GENE TECHNOLOGY BILL 2001

EXPLANATORY NOTES

GENERAL OUTLINE

Objectives of the Legislation

The policy objectives of this Bill are to:

- Provide the Queensland major component of a national scheme established by States, Territory and Commonwealth legislation to protect the public health and safety of people and to protect the environment from risks associated with gene technology;
- Achieve a regulatory framework that efficiently and effectively operates in conjunction with other regulatory schemes relevant to GMOs and genetically modified products (GM products) (e.g. schemes for the regulation of food, agricultural and veterinary chemicals, therapeutic goods, and industrial chemicals);
- Establish an independent national regulator to scientifically assess dealings in gene technology.

Reasons for and Achievements of the Policy Objectives

Consistent with its object, the Bill:

(a) establishes the Queensland component of a national gene technology regulatory scheme that is scientifically based, identifying and assessing risks posed by, or as a result of, gene technology, and managing any risks through the regulation of dealings with genetically modified organisms (GMOs);

(b) establishes the functions of the Gene Technology Regulator (the Regulator), which was established as a statutory officer under the *Gene Technology Act 2000 (Cth)*;

(c) establishes the functions of the three key advisory committees (the Gene Technology Technical Advisory Committee, the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee);

(d) prohibits persons from dealing with GMOs unless the dealing with the GMO is:

(i) exempt;

(ii) a notifiable low risk dealing;

(iii) on the Register of GMOs; or

(iv) licensed by the Regulator;

(e) establishes a scheme for the assessment of risks to human health and the environment associated with various dealings with GMOs which includes opportunities for extensive public input; and

(f) provides for a centralised, publicly available database of all GMOs and GM products approved in Queensland and Australia (the Record of GMO and GM product dealings).

Alternatives to the Bill

There are no alternatives considered appropriate for achieving these policy objectives. The Commonwealth has enacted a Gene Technology Act 2000, however due to Constitutional limitations that statute does not provide full regulatory coverage for gene technology (e.g. it does not cover the activities of State Government agencies nor higher education institutions). Therefore both State and Commonwealth legislation is required to provide full national regulatory coverage.

Estimated Cost of Implementation

As the Commonwealth has enacted the *Gene Technology Act 2000 (Cth)*, the regulatory burden will not be increased by State-level legislation, although the *Gene Technology Bill 2001 (Qld)* will increase the coverage of the regulatory scheme to include State Government agencies and tertiary institutions. However, all State and Territory Governments, along with the Commonwealth, have agreed that regulation is necessary to ensure the health and safety of people and the environment are protected through the regulated management of risks associated with dealings in GMOs.

In the 1999 Budget, the Federal Government committed $7.6 million over 2 years for the development of the gene technology legislation and the establishment of the Regulator. A costing study was undertaken by an independent consultant, with the result that the scheme will cost about $8

million per year to operate part of which will be offset by the levying of fees and charges. The Commonwealth will meet the full cost of this for the first two years of operation (i.e. until 21 June 2003). However, as the gene technology industry is immature, the scheme will impose substantial burdens on the several Departments (in particular Innovation and Information Economy, Primary Industries and Health) in terms of providing expertise and advice on applications of the technology, as well as substantial administrative burden for the Department of Innovation and Information Economy as lead agency in coordinating the Queensland Government's input into the scheme. In the short term, these costs will be met form existing resources.

Consistency with Fundamental Legislative Principles

The Bill has been drafted with regard to Fundamental Legislative Principles.

Consultation

The Interim Office of the Gene Technology Regulator (which was established by the Commonwealth manage the negotiation and establishment of the national regulatory scheme) managed substantial consultation on the scheme with representatives from Queensland Government agencies. These consultations focussed on the *Gene Technology Act 2000 (Cth)*, on which the *Gene Technology Bill 2001 (Qld)* is based, and the *Gene Technology Regulations 2001 (Cth)*. Public consultations were held in Brisbane and Cairns in relation to the Commonwealth Act during 2000 and targeted public consultations on the *Gene Technology Regulations 2001 (Cth)* took place in March 2001 in Brisbane. Both documents were released in consultation draft form for public and industry comment. As this is a national scheme involving consistent legislation and regulations (to ensure consistency), the national consultative process has been relied upon to provide informed public comment.

The following initiatives have been or are currently being undertaken at a State and national level:

- the Departments of Innovation and Information Economy (DIIE) is finalising a 'friendly guide' to biotechnology and its regulation in Queensland for broad distribution. This will include description of the gene technology regulatory regime;

- DIIE has released the *Code of Ethical Practice for Biotechnology in Queensland*. Developed through a consultative process, this is the first of its kind, issued by Government, in Australia;
- the Office of the Gene Technology Regulator (OGTR) releases regular information papers both in hard copy and on its web site addressing current issues;
- the OGTR has distributed a *Gene Technology Handbook* that outlines in simple terms all requirements for organisations conducting dealings in gene technology.

NOTES ON PROVISIONS

PART 1—PRELIMINARY

Clause 1—Short title

This is a formal provision that specifies the short title of the Act as the *Gene Technology Act 2001*

Clause 2—Commencement

Sub-clause 2(1) provides that clauses 1 and 2 of the Act commence on the day on which the Act receives Royal Assent.

Sub-clause 2(2) enables any provisions of the Act do not commence within six months of Royal Assent, those provisions commence on the first day after the end of that period.

The effect of this provision is to enable different parts of the Act to commence at different times.

Clause 3—Object of Act

This clause provides that the object of this Bill 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 terms "environment", "gene technology", "dealings" and "genetically modified organisms" are defined in Schedule 3—Dictionary.

Clause 4—Regulatory framework to achieve object

This clause makes it clear that it is intended that the object of the Bill be achieved through a regulatory system that will be based on an efficient and effective system of scientific assessment. Furthermore, the regulatory framework is to operate in conjunction with other State, Territory and Commonwealth regulatory schemes relevant to GMOs and genetically modified (GM) products. For example:

- foods (including GM foods) are regulated under the *Food Act 1981 (Qld)* with the role of developing Food Standards (for consideration by the Australia New Zealand Food Standards Council) resting with the Australia New Zealand Food Authority under the *Australia New Zealand Food Authority Act 1991 (Cth)*;
- therapeutic goods (including GM therapeutic goods) are regulated under the *Therapeutic Goods Act 1989 (Cth)* administered by the Therapeutic Goods Administration;
- agricultural and veterinary chemicals (including GM agricultural and veterinary chemicals) are regulated through a national scheme administered by the National Registration Authority under the *Agricultural and Veterinary Chemicals (Queensland) Act 1994 (Qld)*, the *Agricultural and Veterinary Chemicals (Administration) Act 1992 (Cth)* and the *Agricultural and Veterinary Chemicals (Code) Act 1994 (Cth)*; and
- industrial chemicals are regulated through the National Industrial Chemicals Notification and Assessment Scheme under the *Industrial Chemicals (Notification and Assessment) Act 1989 (Cth)*.

The Bill will also operate alongside current import arrangements for GMOs (which are administered by the Australian Quarantine and Inspection Service in accordance with the *Quarantine Act 1908*) and in conjunction with existing State legislation that may also affect the use of GMOs (e.g. *Plant Protection Act 1989 (Qld)*).

Sub-clause 4(aa) has been included to reflect the precautionary principle, as defined in the United Nations Conference on Environment and

Development's 1992 Rio Declaration on Environment and Development, which has been ratified by Australia.

Clause 5—Nationally consistent scheme

This clause notes that it is intended that this Bill form the Queensland component of a nationally consistent scheme for the regulation, by States, Territories and the Commonwealth, of dealings with GMOs. The Commonwealth legislation is in place, as is Tasmanian legislation. Other States, such as Victoria and WA are about to introduce legislation to their Parliaments. An Intergovernmental Agreement on Gene Technology (the Gene Technology Agreement) committing jurisdictions to a nationally consistent scheme and establishing a ministerial Council to oversee the scheme has been signed by the Commonwealth and is currently under consideration by the Victoria Premier.

Clause 6—Act binds all persons

Sub-clause 6(1) provides that the Bill will bind the Crown in each of its capacities, as far as the Parliament permits.

Sub-clause 6(2) provides that the Crown may not be prosecuted for a criminal offence against this Bill or ensuing regulations.

Clause 7—External Territories

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 8—Offences and penalties

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 8A—Numbering

This clause has been included to explain that the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act.

Clause 8B—Notes

This clause heading has been included to explain that Notes do not form part of the legislation.

Clause 8C—Outlines

This clause heading has been included to explain that Outline provisions are provided as a general guide to readers.

PART 2—INTERPRETATION AND OPERATION OF ACT

DIVISION 1—Simplified outline of pt 2

Clause 9—Simplified outline of pt 2

This clause gives a simplified outline of the Part.

DIVISION 2—Definitions

Clause 10—Definitions

Sub-clause 10(1) refers readers to Schedule 3—Dictionary.

Sub-clause 10(2) provides that the terms of reference of the Gene Technology Ministerial Council are governed by the Gene Technology Agreement.

Clause 11—Meaning of "intentional release of a GMO into the environment"

The clause provides that a dealing with a GMO involves the intentional release of the GMO into the environment if the GMO is intentionally released into the open environment, whether or not it is released with provision for limiting the dissemination or persistence of the GMO or its genetic material in the environment. This definition is intended to cover

field trials of GM crops and animals and any commercial release of a GMO into the environment.

