address the current outbreak of equine influenza.

Section 72C states that a determination takes effect on the day on which it is made or at a specified later date. In other words, the determination cannot apply retrospectively.

Section 72C(2) provides that a determination ceases to have effect on:

- a date stated in the determination;
- when the determination is revoked; or
- after six months;

whichever comes first.

Section 72C(3) provides that the Minister may extend an emergency dealing determination, by gazette notice.

Section 72C(4) provides that the Minister may extend the emergency dealing determination more than once, for up to six months each time.

Section 72C(5) provides that the Minister may extend the emergency dealing determination only if the relevant Commonwealth Minister has extended or proposes to extend the emergency dealing determination. This section differs from section 72C(5) of the Commonwealth Act which sets out the basis on which the relevant Commonwealth Minister may extend an

emergency dealing determination. The Minister can only extend the emergency dealing determination if:

- he or she has received advice from the person who originally provided advice under paragraph 72B(2)(a) (the "original adviser") that the threat still exists and that extending the emergency dealing determination would, or would be likely to, adequately address the threat; and
- he or she is satisfied that threat still exists and that extending the emergency dealing determination would, or would be likely to, adequately address the threat; and
- he or she is satisfied that the risks posed by the proposed dealings can be managed safely, and have received advice from the Regulator to that effect; and
- the majority of jurisdictions (including States, Territories and the Australian Government) agree to the extension.

Section 72C(6) provides that the extension of the emergency dealing determination takes effect when the original emergency dealing determination was scheduled to end.

Section 72D(1) allows conditions to be imposed on an emergency dealing determination.

Section 72D(2)(a) to (v) give examples of the conditions that may be imposed. These include conditions relating to the quantity of GMO, the scope of dealings, the source of GMO, the person who may deal with the GMO, information required to be given to persons permitted to deal with a GMO, additional information that must be provided to the Regulator, and the storage and security of the GMO amongst other things. Section 72D(2)(w) clarifies that the conditions the Minister may impose are not limited to the matters listed in paragraphs (a) to (v), but that the Minister may impose conditions over any other matter he or she considers appropriate.

Section 72D(4) provides that it is a condition of an emergency dealing determination that a person permitted to deal with a GMO under an emergency dealing determination, must allow the Regulator (or delegate) to enter premises where the dealing is being undertaken, in order to conduct audits, or monitor the dealings covered by the emergency dealing determination. This allows the Regulator to undertake routine or 'on-the-spot' auditing or monitoring of dealings covered by an emergency dealing determination.

Section 72D(5) makes clear that subsection 72D(4) does not limit the conditions that may be placed on an emergency dealing determination.

Section 72E(1) provides that the Minister may vary the conditions of an emergency dealing determination by notice published in the government gazette including imposing new conditions on a determination if the relevant Commonwealth Minister has made or proposes to make the same variations to the corresponding Commonwealth determination. Authorising extension of an emergency dealing determination by notice published in the Government Gazette by the Minister will ensure national consistency is maintained as contemplated by section 5 of the Act as it is not subject to disallowance.

Section 72E(2) provides that the Minister may suspend or revoke an emergency dealing determination by notice published in the government gazette, if the relevant Commonwealth Minister proposes to or has suspended or revoked the corresponding Commonwealth determination. Section 72E(2) of the Commonwealth Act differs from the proposed provision and provides that the Minister may suspend or revoke a dealing in three circumstances:

- if the Minister becomes aware of risks to the health and safety of people or the environment posed by the dealing that cannot be adequately addressed;
- if the Minister is satisfied that the threat no longer exists or is no longer sufficiently serious as to warrant an emergency dealing determination; or
- if the Minister is no longer satisfied that the dealings covered by the determination are likely to adequately address the threat.

Note to section 72E(2) refers to Section 72E(3) of the Commonwealth Act which provides that the Minister must consult the States before varying, suspending or revoking an emergency dealing determination.