This definition is important for identifying the appropriate assessment path to be applied in relation to the dealing with the GMO. The process for approval of dealings with GMOs (as described in Part 5) varies depending on whether the dealing is to occur under conditions of containment or whether the dealing involves a deliberate release of the GMO into the environment. This flexibility has been built into the scheme because of the potential for different, or more serious, risks developing in relation to public health and safety and the environment from dealings involving a release into the environment, thereby necessitating a more comprehensive public consultation and risk assessment process.

Clause 12—Meaning of "corresponding State law"

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No definition has been included as this term refers to the interaction of State and Commonwealth gene technology legislation.

Clause 12A—Meaning of "recklessness"

This definition, which is based on that provided in the *Criminal Code (Cth)*, has been included to releflect the nationl nature of the regualtory scheme. As the scheme establishes criminal offences, it necessarily requires the interaction of State and Commowenalth Criminal Codes. The criminal justice system in Queensland is a Code system (i.e. crimes are specified), whereas the Commonwealth system, and those of some other States (e.g. Victoria) use a Code and icnorporate the principle of mens rea (i.e. criminal intent). Recognising that the term is a commonly used term in the language, this definition has been included to provide maximum clarity as to the intended meaning of the term "recklessness".

To ensure prosecutions are carried out in a manner consistent across the continent, this definition has been included. The WA Bill will include the same approach, as that State operates under the similar criminal justice system as Queensland.

DIVISION 3—Operation of Act

Clause 13—Operation of Act

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included as the clause in the Commonwealth Act is used only to establish the constitutionality of that Act.

Clause 14—Wind-back of reach of Act

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included as the State level Bill will not wind back. Rather, the corresponding clause in the Commonwealth Act provides for a "wind-back" of the reach of that Act where a State has enacted a corresponding State law.

Clause 15—Relationship to other State laws

This clause clarifies that this Bill is not intended to "cover the field" in respect of GMOs. This clause makes it clear that the provisions of the Bill are in addition to, and not in substitution for, the requirements of any other Queensland law, whether that law has been passed or made before or after the commencement of the Bill.

DIVISION 4—Provisions to facilitate a nationally consistent scheme

Subdivision 1—General provisions

Clause 16—State laws may operate concurrently

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 17—Conferral of functions on Commonwealth officers and bodies

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 18—No doublingup of liabilities

This clause establishes that there be no 'double jeopardy' under the Bill or a corresponding State law.

Sub-clause 18(1) provides that if an act or omission is an offence against the Bill and is also an offence against the Commonwealth Act, and the offender has been punished for the offence under the Commonwealth Act, then the offender is not also liable to be punished for the offence under the Bill.

Sub-clause 18(2) provides that, if a person has been ordered to pay a pecuniary penalty under the Commonwealth Act because of certain conduct, the person is not liable to a pecuniary penalty under the Bill for the same conduct.

Clause 19—Review of certain decisions

This clause provides the capacity for the Administrative Appeals Tribunal to review decisions made under this Bill, for example, where the 'wind-back' of this Bill has taken effect and the decision by the Regulator is made under State legislation.

Clause 20—Things done for multiple purposes

This clause provides that licences, certificates and other things issued or done under the Bill remain valid although they may have been done for the purposes of the Commonwealth Act.

Subdivision 2—Policy principles, policy guidelines and codes of practice

Clause 21—Ministerial Council may issue policy principles

Sub-clause 21(1) enables the Ministerial Council to issue policy principles in relation to prescribed matters (e.g. ethical issues relating to

dealings with GMOs, recognition of areas designated under State law for the purposes of identity preservation of particular produce for marketing purposes). The Regulator will be required to observe such principles and must not issue a licence under the legislation if to do so would be inconsistent with a policy principle issued by the Ministerial Council.

Sub-clause 21(2) requires that the Ministerial Council must be satisfied that adequate consultation on the policy principle has occurred in accordance with the requirements of clause 22 of the Commonwealth Act. (Note: this clause is not replicated in the Queensland Bill.)

Sub-clause 21(3) clarifies that regulations made describing issues in relation to which policy principles may be made, may relate to matters beyond public health and safety and the environment (such as cultural matters), but that the principles must not detract from the protection of public health and safety and the environment. For example, policy principles could not be made in relation to trade if the effect of the principles were to override the primary object of the Bill (i.e. the protection of the health and safety of people and the environment).

Clause 22—Consultation on policy principles

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 23—Ministerial Council may issue policy guidelines

This clause allows the Ministerial Council to issue policy guidelines in relation to matters relevant to the functions of the Regulator. These are distinguishable from policy principles as policy guidelines will not be binding on the Regulator. Rather, the Regulator will be required to take account of policy guidelines when deciding on an application for a licence.

Clause 24—Ministerial Council may issue codes of practice

This clause allows the Ministerial Council to issue codes of practice in relation to gene technology. Sub-clause 24(2) of the Commonwealth Act describes the requirements for consultation which must be met before the Ministerial Council may issue a code of practice. This sub-clause is referenced in the Queensland Bill.

PART 3—THE GENE TECHNOLOGY REGULATOR

Clause 25—Simplified outline of pt 3

This clause gives a simplified outline of the Part.

Clause 26—The Gene Technology Regulator

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included. The Regulator is established as a statutory office holder under the Commonwealth Act.

Clause 27—Functions of the Regulator

This clause sets out the functions of the Regulator. The Regulator will be responsible for:

(a) performing functions in relation to GMO licences as set out in Part 5. Part 5 describes the process for initial consideration, assessment and decision making in relation to applications for licences under the Bill;

(b) developing draft policy principles and policy guidelines as requested by the Ministerial Council;

(c) developing codes of practice;

(d) issuing technical and procedural guidelines in relation to GMOs;

(e) providing information and advice to other regulatory agencies about GMOs and GM products;

(f) providing information and advice to the public about the regulation of GMOs;

(g) providing advice to the Ministerial Council about the operations of the Regulator and the Gene Technology Technical Advisory Committee; and about the effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation;

(h) undertaking or commissioning research in relation to risk assessment and the biosafety of GMOs;

(i) promoting the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies;

(j) monitoring international best practice in relation to the regulation of GMOs;

(k) maintaining links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia; and

(l) performing such other functions as are conferred on the Regulator by this Bill, the regulations or any other law.

Clause 28—Powers of the Regulator

This clause clarifies that the Regulator has power to do all things necessary or convenient to be done in connection with the performance of the Regulator's functions.

Clause 29—Delegation

This clause allows the Regulator to delegate the Regulator's powers or functions to State officers where the functions of such officers relate directly or indirectly to GMOs or GM products. This is important so that, with their agreement, State officers can be enlisted to assist the Regulator in, for example, undertaking monitoring activities.

Sub-clause 29(2) requires that delegates comply with any directions issued by the Regulator.

Clause 30—Independence of the Regulator

This clause entrenches the Regulator's independence and discretion in relation to the exercise of powers or functions. It specifically provides that the Regulator may not be directed by anyone in respect of whether or not a particular application for a GMO licence is issued or refused, nor in respect of conditions to which a particular GMO licence may be subject.

PART 4—REGULATION OF DEALINGS WITH GMOS

DIVISION 1—Simplified outline

Clause 31—Simplified outline of pt 4

This clause gives a simplified outline of the Part.

DIVISION 2—Dealings with GMOs must be licensed

Clause 32—Person not to deal with a GMO without a licence with full knowledge or recklessness

This clause describes the central prohibition in this legislation. It provides that a person is guilty of an offence if:

(a) the person deals with a GMO knowing that it is a GMO; and

(b) the person knows that the dealing with the GMO is not authorised by a GMO licence or is reckless as to whether or not the dealing is so authorised; and

(c) the person knows that the dealing is not a notifiable low risk dealing (as described in clause 74) or is reckless as to whether or not the dealing is a notifiable low risk dealing; and

(d) the person knows that the dealing is not an exempt dealing (as specified by the regulations) or is reckless as to whether or not the dealing is an exempt dealing; and

(e) the person knows the dealing is not included on the GMO Register (as established under clause 76) or is reckless as to whether or not the dealing is included on the GMO Register.

A person must not, therefore, deal with a thing they know to be a GMO without a licence authorising that dealing, unless the dealing is a notifiable low risk dealing, has been specifically exempted from the application of the legislation under the regulations, or has been placed on the GMO Register.

The clause also describes the maximum penalties that may be imposed in relation to an offence under sub-clause 32(1). If the offence is an aggravated offence (as defined in clause 38 as being an offence that causes significant damage, or is likely to cause significant damage, to the health

and safety of people or the environment) the penalty is 5 years imprisonment or 2,933 penalty units. This equates to $219,975 for an individual and $1,099,875 for a body corporate (in Queensland a penalty unit is currently equivalent to $75). All fines in this Bill have been set to be as consistent as possible with fines specified under the Commonwealth Act.

In any other case, the maximum penalty is 2 years imprisonment or 733 penalty units which equates to $54,975 for an individual and $274,875 for a body corporate.

Clause 33—Person not to deal with a GMO without a licence

This clause describes the same offence as clause 32 but enables strict liability to apply in respect of the offence. This means that a smaller penalty (293 penalty units in the case of an aggravated offence and 73 penalty units in any other case) may be applied in relation to lesser offences without the need to establish all of the fault elements of the offence.

While it is necessary to establish that the person dealt with the GMO knowing that it was a GMO, the fact that they dealt with the GMO without a licence or without the dealing being a notifiable low risk dealing, exempt dealing or dealing on the GMO Register, is sufficient. It will not be necessary to establish that they knowingly or recklessly dealt with the GMO without approval under the legislation.

Clause 34—Person must not breach conditions of a GMO licence with full intention, knowledge and recklessness

Sub-clause 34(1) provides that a holder of a GMO licence is guilty of an offence if they intentionally do something, or fail to do something, that they know will result in a breach of a condition of licence.

Sub-clause 34(2) establishes a similar offence for persons covered by a GMO licence who do something, or fail to do something, which results in a breach of a condition of licence. However, in this case it is also necessary for the prosecution to establish that the person had knowledge of the conditions of licence. By contrast, in relation to offences committed by holders of a licence (under sub-clause 34(1)) it is assumed that all licence holders would necessarily have knowledge of the conditions of a licence.

Similar penalties apply as under clause 32.

Clause 35—Person must not breach conditions of a GMO licence

This clause describes the same offences as clause 34, but enables strict liability to apply in respect of the offences. Under this clause, if a licence holder breaches a condition of licence, it is not necessary to establish that they did so knowingly or recklessly in order for the penalty to be applied. This means that a smaller penalty may be applied in relation to lesser offences (such as a breach of more minor conditions of licence) without the need to establish all of the fault elements of the offence.

Similar penalties apply as under clause 33.

Clause 36—Person must not breach conditions on GMO Register

This clause provides that a person is guilty of an offence if the person deals with a GMO knowing that it is a GMO, and the dealing is in breach of a condition specified on the GMO Register (described in Part 6, Division 3) relating to the dealing.

Recognising that dealings with GMOs are only entered on the GMO Register after a period of licensing and after the Regulator is satisfied that any risks are minimal and that it is no longer necessary for the GMO to be licensed directly, the penalty for breach of any condition is smaller than the penalties for breach of a condition of licence (maximum 73 penalty units).

Clause 37—Offence relating to notifiable low risk dealings

This clause provides that a person is guilty of an offence if they deal with a GMO knowing that it is a GMO, that the dealing is a notifiable low risk dealing (defined in clause 74), and that the dealing has been undertaken in contravention of the regulations (which describe the conditions to be observed). The maximum penalty is 73 penalty units.

Clause 38—Aggravated offences—significant damage to health or safety of people or to the environment

This clause describes the concept of an "aggravated offence", as referenced in clauses 32, 33, 34 and 35. An aggravated offence is one that causes significant damage, or is likely to cause significant damage, to the health and safety of people or to the environment. This recognises that some offences against the Bill are potentially more serious than others (given the possible significant consequences that may flow from an action),

and that in the event of such serious offences there should be higher penalties.

Sub-clause 38(2) provides that in order to prove an aggravated offence, the prosecution must prove that the person who committed the offence intended his or her conduct to cause significant damage to the health and safety of people, or to the environment or that the person was reckless as to whether his or her conduct would cause such significant damage.

PART 5—LICENSING SYSTEM

DIVISION 1— Simplified outline

Clause 39—Simplified outline of pt 5

This clause gives a simplified outline of the Part.

DIVISION 2—Licence applications

Clause 40—Person may apply for a licence

This clause describes the requirements for applying to the Regulator for a licence to undertake certain dealings with GMOs.

Sub-clause 40(2) provides that the licence applicant must apply in writing and must provide all of the information requested by the Regulator. The applicant will be required to provide the Regulator with all of the information that is necessary to support the assessment of the application including information about potential risks associated with the proposed dealings and how the applicant proposes to manage any such risks.

Sub-clause 40(3) requires that the application specify whether any of the dealings proposed would involve the intentional release of a GMO into the environment. This is important as it determines the assessment process applied in relation to the application.

Sub-clause 40(4) clarifies that an application may be made in respect of one dealing, one or more specified dealings, or in respect of a class of dealings with specified GMOs or classes of GMOs.

Sub-clause 40(5) clarifies that the applicant may apply for authorisation for the dealings with the GMO to be undertaken by a named person, a class of persons or all persons.

Sub-clause 40(6) provides that the application must be accompanied by an application fee if such an application fee is prescribed in the regulations.

Clause 41—Application may be withdrawn

This clause allows the applicant to withdraw a licence application at any time before the licence is issued.

Sub-clause 41(2) provides that the application fee is not refundable if the applicant withdraws the application. This has been included to ensure that costs the Regulator may have incurred are covered.

Clause 42—Regulator may require applicant to give further information

This clause enables the Regulator to require an applicant for a licence to give the Regulator such further information in relation to the application as the Regulator requires. The request for further information must be by notice in writing and may specify the period within which information is to be provided.

Clause 43—Regulator must consider applications except in certain circumstances

This clause enables the Regulator to undertake an initial "screening" of an application before he or she accepts the application. As part of this initial screening, the Regulator looks at whether:

- the application contains the required information, including any further information previously requested by the Regulator;
- the application indicates whether it involves a deliberate release into the environment or not (as this will be important for determining the assessment process undertaken);
- it is accompanied by the requisite application fee; and
- the application is inconsistent with a policy principle issued by the Ministerial Council under clause 21.

If the application is inadequate on any of these grounds, the Regulator may refuse to undertake any further consideration of the application.

Sub-clause 43(3) provides that the Regulator must issue the licence or refuse to issue the licence within prescribed statutory timeframes.

Clause 44—Regulator may consult with applicant

This clause provides capacity for the Regulator to hold 'pre-conferences' with applicants to assist their understanding of the regulatory requirements. If the application relates to a GMO that will also require approval from an existing regulator or regulators at some point during the life cycle of the GMO or its products, the Regulator may also involve these other relevant regulators to ensure an effective and efficient interface between the relevant regulatory agencies.

Clause 45—Regulator must not use certain information in considering licence application

This clause provides that, where a person provides confidential commercial information in support of a licence application, the Regulator must not use that information to consider a licence application by another person unless the first person has given written consent for the information to be used.

This clause is intended to combat the 'free rider' effect, where it would be possible for a second applicant to minimise the resource implications of a licence application by referring to, or using, information already made available to the Regulator in support of another application.

Whilst the Regulator may not consider the information submitted by the first party in relation to an application by a second party (without the written permission of the first party) this does not preclude the Regulator from utilising resources generated by the Regulator in relation to the first application (eg literature searches) in considering the second application. Further, the Regulator may use information he or she learns about risk in respect of the first application, to aid consideration of the second.

DIVISION 3—Initial consideration of licences for dealings not involving intentional release of a GMO into the environment

Clause 46—Applications to which div 3 applies

This clause provides that Division 3 applies to an application for a GMO licence where the Regulator is satisfied that none of the dealings proposed to be authorised by the licence would involve the intentional release of a GMO into the environment (as defined in clause 11). This would include, for example, applications in respect of dealings with GMOs within a contained laboratory.

Clause 47—What the Regulator must do in relation to application

This clause sets out the steps that the Regulator must take in assessing an application and before a decision on the application is made.

Sub-clause 47(1) provides that before issuing a licence, the Regulator must prepare a risk assessment and risk management plan in relation to the GMO and the proposed dealings in the licence application. The risk assessment must take into account any risks posed to health and safety of people or the environment, by the proposed dealing with the GMO. The risk management plan must take into account how any such risks may be managed so as to protect the health and safety of people and the environment.

Sub-clause 47(4) provides that the Regulator may consult the Commonwealth, the Gene Technology Technical Advisory Committee, relevant Commonwealth authorities and local councils, as well as any other person, on any aspect of the application.

DIVISION 4—Initial consideration of licences for dealings involving intentional release of a GMO into the environment

Clause 48—Applications to which div 4 applies

This clause provides that Division 4 applies where the Regulator is satisfied that at least one of the dealings proposed to be authorised by the licence involves the intentional release of a GMO into the environment (as defined in clause 11). For example, this Division applies to GMO crop

field trials as well as applications for commercial release of a GMO for commercial propagation and sale.

Clause 49—Dealings that may pose significant risks to the health and safety of people or the environment

This clause describes the process that the Regulator must follow, and the matters the Regulator must consider, where at least one of the dealings proposed to be authorised by the licence may pose significant risks to the health and safety of people or the environment.

Recognising that applications for licences involving the intentional release of GMOs into the environment may be varied, and that the risks posed by applications also vary, it is important that the Regulator have the capacity to apply an assessment process appropriate for considering the risks posed by the particular application.

Sub-clause 49(1) requires that the Regulator inform stakeholders and the community of the receipt of all applications relating to dealings that may pose significant risks to the health and safety of people or to the environment (in the Government Gazette, newspapers and on the Regulator's website).

Sub-clause 49(2) sets out the matters that the Regulator must have regard to in determining whether the dealings proposed to be authorised by the licence may pose significant risks to the health and safety of people or the environment.

Sub-clause 49(3) sets out certain requirements for the content of the public notification in respect of the application. The notice must: state that an application has been made; state that a person may request further information about the application; invite written submissions on the application; and specify the closing date for submissions (being no earlier than 30 days after the date on which the notice was published). The Regulator may however decide on a longer period of consultation.

Clause 50—Regulator must prepare risk assessment and risk management plan

Sub-clause 50(1) provides that, before issuing a licence, the Regulator must prepare a comprehensive risk assessment and risk management plan. The risk assessment would:

- identify any hazards to public health and safety or the environment associated with the dealing, based on objective information;
- estimate the probabilities of hazards occurring; and
- estimate the risk that is a function of the above two factors.