Sections 72E(4) provides that a variation, suspension or revocation takes effect on the day it is made if the Minister states that it is necessary to prevent imminent risk of death, serious illness or serious injury or serious environmental damage or otherwise on the day stated by the Minister.

Section 72E(5) provides that the date stated for it to take effect must be 30 days or more after it is made.

Amendment of s 78 (Regulator may include dealings with GMOs on GMO register)

Clause 25 amends section 78(4) of the Act to remove the requirement that a registration of a dealing, made on the application of a licence holder, can only take effect if the licence authorising the dealing ceases to be in force.

Amendment of s 82 (Simplified outline of Part 7)

Clause 26 inserts words into section 82(2) and (4) to take into account that the conditions of an emergency dealing determination could require a facility to be certified to a certain containment level and could require supervision by an institutional biosafety committee respectively.

Amendment of s 83 (Application for certification)

Clause 27 amends the note to section 83 to clarify that the conditions of an emergency dealing determination could require a facility to be certified to a certain containment level.

Amendment of s 89 (Regulator to notify of proposed suspension, cancellation or variation)

Clause 28 adds subsection (7) to section 89 to provide that notice requirements of proposed variations do not apply where the proposed variation is of minor significance or complexity.

Insertion of new s 89A

Clause 29 provides for the insertion of:

- Section 89A(1) which provides for transfers of certification by way of a joint application between the holder of the certification and the transferee;
- Section 89A(2) which requires the application to be in writing and contain information prescribed by the regulations or specified in writing by the Regulator;
- Section 89A(3) which prohibits the Regulator from transferring certification unless satisfied that the conditions to which the certification is subject will continue to be met;
- Section 89A(4) which requires the Regulator to give written notice of his or her decision to the applicants; and

- Section 89A(5) which provides for the transfer, if approved, to take effect on the date specified in the notice, for the certification to continue in force and for the certification to be subject to the same conditions which applied before the transfer.

Amendment of s 91 (Application for accreditation)

Clause 30 replaces the note to section 91(10) to clarify that the conditions of an emergency dealing determination could require supervision by an Institutional Biosafety Committee.

Amendment of s 92 (Regulator may accredit organisations)

Clause 31(1) amends section 92(2)(a) of the Act to remove the obligation for the Regulator to have regard to whether or not an organisation proposes to establish an Institutional Biosafety Committee for the purposes of deciding whether to accredit an organisation.

Clause 31(2) amends:

- section 92(2)(b) of the Act to require the Regulator, for purposes of accrediting organisations, to have regard to whether an organisation will be able to maintain an Institutional Biosafety Committee already established.
- section 92(2)(c) of the Act to require the Regulator, for the purposes of accrediting organisations, to have regard to whether an organisation has appropriate indemnity arrangements if the organisation has established an Institutional Biosafety Committee.

Clause 31(2) inserts a new subsection 92(2)(ca) into the Act which requires the Regulator to consider whether or not the organisation will be in a position to use an Institutional Biosafety Committee established by another accredited organisation as a matter to which the Regulator must have regard in deciding whether to accredit an organisation.

Amendment of s 97 (Regulator to notify of proposed suspension, cancellation or variation)

Clause 32 adds a new subsection (7) to section 97 to provide that the notice requirements of proposed variations of accreditation, do not apply where the proposed variation is of minor significance or complexity.

Replacement of s 107 (Function of consultative committee)

Clause 33 replaces the existing section 107 which currently provides for the functions of the Gene Technology Community Consultative Committee. It is proposed that the Gene Technology Community Consultative Committee and the Gene Technology Ethics Committee are combined into one advisory committee. The combined committee will be known as the Gene Technology Ethics and Community Consultative Committee (the Ethics and Community Committee) and will carry out the combined functions of both committees as well as providing advice on risk communication and community consultation in relation to intentional release licence applications.

The object of these proposed amendments is to increase efficiency by addressing the overlap between the roles of the Ethics Committee and the Consultative Committee. The new committee would also allow relevant skills to be distributed across its membership so that the committee is able to provide clear, balanced, appropriate, and more coordinated advice. The GTMC will review the performance of the new advisory committee after 18 months, but before it has been operating for two years.