Following the estimation of risk, a risk management plan would identify measures for managing any risks identified in order to reduce the probability of hazards occurring. The risk management plan may provide that the risks cannot be managed and, as such, a licence should not be granted. Alternatively the plan could set out conditions that would be necessary for the risks to be effectively managed.

Sub-clause 50(2) clarifies that, regardless of the Regulator's initial consideration regarding the risks of the proposed dealings and whether or not a first round of public consultation was therefore necessary, the Regulator must prepare a comprehensive risk assessment and risk management plan (such assessments and plans must then be notified publicly under clause 52).

Sub-clause 50(3) provides that, in preparing a risk assessment and risk management plan, the Regulator must seek advice from a range of parties, including the Gene Technology Technical Advisory Committee, States, the Commonwealth Environment Minister, prescribed Commonwealth agencies and relevant local councils.

Clause 51—Matters Regulator must take into account in preparing risk assessment and risk management plan

Sub-clause 51(1) details a range of matters that must be considered by the Regulator in preparing the risk assessment (e.g. advice provided by the Gene Technology Technical Advisory Committee and State Governments).

Sub-clause 51(2) details the range of matters that must be considered by the Regulator in preparing the risk management plan (e.g. means of managing risks, submissions made to the Regulator, advice provided by the Gene Technology Technical Advisory Committee and State Governments).

Sub-clause 51(3) provides that, in ascertaining the best means of managing the risks associated with the GMO, the Regulator is not limited to considering submissions or advice made or given (i.e. the Regulator may seek advice through other means such as independent research).

Clause 52—Public notification of risk assessment and risk management plan

This clause provides that the Regulator must advise the public that a draft risk management plan has been prepared (in the Government Gazette, newspapers and on the Regulator's website). The advice must: inform people that they may request a copy of the risk assessment and risk management plan (in accordance with clause 54); invite written submissions on the risk assessment and risk management plan; and specify the closing date for submissions (which may not be earlier than 30 days after the notice was published).

Sub-clause 52(3) also requires the Regulator to seek the views of the Gene Technology Technical Advisory Committee, States, Commonwealth agencies prescribed in regulations and such local councils as the Regulator considers appropriate.

Clause 53—Regulator may take other actions

This clause allows the Regulator to take other actions to determine whether the range of dealings proposed by the application do indeed pose risks to the health and safety of people or the environment. These actions may include a public hearing.

Sub-clauses 53 (2)—(4) set out certain requirements in relation to public hearings, including the capacity for the Regulator to give directions restricting the publication of evidence given at a public hearing (sub-clause 53(3)) and a penalty where such directions are contravened.

Clause 54—Person may request copies of certain documents

This clause clarifies that when a person requests a copy of a licence application or risk assessment or risk management plan, the Regulator must provide the person with the information, excluding any confidential commercial information and any information about the applicant's relevant convictions (within the meaning of clause 58).

DIVISION 5—Decision on licence etc.

Clause 55—Regulator must make a decision on licence and licence conditions

This clause provides that, after taking the steps required in Division 3 or 4 of part 5 in relation to an application for a GMO licence, the Regulator must decide whether or not to issue a licence. If the Regulator decides to issue a licence, conditions may be imposed in relation to the dealings with the GMO.

Clause 56—Regulator must not issue the licence unless satisfied as to risk management

Sub-clause 56(1) provides that the Regulator must not issue the licence unless he or she is satisfied that any risks posed by the proposed dealings are able to be managed in such a way as to protect the health and safety of people and the environment.

Sub-clause 56(2) specifies the matters that the Regulator must have regard to in making a decision under sub-clause 56(1) as including: a risk assessment; the risk management plan; any submissions received on the risk assessment and risk management plan; and any policy guidelines in force under clause 23 (as issued by the Ministerial Council).

Clause 57- Other circumstances in which Regulator must not issue the licence

This clause sets out the other circumstances in which the Regulator must not issue the licence. These circumstances include:

(a) where the issue of the licence would be inconsistent with a policy principle issued by the Ministerial Council under clause 21; and

(b) where the Regulator is not satisfied that the applicant is a suitable person to hold the licence. Matters that the Regulator must take into account when determining an applicant's suitability are described in clause 58.

Clause 58—Matters to be taken into account in deciding whether a person is suitable to hold a licence

This clause allows the Regulator to consider a range of matters in deciding whether a natural person or a corporation is suitable to hold a licence.

Sub-clause 58(1) specifies that the Regulator must have regard to any relevant convictions of persons, and any revocation or suspension of a licence or permit relating to the health and safety of people or the environment which is or was held by the person under a law of the Commonwealth, a State, or a foreign country. The Regulator must also consider the capacity of the person to meet the conditions of the licence (i.e. may include consideration of the person's financial viability and/or skills and experience).

Sub-clause 58(2) specifies that the Regulator must have regard to any relevant conviction of a body corporate and, where there is a relevant conviction, whether the offence was committed at a time when any person who is presently a director, officer or shareholder of the corporation was a director, officer or shareholder. This sub-clause also requires the Regulator to consider any revocation or suspension of a licence or permit relating to the health and safety of people or the environment which is or was held by the corporation under a law of the Commonwealth, a State, or a foreign country. The Regulator must also consider the capacity of the corporation to meet the conditions of the licence.

Sub-clause 58(3) clarifies that the clause does not affect the operation of the *Criminal Law (Rehabilitation of Offenders) Act 1986*.

Sub-clause 58(4) clarifies the meaning of a 'relevant conviction'. Not only must the offence have related to a law concerning the health and safety of people or the environment, but the offence must have been committed within the period of 10 years immediately before the making of the application for the licence, and the offence must have been punishable by a fine of $5,000 or more, or by a term of imprisonment of one year or more.

Clause 59—Notification of licence decision

This clause requires that the Regulator provide a written notification to the applicant of the Regulator's decision, including any conditions imposed.

Clause 60—Period of licence

This clause specifies that a licence issued under the Bill remains valid either until the end of a specified period, or until it is cancelled or surrendered.

Sub-clause 60(2) provides that a licence is not in force during any period of suspension.

DIVISION 6—Conditions of licences

Clause 61—Licence is subject to conditions

This clause provides that licences may be subject to a range of conditions, including conditions set out in clauses 63, 64 and 65, conditions prescribed by the regulations and conditions imposed by the Regulator at the time of issuing the licence or at any time thereafter.

Clause 62—Conditions that may be prescribed or imposed

Sub-clause 62(1) enables the Regulator to impose conditions in relation to the GMO that relate to the 'full life-cycle' of the GMO, including any products derived from that GMO.

Sub-clause 62(2) and sub-clause 62(3) list some of the possible licence conditions which may be imposed. Licence conditions may, for example, relate to: limiting the scope of the dealings authorised by the licence, the purposes for which the dealings may be undertaken, and the geographic area in which the dealings authorised by the licence may occur; labeling of the GMO; limiting the dissemination or persistence of GMO in the environment; and contingency planning in respect of unintended effects of the dealings authorised by the licence.

Clause 63—Condition about informing people of obligations

This clause makes it a condition of a licence that the licence holder inform any person covered by the licence, and to whom a particular condition of the licence applies, of specified matters (e.g. cancellation or suspension of the licence).

Clause 64—Condition about monitoring and audits

This clause requires that, where a person is authorised to deal with a GMO, and a particular licence condition applies to that dealing, the person authorised to deal with the GMO must allow the Regulator (or his or her delegate) to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing. This enables the Regulator to undertake routine or "on-the-spot" auditing and/ or monitoring of licensed dealings with GMOs to ensure that any conditions imposed are being complied.

Clause 65—Condition about additional information to be given to the Regulator

This clause makes it a condition of a licence, and therefore compels the licence holder, to provide information to the Regulator in the following circumstances:

- where he or she becomes aware of additional information as to any risks to the health and safety of people or to the environment associated with the dealings authorised by the licence; or
- where he or she becomes aware of any contraventions of the licence by a person covered by the licence; or
- where he or she becomes aware of any unintended effects of the dealings authorised by the licence.

Clause 66—Person may give information to Regulator

This clause provides that a person covered by a licence may inform the Regulator if he or she becomes aware of additional information as to any risks associated with the dealings authorised by the licence that may pose risks to the health and safety of people or to the environment. A person who becomes aware of any contraventions of the licence by a person covered by the licence, or becomes aware of any unintended effects, may also provide such information to the Regulator.

Clause 67—Protection of persons who give information

This clause provides that civil proceedings may not be brought against a person who has given information to the Regulator because another person has suffered loss, damage or injury as the result of the disclosure of

information to the Regulator. This clause does not, however, affect any rights a person may have against an informer who published the information more broadly than just to the Regulator—this clause only provides protection in respect of civil proceedings in relation to the disclosure of the information to the Regulator.

DIVISION 7—Suspension, cancellation and variation of licences

Clause 68—Suspension and cancellation of licence

This clause gives the Regulator the power to suspend or cancel a licence by giving written notice to the licence holder. The grounds for the exercise of this power are listed.

Clause 69—Surrender of licence

This clause allows a licence holder to surrender a licence, with the consent of the Regulator.

Clause 70—Transfer of licences

This clause allows for a licence to be transferred from the licence holder to a 'transferee' provided that certain requirements are met.

Sub-clause 70(1) provides that a licence holder and the transferee may jointly apply to the Regulator for the licence to be transferred.

Sub-clause 70(2) specifies that the application must be in writing and must include information specified by the Regulator and/or prescribed in the regulations.

Sub-clause 70(3) requires that, in deciding whether to approve the transfer of the licence, the Regulator must be satisfied that any risks posed by the dealings will continue to be managed in such a way as to protect the health and safety of people, and the environment.