The function of the Ethics and Community Committee will be to provide advice, at the request of the Regulator or the Ministerial Council, on:

- matters on which the Ethics Committee currently advises - ethical issues relating to gene technology (proposed section 107(a)); the need for, and content of, codes of practice in relation to ethics for conducting dealings with GMOs (proposed section 107(b); and the need for, and content of, policy principles for dealings with GMOs that should not be conducted for ethical reasons (proposed section 107(c));

- matters on which the Consultative Committee currently advises - matters of general concern identified by the Regulator in relation to applications (proposed section 107(g), matters of general concern in relation to GMOs (proposed section 107(h)) and the need for policy principles, policy guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products and the conduct of such principles, guidelines and codes (proposed section 107(d))

- community consultation matters relating to intentional release licence applications (proposed section 107(e)); and

- risk communication matters relating to dealings that involve the intentional release of a GMO into the environment (proposed section 107(f)).

Risk communication involves an interactive dialogue between risk assessors, risk managers and stakeholders. It underpins the processes of risk assessment and risk management.

The proposed new section 107 is not intended to mandate the examination of every intentional release application, instead it is intended to permit the Regulator to seek advice in relation to certain types of releases that might be precipitated by such an application.

Replacement of ss 110 and 110A and Part 8, Division 4

Clause 34 updates the notes contained in sections 110, 111 and 112 of the Act to reflect the changes to the Commonwealth Act as a result of combining the roles of the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee.

Amendment of s 136A (Quarterly reports)

Clause 35 inserts two new subsections 136A(2)(ba) and 136A(2)(bb) into the Act which provide that quarterly reports prepared by the Regulator and given to the Minister must include information about any emergency dealing determinations issued by the Minister and any breaches of conditions of an emergency dealing determination that have come to the Regulator's attention during the quarter.

Amendment of s 138 (Record of GMO and GM product dealings)

Clause 36 inserts a new subsection 138(1A) into the Act providing that the Record of GMO and GM Product dealings required to be maintained by the Regulator under Division 6, must include certain information, except confidential commercial information, on the content of emergency dealing determinations:

- dealings stated in the emergency dealing determination, including any conditions;
- the dates the determination takes effect and ceases.

Amendment of s 145 (Simplified outline of Part 10)

Clause 37(1) inserts the phrase "or for certain other reasons" to the end of paragraph 145(a)(ii) in the simplified outline at the start of Part 10 of the Act. This clarifies that the circumstances under which the Regulator may give directions have been expanded.

Clause 37(2) inserts a new subsection into the simplified outline in section 145(a)(ii) of the Act. This makes it clear that Part 10 of the Act enables the Regulator to give directions to a person permitted to deal with a GMO under an emergency dealing determination.

Amendment of s 146 (Regulator may give directions)

Clause 38(1) inserts an additional subsection in section 146 into the Act. Subsection 146(1)(b)(ii) provides that the Regulator may give directions to a licence holder, requiring that he or she take steps to comply with the Act, if it is desirable in the public interest to do so.

Clause 38(2) replaces section 146(1)(a) to provide that the Regulator may give directions to a person dealing with, or has dealt with, a GMO specified in an emergency dealing determination and replaces section 146(1)(b) to provide that the Regulator may give directions to a person if it is desirable in the public interest to do so.

Clause 38(3) inserts a new section 146(2A) into the Act, setting out the matters that the Regulator should consider in deciding whether it is in the public interest to make a direction. These matters would include:

- the type of the GMO dealing and whether it is a one-off or ongoing dealing;
- whether any steps have been taken to address the non-compliance issue;
- the likelihood of a repeat of the noncompliance;
- the severity of the noncompliance issue;
- the compliance history of the licensee or the person covered by the licence;
- whether it would be more appropriate to address the noncompliance by another means such as variation, suspension or cancellation of the licence;
- whether the noncompliance was deliberate; and
- the need for deterrence.