Sub-clause 70(4) also requires that the Regulator decide whether the transferee is a 'suitable person' to hold the licence. The criteria described in clause 58 would be used by the Regulator in making such an assessment.

Sub-clause 70(5) requires that the Regulator provide written notice of his or her decision to the licence holder and the transferee.

Sub-clause 70(6) sets out the effect of a transfer. The transfer takes effect on the date specified in the written notice provided to the licence holder and the transferee by the Regulator and the licence continues in force under clause 60 subject to the same conditions as in force immediately before the transfer. The Regulator may however subsequently vary the conditions of licence (if necessary) in accordance with clause 71.

Clause 71—Variation of licence

This clause allows the Regulator to vary a licence where he or she is satisfied that any variation will have the effect of ensuring that any risks to the health and safety of people and the environment are properly managed.

Clause 72—Regulator to notify of proposed suspension, cancellation or variation

Sub-clauses 72(1), (2) and (3) specify that the Regulator must give written notice of a proposed suspension, cancellation, or variation of a licence to the licence holder. The notice must state the Regulators intentions regarding the suspension, cancellation or variation of the licence. The notice may also require the licence holder to give the Regulator specified information which is relevant to the proposed changes to the licence, and may invite the licence holder to make a written submission to the Regulator about the proposed suspension, cancellation or variation. The licence holder must be given at least 30 days in which to provide the requested information or make a written submission.

Sub-clause 72(4) requires that the Regulator consider any submission made by the licence holder in making the decision to suspend, cancel or vary the licence.

Sub-clause 72(5) clarifies that the requirements set out in this clause are not necessary where the suspension, cancellation or variation has been requested by the licence holder.

Sub-clause 72(6) waives the formal requirements for notification to the licence holder where the Regulator considers that the suspension, cancellation or variation is necessary in order to avoid an imminent risk of death, serious illness, serious injury or serious damage to the environment.

Clause 72A GMO licence—annual charge

This clause provides that a licence holder may be charged a fee.

PART 6—REGULATION OF NOTIFIABLE LOW RISK DEALINGS AND DEALINGS ON THE GMO REGISTER

DIVISION 1—Simplified outline

Clause 73—Simplified outline of pt 6

This clause gives a simplified outline of the Part.

DIVISION 2—Notifiable low risk dealings

Clause 74—Notifiable low risk dealings

This clause allows regulations to be made which declare a particular dealing with a GMO to be a 'notifiable low risk dealing' for the purposes of this Bill. These would be low risk dealings in contained facilities that the Regulator determines to be low risk on the basis of experience and previous risk assessments of the class of dealings. A notifiable low risk dealing can never involve the intentional release of the GMO into the environment.

Clause 75—Regulation of notifiable low risk dealings

This clause allows regulations to be made which regulate one notifiable low risk dealing, or a specified class of notifiable low risk dealings and specifies that the regulations may contain certain conditions which must be complied with by persons undertaking notifiable low risk dealings.

DIVISION 3—The GMO Register

Clause 76—GMO Register

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included. No GMO Register is established by this Bill so as to avoid duplication with the Commonwealth Act.

Clause 77—Contents of Register

This clause provides that, where the Regulator determines that a dealing with a GMO is to be included in the GMO Register, the Register must contain: a description of the dealing with the GMO; and any condition(s) to which a particular dealing with a GMO is subject.

Clause 78—Regulator may include dealings with GMOs on GMO Register

Sub-clause 78(1) provides that the Regulator may place a GMO on the Register where the dealing with the GMO is, or has previously been, authorised by a GMO licence.

Under sub-clause 78(2), a determination to place something on the GMO Register may be made on application by a GMO licence holder, or on the initiative of the Regulator.

Sub-clause 78(3) provides that a determination takes effect on the day specified in the determination. Further, in the circumstances whereby a licence holder has applied to have certain licensed dealings with GMOs entered on the Register, the date specified in the determination must not be before the licence ceases to be in force. That is, the licence must "run its course" before the dealing with the GMO may be placed on the Register.

Sub-clause 78(4) provides that a determination to include a GMO dealing on the GMO Register is a disallowable instrument for the purposes of section 46A of the *Acts Interpretation Act 1901*.

Clause 79—Regulator not to make determination unless risks can be managed

This clause prevents the Regulator from placing a dealing with a GMO on the Register unless the Regulator is satisfied that any risks posed by the dealing are minimal, and that it is not necessary for the persons undertaking the dealing to hold, or be covered by, a GMO licence in order to protect the health and safety of people and the environment.

Clause 80—Variation of GMO Register

This clause allows the Regulator to vary the GMO Register by written determination so as to: remove a dealing from the GMO Register; revoke or vary conditions to which the dealing is subject; or impose additional

conditions on the dealing. A written determination varying the GMO Register in any of these ways is a disallowable instrument for the purposes of section 46A of the *Acts Interpretation Act 1901*.

Clause 81—Inspection of Register

This clause requires the Regulator to permit any person to inspect any part of the GMO Register.

PART 7—CERTIFICATION AND ACCREDITATION

DIVISION 1—Simplified outline

Clause 82—Simplified outline of pt 7

This clause gives a simplified outline of the Part.

DIVISION 2—Certification

Clause 83—Application for certification

This clause allows a person to apply to the Regulator for certification of a facility to a particular containment level. The application must be in writing, must contain such information, as the Regulator requires. Certification will be required of any organisation who wishes to undertake notifiable low risk dealings, or who holds a licence for dealings with GMOs where the licence includes a condition that the work with the GMO be conducted in a facility certified to a particular containment level.

Clause 84—When the Regulator may certify the facility

This clause allows the Regulator to certify the facility to a specified containment level where the facility meets the requisite containment standards, which are to be specified in guidelines issued by the Regulator under clause 90.

Clause 85—Regulator may require applicant to give further information

This clause allows the Regulator to request an applicant for certification of a facility to provide the Regulator, within a specified period, with additional information to assist the Regulator's consideration of the application.

Clause 86—Conditions of certification

This clause provides that the certification of a facility is subject to several types of conditions: those imposed by the Regulator at the time of certification; those imposed after certification as a variation to the original certification; and any conditions prescribed in the regulations.

Clause 87—Variation of certification

This clause allows the Regulator to vary the certification of a facility, by notice in writing, to the holder of the certification. The Regulator has discretion to impose additional conditions or remove or vary the conditions originally imposed.

Clause 88—Suspension or cancellation of certification

This clause allows the Regulator to suspend or cancel the certification of a facility where the Regulator believes that, on reasonable grounds, a condition of the certification has been breached.

Clause 89—Regulator to notify of proposed suspension, cancellation or variation

This clause requires that, before suspending, cancelling or varying a certification, the Regulator will provide written notice to the holder of the certification. The formal requirements of the notice are specified in sub-clauses.

Clause 90—Guidelines

This clause allows the Regulator to issue technical or procedural guidelines (for example, about the requirements for the certification of

facilities to specified containment levels) and to vary or revoke those guidelines by written instrument.

DIVISION 3—Accredited organisations

Clause 91—Application for accreditation

This clause enables a person to apply to the Regulator for accreditation of an organisation. The application must be in writing, and contain such information, as the Regulator requires.

Clause 92—Regulator may accredit organisations

This clause enables the Regulator to accredit an organisation (by written instrument) and that the Regulator must have regard to matters.

Clause 93—Regulator may require applicant to give further information

This clause enables the Regulator to require an applicant for accreditation of an organisation to give the Regulator, within a designated period, relevant further information in relation to the application.

Clause 94—Conditions of accreditation

This clause specifies that the conditions to which accredited organisations are subject are: those imposed by the Regulator at the time of accreditation; those imposed by the Regulator later by variation; and those prescribed by the regulations.

Clause 95—Variation of accreditation

This clause gives the Regulator power to vary the organisation's accreditation, at any time, by notice in writing.

Clause 96—Suspension or cancellation of accreditation

This clause enables the Regulator to suspend or cancel the accreditation of an organisation if the Regulator believes, on reasonable grounds, that a condition of the accreditation has been breached.

Clause 97—Regulator to notify of proposed suspension, cancellation or variation

This clause provides that the Regulator must provide notice in writing of the proposed suspension, cancellation or variation to the holder of the accreditation. The notice may request relevant information and invite a written submission from the holder of the accreditation, within a designated timeframe. The Regulator must consider any written submissions made to him or her.

Clause 98—Guidelines

This clause enables the Regulator to issue guidelines containing requirements that must be met in order for an organisation to be accredited.

Sub-clause 98(2) provides that such guidelines may relate to, but are not limited to, the establishment and maintenance of Institutional Biosafety Committees.

Sub-clause 98(3) also allows the Regulator to vary or revoke the guidelines by written instrument.

PART 8—THE GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE, THE GENE TECHNOLOGY COMMUNITY CONSULTATIVE GROUP AND THE GENE TECHNOLOGY ETHICS COMMITTEE

DIVISION 1—Simplified outline

Clause 99—Simplified outline of pt 8

This clause gives a simplified outline of the Part.

DIVISION 2—The Gene Technology Technical Advisory Committee

Clause 100—The Gene Technology Technical Advisory Committee

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included. No Committee is established by this Bill so as to avoid duplication with the Commonwealth Act.

Clause 101—Function of the Gene Technology Technical Advisory Committee

This clause specifies that the function of the Gene Technology Technical Advisory Committee is to provide advice, on the request of the Regulator, or of the Ministerial Council, on a range of matters that include:

(a) gene technology, GMOs and GM products;

(b) applications made under the Bill;

(c) the biosafety aspects of gene technology; and

(d) the need for policy principles, policy guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products and the content of such principles, guidelines and codes.

Clause 102—Expert advisers

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 103—Remuneration

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 104—Members and procedures

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 105—Subcommittees

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

DIVISION 3—The Gene Technology Community Consultative Committee

Clause 106—The Gene Technology Community Consultative Committee

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included. No Committee is established by this Bill so as to avoid duplication with the Commonwealth Act.

Clause 107—Function of Consultative Group

This clause provides that the function of the Consultative Group is to provide advice, on the request of the Regulator or the Ministerial Council, on matters of general concern in relation to GMOs, and on the need for (and content of) policy principles, guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GMO products.

Clause 108—Membership

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 109—Remuneration

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 110—Regulations

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 110A Subcommittees

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

DIVISION 4—The Gene Technology Ethics Committee

Clause 111—The Gene Technology Ethics Committee

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included. No Committee is established by this Bill so as to avoid duplication with the Commonwealth Act.

Clause 112—Function of the Gene Technology Ethics Committee

This clause provides that the function of the Ethics Committee is to provide advice, on the request of the Regulator or of the Ministerial Council, on: ethical issues relating to gene technology; the development of codes of practice in relation to ethics in respect of conducting dealings with GMOs; and the development of policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons.

Clause 113—Expert advisers

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 114—Remuneration

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 115—Members and procedures

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 116—Subcommittees

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

PART 9—ADMINISTRATION

DIVISION 1—Simplified outline

Clause 117—Simplified outline of pt 9

This clause gives a simplified outline of the Part.

DIVISION 2—Appointment and conditions of Regulator

Clause 118—Appointment of the Regulator

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included as the Commonwealths Act provides for the appointment of the Regulator.

Clause 119—Termination of appointment

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 120—Disclosure of interests

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 121—Acting appointment

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 122—Terms and conditions

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 123—Outside employment

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 124—Remuneration

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 125—Leave of absence

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 126—Resignation

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

DIVISION 3—Money

Clause 127—Regulator may charge for services

This clause provides that the Regulator may charge for services provided by, or on behalf of, the Regulator in the performance of the Regulator's functions.

Clause 128—Notional payments by the Commonwealth

As the Bill applies to all persons, this clause is included to clarify that fees and charges under this Bill are notionally payable by the Commonwealth (or parts of the Commonwealth).

Clause 129—Gene Technology Account

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 130—Credits to Account

This clause sets out the amounts that must be transferred to the Gene Technology Account. These include amounts received in connection with the performance of the Regulator's functions (e.g. annual licence fees).

Clause 131—Recovery of Amounts

This clause provides that some amounts may be recoverable in a court as debts due to the State (e.g. annual licence fees).

Clause 132—Purposes of Account

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

DIVISION 4—Staffing

Clause 133—Staff assisting the Regulator

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included. Staff assisting the Regulator are to be engaged under the *Public Service Act 1999 (Cth)* and are made available by the Secretary of the Commonwealth Department Health and Aged Care. This does not preclude the Regulator undertaking recruitment to ensure employees are suitably skilled and qualified. Technically however, the staff would be employed under the certified agreement of the relevant Secretary, their positions being funded by the Regulator.

Clause 134—Consultants

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 135—Seconded officers

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

DIVISION 5—Reporting requirements

Clause 136—Annual Report

This clause requires the Regulator to provide an annual report for the Minister and requires the Minister to cause a copy of the Report to be tabled before the Legislative Assembly.

Clause 136A Quarterly reports

This clause requires the Regulator to provide a quarterly report for the Minister and requires the Minister to cause a copy of the Report to be tabled before the Legislative Assembly.

Clause 137—Reports to Parliament

This clause provides that the Regulator may, at any time, report about matters relating to the Regulator's functions to the Legislative Assembly and that the Regulator must give a copy to the Minister.

DIVISION 6—Record of GMO and GM Product Dealings

Clause 138—Record of GMO and GM Product Dealings

This clause provides that the Regulator must maintain a comprehensive record of GMO and GM product dealings, to be known as ‘the Record’. This Record would be likely to take the form of a computerised database.

In relation to GMO licences, sub-clauses require that the Record contain certain information (other than confidential commercial information) in relation to every GMO licence which has been issued (e.g. name of licence holder) and information prescribed by regulation.

Clause 139—Inspection of Record

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

DIVISION 7—Reviews of notifiable low risk dealings and exemptions

Clause 140—Regulator may review notifiable low risk dealings

This clause allows the Regulator, at any time, to consider whether a dealing with a GMO should become a notifiable low risk dealing, or whether an existing notifiable low risk dealing should no longer be recognised as such. This enables the legislation to respond to changes in technology and to any additional information that becomes available regarding the risks of certain dealings with GMOs, or the absence thereof.

Clause 141—Regulator may review exemptions

This clause allows the Regulator, at any time, to consider whether a dealing with a GMO should be an exempt dealing, and whether an existing exemption should no longer be such.

Clause 142—Regulator may give notice of consideration

This clause enables the Regulator to place a public notice, at any time, calling for submissions from the public about what dealings with GMOs should be removed or added to the list of notifiable low risk dealings or exemptions.

Clause 143—What Regulator may do after consideration

This clause provides that the Regulator may recommend to the Ministerial Council certain action about what dealings with GMOs that should be removed or added to the list of notifiable low risk dealings or exemptions.

Clause 144—Regulator not required to review matters

This clause clarifies that the requirement to review notifiable low risk dealings or exemptions is at the discretion of the Regulator.

PART 10—ENFORCEMENT

Clause 145—Simplified outline of pt 10

This clause gives a simplified outline of the Part.

Clause 146—Regulator may give directions

This clause provides that, if a licence holder or a person covered by a licence is not acting in compliance with the legislation, and their actions are likely to cause, or are causing harm to the health and safety of people or to the environment, then the Regulator may give written directions to the person directing them to do things necessary to ensure compliance. This provision effectively enables a "clean-up" or remediation to be undertaken, either by the Regulator or via the direction of the Regulator and that where costs are incurred by the Regulator such costs may be recovered. This clause should also be read in conjunction with clause 158, which enables an inspector to take immediate action where there is an imminent risk of danger to health and safety of people or to the environment.

Clause 147—Injunctions

If a person has engaged, or is engaging, or is proposing to engage in any conduct that is or would be an offence against the Bill or regulations, sub-clause 147(1) provides that the Supreme Court may grant an injunction, on application by the Regulator or any other aggrieved person, to restrain that person from engaging in that conduct.

Clause 148—Forfeiture

This clause provides that states that if a court convicts a person of an offence against this Bill the court may order forfeiture to the State of any substance or thing used, or otherwise involved in the commission of the offence.

PART 11—POWERS OF INSPECTION

DIVISION 1—Simplified outline

Clause 149—Simplified outline of pt 11

This clause gives a simplified outline of the Part.

DIVISION 2—Appointment of inspectors and identity cards

Clause 150—Appointment of inspectors

Sub-clause 150(1) enables the Regulator to appoint, by instrument in writing, appropriate officers to be inspectors for the purposes of exercising all the powers under this Part. The persons the Regulator may appoint as inspectors are Commonwealth employees or State or Territory employees.

Sub-clause 150(2) requires a person appointed as an inspector to comply with any directions of the Regulator when exercising powers or performing functions in that capacity.

Clause 151—Identity card

This clause requires the Regulator to issue an identity card to every person appointed as an inspector and the inspector to carry the card at all times when exercising powers or performing functions as an inspector.

DIVISION 3—Monitoring powers

Clause 152—Powers available to inspectors for monitoring compliance

This clause confers powers upon an inspector to enter any premises and to exercise any or all of the powers set out in clause 153 for the purposes of establishing whether or not the Bill or regulations are being complied with.

Clause 153—Monitoring powers

This clause describes the monitoring powers that an inspector may exercise for the purposes of finding out whether the Bill or regulations have been complied with. Some of these powers may be exercised without a warrant and others require a warrant.

DIVISION 4—Office-related powers

Clause 154—Searches and seizures related to offences

This clause sets out the powers of an inspector who enters and conducts searches of premises to obtain evidence of a commission of an offence, and the circumstances under which those powers may be exercised.

Clause 155—Offence-related powers of inspectors in relation to premises

This clause sets out the general powers inspectors may exercise under paragraph 154(2)(b). These include the power to: search premises and any thing found on premises for evidential material; to inspect, examine, take measurements of, conduct tests on, or take samples of the evidential material; take photographs or other forms of recordings of the premises or the evidential material; and take onto the premises such equipment and materials as the inspector requires for the purposes of exercising powers in relation to the premises.

Clause 156—Use of electronic equipment at premises

This clause provides that an inspector may operate equipment at the premises to see whether evidential material is accessible, if he or she believes that the equipment may be operated without damaging it.

DIVISION 5—Expert assistance

Clause 157—Expert assistance to operate a thing

This clause provides that an inspector may secure the thing (for example, certain equipment) by locking it up or guarding it, if he or she believes on reasonable grounds that evidential material may be accessible by operating

the thing at the premises, but that expert assistance is needed to operate the thing and the evidential material may be destroyed or otherwise interfered with if the thing is not secured in the meantime. This is necessary to ensure that where, for example, the equipment is more sophisticated than expected and cannot be accessed or moved, the opportunity to obtain expert assistance and to preserve evidential material is not lost.

Sub-clause 157(2) requires the giving of notice to the occupier in cases where equipment may be secured for a period not exceeding 24 hours.

DIVISION 6—Emergency powers

Clause 158—Powers available to inspectors for dealing with dangerous situations

This clause describes the powers an inspector may use when the inspector has reasonable grounds for suspecting that there may be, on any premises, a particular thing that is not in compliance with the requirements of the Bill or regulations, and where it is necessary to exercise the powers under this clause to avoid an imminent risk of death, serious illness, serious injury or to protect the environment (e.g. the power to enter premises without a warrant or the consent of an occupier).

DIVISION 7—Obligations and incidental powers of inspectors

Clause 159—Inspector must produce identity card on request

This clause makes it clear that an inspector cannot exercise any of the powers under this Part in relation to premises unless he or she produces his or her identity card upon being requested to do so by the occupier of those premises.

Clause 160—Consent

This clause provides that, before obtaining consent from a person to enter premises (under paragraphs 152(2)(a) or 154(2)(a)), the inspector must inform the person that he or she may refuse consent.

Clause 161—Details of warrant to be given to occupier etc.

This clause provides that, if a warrant in relation to premises is being executed, a copy of the warrant must be made available to the occupier of the premises or another person who represents the occupier, where the occupier or their representative are present at the premises. The inspector responsible for the execution of the warrant must identify himself or herself.

Clause 162—Announcement before entry

This clause provides that, before an inspector enters premises under a warrant they must announce that they are authorised to enter and give any person at the premises an opportunity to allow entry to the premises, unless there are reasonable grounds to believe that immediate entry to the premises is required to ensure the safety of a person or to prevent serious damage to the environment, or so that the effective execution of the warrant is not frustrated.

Clause 163—Compensation for damage

This clause provides that if damage is caused to a thing as a result of it being operated (see clauses 153 and 156) and the damage resulted from insufficient care being exercised by the inspector either in selecting the person to operate the equipment or by the person operating it, compensation is payable by the Regulator to the owner. This clause has been drafted so as to be consistent with the national regulatory scheme.

DIVISION 8—Power to search goods, baggage etc.

Clause 164—Power to search goods, baggage etc.

This clause empowers an inspector to search goods and baggage taken off ships or aircraft travelling from a place outside Australia to Australia or from a place outside an external Territory to that Territory. This clause will enable inspectors (who may be officers of the Australian Quarantine and Inspection Service appointed as inspectors under this legislation) to search goods and baggage imported into Australia.

Clause 165—Seizure of goods

This clause provides that an inspector may seize any goods if there is a reasonable suspicion that the goods have been used, or otherwise involved, in the commission of an offence against the Bill or the regulations, or that the goods will provide evidence of an offence against the Bill or the regulations.

DIVISION 9—General provisions relating to search and seizure

Clause 166—Copies of seized things to be provided

This clause provides that if an inspector seizes, under a warrant, documents, film, computer files or storage devices etc, the inspector must, on request of the occupier or their representative who is present when the warrant is executed, give a copy of the thing or the information seized to the occupier or their representative as soon as practicable after the seizure.

Sub-clause 166(2) provides that this clause does not apply where the thing seized was seized under paragraphs 156(2)(b) or (c), or where possession by the occupier of the thing seized could constitute an offence.

Clause 167—Occupier entitled to be present during search

This clause provides that occupiers or their representatives may choose to observe the searching of the premises providing they do not impede the conduct of the search in any way. The right to search does not preclude inspectors from searching 2 or more areas of the premises at the same time.

Clause 168—Receipts for things seized

This clause provides that receipts are to be issued to occupiers for things seized. Under this provision, it will be possible for the items to be listed on the same receipt. It is not envisaged that inspectors would be required to identify absolutely every item individually where those items can be adequately identified by a class description.

Clause 169—Retention of seized things

This clause describes when things seized under this Part of the Bill must be returned. Unless a court has ordered otherwise, or it is forfeited or

forfeitable to the Commonwealth, the seized thing must be returned where the reason for its seizure no longer exists, or where it will not be used as evidence, or after 60 days have expired from the day it was seized.

Sub-clause 169(2) provides that an inspector must take reasonable steps to return the thing to the person from whom it was seized after the 60 days referred to in sub-clause 169(1), unless proceedings in which the seized thing will be used have been brought against an offender within the 60 day limit and the proceedings have not finished, or an extension of time for the retention of the seized thing has been granted by a magistrate, or returning the thing could cause an imminent risk of death, serious illness, serious injury or serious damage to the environment, or an inspector is otherwise authorised to dispose of it pursuant to some law or court order.

Sub-clause 169(3) provides that where the seized thing is returned, it may be returned unconditionally or on such terms and conditions as the Regulator sees fit.

Clause 170—Magistrates Court may permit a thing to be retained

This clause describes how an inspector may apply to the Magistrates Court for an order to retain a seized thing beyond the 60 day retention period (or before the end of a period specified in an order of the Magistrates Court) where proceedings in respect of which the thing may afford evidence have not commenced.

Sub-clause 170(2) provides that if the Magistrates Court is satisfied that it is necessary for an extension of time to be granted to enable an inspector to investigate whether or not an offence has been committed against the Bill or to enable the evidence to be secured for the purposes of a prosecution, the Magistrates Court may grant an extension for such period as is specified in an order. Before making an application under this section, an inspector must take reasonable steps to establish who has an interest in the retention of the seized goods and, if practicable, notify such persons.

Clause 171—Disposal of goods if there is no owner or owner cannot be located

This clause provides that the Regulator may dispose of a thing seized under this Part, in a manner the Regulator considers appropriate, if there is no owner of the thing or the Regulator has made reasonable efforts to locate the owner and cannot locate the owner.

DIVISION 10—Warrants

Clause 172—Monitoring warrants

This clause enables a magistrate to issue a warrant that permits more than one inspector to enter the same premises for the purposes of establishing whether the Bill and regulations have been complied with.

Sub-clause 172(3) provides that the magistrate must not issue the warrant unless the inspector or some other person has given the magistrate any information the magistrate requires concerning the grounds on which the issue of the warrant is being sought.

Sub-clause 172(4) describes the matters that must be contained in a warrant issued by a magistrate under this clause. For example, the warrant must: authorise the inspectors to enter the premises and exercise powers under clause 153; state when the entry is authorised to be made; specify the day on which the warrant ceases to have effect; and state the purpose for which the warrant is issued.

Clause 173—Offence-related warrants

This clause describes how an inspector may apply to a magistrate for a warrant under this clause in relation to premises for the purposes of identifying and/or seizing evidence.

Sub-clause 173(1) provides that an inspector may apply to a magistrate for a warrant in relation to premises.

Sub-clause 173(2) enables the magistrate to issue a warrant if satisfied, by information given under oath, that there are reasonable grounds for suspecting that there is, or there may be within the next 72 hours, evidential material in or on the premises in relation to which an application for a warrant is being made.

Sub-clause 173(3) prevents the magistrate from issuing a warrant unless the inspector or some other person has given to the magistrate, either verbally or by affidavit, such further information (if any) as the magistrate should require concerning the grounds on which the issue of the warrant is being sought.

Sub-clause 173(4) prescribes what must be included in a warrant. The warrant must include the name of one or more inspectors and it must authorise all those named to enter the premises and exercise the powers set out in sub-clause 154(3) and in clause 155, and to seize the evidential

material. The warrant must also state whether the entry is authorised to be made at any time during the night or day, or whether entry is restricted to specified hours of the day or night. The warrant must also specify when the warrant ceases to have effect (being a day not later than a week after the issue of the warrant), and also state the purposes for which the warrant is being issued.

Clause 174—Offence-related warrants by telephone, telex, fax etc.

This clause sets out the circumstances in which a warrant may be obtained over the telephone or by telex, facsimile or other electronic means.

Sub-clause 174(1) provides that, in urgent cases where an inspector considers it necessary, the inspector may apply to a magistrate for a warrant under clause 173 either by telephone, telex, facsimile or other electronic means.

Sub-clause 174(2) provides that the magistrate may require communication by voice to the extent that it is practicable in the circumstances.

Sub-clauses 174(3) and (4) require the inspector to prepare any information mentioned in sub-clause 173(2) setting out the grounds on which the warrant is sought. The inspector may apply for the warrant before the information is sworn, where this is necessary in the circumstances.

Sub-clause 174(5) provides that, if the magistrate is satisfied that there are reasonable grounds for issuing the warrant (after having considered relevant information), the magistrate may issue the same warrant that the magistrate would issue under clause 173 as if the application for the warrant had been made under that clause.

Sub-clause 174(6) provides that, if the magistrate completes and signs the warrant for the inspector, the magistrate must inform the inspector what the terms of the warrant are, the day on which and the time at which the warrant was signed, the day on which the warrant ceases to have effect (being a day not more than a week after the magistrate completes and signs the warrant), and must record on the warrant the reasons for granting the warrant. The inspector must also complete a form or warrant in the same terms as the warrant completed and signed by the magistrate, and must write on the form the name of the magistrate and the day on which and the time at which the warrant was signed.

Sub-clause 174(7) requires the inspector to send to the magistrate the form of warrant completed by the inspector under this clause, and the information required to be prepared when the inspector applied for the warrant over the telephone, the information prepared must have been duly sworn. The inspector is required to send this to the magistrate not later than the day after the expiry or the execution of the warrant, whichever is the earlier day.

Sub-clause 174(8) provides that when the magistrate receives these documents, the magistrate must attach them to the warrant, completed and signed, and deal with the documents in the same way the magistrate would have dealt with the information if the application for the warrant had been made under clause 173.

Sub-clause 174(9) provides that a form of warrant completed in accordance with sub-clause 174(6) is authority for any entry, search, seizure or other exercise of power that the warrant signed by the magistrate authorises.

Sub-clause 174(10) states that, in any proceedings where the court must be satisfied that the exercise of a power was authorised by this clause, and the warrant signed by the magistrate authorising the exercise of that power cannot be produced, the court must assume, unless the contrary is proved, that the exercise of the power was not authorised by such a warrant.

Sub-clause 174(11) states that any reference in this Part to a warrant under clause 173 is taken to include a warrant signed by a magistrate under this clause.

Clause 175—Offences relating to warrants

This clause sets out offences in relation to an application for a warrant.

Sub-clause 175(1) provides that it is an offence, attracting a maximum penalty of imprisonment for 2 years or 120 penalty units, if a person makes a statement, when applying for a warrant, that he or she knows to be false or misleading in a material particular.

Sub-clause 175(2) sets out other actions that attract a maximum penalty of 2 years imprisonment or 120 penalty units. These include:

(a) a person stating in a document purporting to be a form of warrant under clause 174 the name of a magistrate who was not the magistrate that issued the warrant;

(b) stating, for the purposes of clause 174, on the form of warrant something that, to the person's knowledge, departs in a material particular from the form authorised by the magistrate;

(c) purporting to execute or present to another person a document purporting to be a form of warrant under clause 174 when the person knows it had not been approved by the magistrate under that clause or where it departs in a material particular from the terms authorised by a magistrate under clause 174; or

(d) giving to a magistrate a form of warrant under clause 174 that was not the form of warrant the person purported to execute.

DIVISION 11—Other matters

Clause 176—Part not to abrogate privilege against self-incrimination

This clause clarifies that nothing in this Part affects the right of a person to refuse to answer a question, give information, or produce a document on the ground that the answer to the question, the information or the production of the document, might tend to incriminate him or her, or make him or her liable to a penalty.

Clause 177—Part does not limit power to impose licence conditions

This clause makes it clear that the powers exercisable under this Part in no way affect the ability of the Regulator to impose licence conditions. For example, the Regulator may impose additional conditions relating to auditing and monitoring requirements.

PART 12—MISCELLANEOUS

DIVISION 1—Simplified outline

Clause 178—Simplified outline of pt 12

This clause gives a simplified outline of the Part.

DIVISION 2—Review of decisions

Clause 179—Meaning of "reviewable decision" and "eligible person"

This clause sets out a table describing those decisions under the Bill that are subject to review by the Administrative Appeals Tribunal (reviewable decisions), and those persons who are able to seek review in relation to reviewable decisions (eligible persons).

Clause 180—Notification of decisions and review rights

This clause provides that, as soon as practicable after making a reviewable decision under the Bill, the Regulator must notify each eligible person in writing. The notification must include information about the terms of the decision, the reasons for the decision and a statement setting out the review rights of the person.

Sub-clause 180(2) provides that, if the Regulator fails to properly notify eligible persons of their review rights (under sub-clause 180(1)), this does not affect the validity of the decision.

Clause 181—Internal review

This clause provides that an eligible person may apply to the Regulator for an internal review of a reviewable decision within 30 days after the decision came to the notice of the applicant, or within some further period, if any, specified by the Regulator.

If a person seeks internal review by the Regulator, the Regulator must conduct such a review personally and may affirm, vary or revoke the original reviewable decision. If the Regulator revokes the original reviewable decision, the Regulator may make such other decisions as the Regulator considers appropriate.

A person may not seek internal review of a reviewable decision if the Regulator personally made the original decision (as opposed to a delegate of the Regulator having made the original decision).

Clause 182—Deadlines for making reviewable decisions

This clause provides that, if a person applies to the Regulator for internal review of a reviewable decision and the Regulator does not notify the

applicant of the Regulator's decision within any time period set out in the Bill or regulations for the Regulator to advise the applicant of the outcome of the internal review, then the Regulator is taken to have rejected the application for internal review.

Clause 183—Review of decisions by Administrative Appeals Tribunal

This clause provides that an eligible person may apply to the Administrative Appeals Tribunal in relation to a reviewable decision if they have exhausted their rights of internal review (under clause 181), or if the original reviewable decision was made personally by the Regulator and, as such, there is no opportunity for internal review.

Clause 183A Extended standing for judicial review

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

DIVISION 3—Confidential commercial information

Clause 184—Application for protection of confidential commercial information

This clause provides that a person may apply to the Regulator for a declaration that specified information to which this Bill relates is confidential commercial information for the purposes of this Bill. Such an application must be made in writing in the approved form.

Clause 185—Regulator may declare that information is confidential commercial information

This clause describes the circumstances in which the Regulator must declare information to be confidential commercial information for the purposes of the Bill.

Sub-clause 185(1) sets out the criteria in relation to which the Regulator must be satisfied before they can declare information to be confidential commercial information. The person applying for a declaration must satisfy the Regulator that the information in the application for declaration is: a trade secret; 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 commercial or financial affairs of a person, organisation or undertaking which if disclosed, could unreasonably affect the person, organisation or undertaking.

Sub-clause 185(2) enables the Regulator to consider the public interest and, if satisfied that the public interest in disclosure outweighs the prejudice that the disclosure would cause to any person, the Regulator may refuse to declare that the information is confidential commercial information.

Sub-clauses 185(3) and (4) provide that the Regulator must give the applicant written notice of his or her decision about the application and that, if the Regulator refuses to declare the information to be confidential commercial information, the Regulator must, nevertheless, continue to treat the information as confidential commercial information until such time as any review rights under clauses 181 (internal review) and 183 (review before the Administrative Appeals Tribunal) have been exhausted.

Clause 186—Revocation of declaration

This clause enables the Regulator to revoke a declaration made under clause 185 if the Regulator is satisfied that the information no longer meets the criteria set out in sub-clauses 185(1)(a), (b) or (c), or that the public interest in disclosure of the information outweighs the prejudice that disclosure would cause to any person. As for a decision made under clause 185, the revocation of a declaration does not take effect until any review rights have been exhausted.

Clause 187—Confidential commercial information must not be disclosed

This clause provides that a person who has access to confidential commercial information must not disclose such information unless: it is in the act of carrying on the course of their duties under the Bill; or is in relation to a Court order; or they have received the consent of the person who applied to have the information declared as confidential commercial information.

This provision enables the Regulator to provide confidential commercial information to Commonwealth agencies or authorities, State agencies and the Gene Technology Technical Advisory Committee but ensures that such

agencies may not disclose the information outside their organisations unless compelled to by court order or with the consent of the person who applied to have the information treated as confidential commercial information.

DIVISION 4—Conduct by directors, employees and agents

Clause 188—Conduct by directors, employees and agents

This clause provides for the determination of the elements of an offence when it involves a body corporate, including extending liability to ostensible agents of a body corporate.

Clause 189—Meaning of terms

This clause defines terms used in clause 188 of the Bill, including "the state of mind of a person" and "a director of a body corporate".

Sub-clause 189(2) states that a a reference to a director or a body corporate includes a reference to a constituent member of a body corporate. This provides that where an offence has been committed, the prosecuting authority may prosecute both the organisation and the individuals that manage that organisation.

DIVISION 5—Transitional provisions

Clause 190—Transitional provision—dealings covered by Genetic Manipulation Advisory Committee advice to proceed

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 191—Regulations may relate to transitional matters

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

DIVISION 6—Other

Clause 192—False or misleading information or document

This clause provides that a person must not give false or misleading information, or produce a document that is false or misleading in a material particular, in connection with any application made to the Regulator under this Bill or the regulations, or in compliance or purported compliance with this Bill or the regulations. The penalty for knowingly providing such false or misleading information or documents is 88 penalty units or 1 year imprisonment. While perhaps onerous, this requirement has been included to ensure applications made to the Regulator are factual and that those making the applications are well versed on the dealings they wish the Regulator to approve.

Clause 192A Interference with dealings with GMOs

This clause has been inserted to protect the property rights of those who have applied to, and gained from the Regulator, authority to conduct specified dealings with GMOs.

Clause 192B Cloning of human beings prohibited

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 192C Certain dealings involving animal eggs prohibited

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 192D Certain experiments involving putting human and animal cells into a human uterus prohibited

This clause heading has been included to ensure the Queensland Bill maintains, as much as possible, consistent numbering with the Commonwealth Act. No clause has been included.

Clause 192E Attempts to commit offences against this Act

This clause has been included to ensure consistency with the Commonwealth Act and to apply the *Criminal Code (Qld)*. This clause does not form part of the Commonwealth Act.

Clause 192F Proceedings for an offence

This clause has been included to apply the State's jurisdiction and consistency with the *Crimes Act 1914 (Cth)* section 4J. This clause does not form part of the Commonwealth Act.

Clause 192G Approved forms

This clause allows that the chief executive, Department of Innovation and Information Economy, may approve forms for use under this Act as may be required from time to time.

Clause 193—Regulation making power

This clause empowers the Governor in Council to make regulations prescribing matters required or permitted to be prescribed by the Bill, or necessary or convenient to be prescribed for carrying out or giving effect to the Bill.

Sub-clause 193(2) clarifies that, without limiting the matters that may be prescribed in regulations, regulations may be made requiring a person to comply with codes of practice or guidelines issued under this.