These matters are similar to those listed in the OGTR's Non-Compliance Protocol of 10 May 2002. The protocol gives the Regulator guidance on what matters he or she should consider in deciding whether to conduct a criminal investigation.

Amendment of s 149 (Simplified outline of Part 11)

Clause 39 inserts a reference to emergency dealing determinations into the simplified outline in section 149 of the Act. This makes clear that Part 11 of the Act does not limit the conditions to which an emergency dealing determination can be subject.

Amendment of s 152 (Powers available to inspectors for monitoring compliance)

Clause 40 inserts a section 152(2)(d) of the Act to make it clear that an inspector may enter premises and exercise the monitoring powers set out in section 153, for the purpose of finding out whether the Act has been complied with, if the occupier of the premises is a person dealing with, or who has dealt with, a GMO stated in an emergency dealing determination and entry is at a reasonable time.

Amendment of s 177 (Part does not limit power to impose licence conditions)

Clause 41 inserts a reference to the Minister's power to impose conditions on an emergency dealing determination into section 177 of the Act. This clarifies that Part 11 does not limit the Minister's power to impose conditions on an emergency dealing determination.

Amendment of s 182 (Deadlines for making reviewable decisions)

Clause 42(1) amends the wording of section 182(a) of the Act so as to extend the application of section 182 to all applications to the Regulator, not just applications to the Regulator to make a reviewable decision.

Clause 42(2) amends section 182 of the Act to clarify that a deemed rejection of an application on account of elapse of time is reviewable under the Act.

Amendment of s 185 (Regulator may declare that information is confidential commercial information)

Clause 43 adds a new subsection 185(3B) into the Act which provides that information stated for purposes of an application for a declaration that information is confidential commercial information ('CCI'), is treated as CCI until the Regulator has made a decision on the application.

Amendment of s 192A (Interference with dealings GMOs)

Clause 44(1) inserts a new paragraph into subsection 192A(2) of the Act to provide that authorised GMO dealings include dealings that are stated in an emergency dealing determination and are not prohibited from being undertaken at the premises or facility by a condition of the emergency dealing determination.

Clause 44(2) amends paragraph (d) of the definition of authorised GMO dealings in subsection 192A(2) of the Act, to refer to 'dealings included on the GMO Register' instead of 'included on the GMO register'.

Amendment of s 194 (Review of operation of Act)

Clause 45 amends the section 194(1) to synchronise any future review of the Queensland Act with any Statutory Review of the Commonwealth Act and section 194(2) places an obligation on the Minister to table the report within 14 sitting days after its receipt.

Amendments of Schedule 1 (Reviewable decisions and eligible persons)

Clause 46 adds the following items to the list of reviewable decisions under Schedule 1:

- Item 1A, a decision by the Regulator under section 43(2)(f) to refuse to consider an application on the basis that the applicant is not a suitable person to hold a licence.
- item 3A, a decision by the Regulator under section 70 to refuse to transfer a licence.
- item 4A, a decision by the Regulator under section 71 to refuse to vary a licence.
- item 7A, a decision by the Regulator under section 89A to refuse to transfer a certification.

Amendment to Schedule 3 (Dictionary)

Clause 47(2) inserts in the definitions of ***Corresponding Commonwealth emergency dealing determination, Emergency dealing determination, Ethics and community committee, Inadvertent dealings applications*** into Schedule 3 of the Act.

Clause 47(3) amends the definition of ***deal with*** in relation to a GMO by including transport of a GMO and disposal of the GMO as dealings. Possession, supply and use of the GMO remain dealings when used for the purposes of, or in the course of a dealing described in the definition.

Clause 47(4) amends the definition of institutional biosafety committee with the intention of clarifying its meaning as an organisation established in accordance with guidelines issued by the Regulator under section 98 of the Act.

Schedule Minor amendments

There is a schedule of minor amendments to Part 8 of the Act are made to take into account the combination of the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee.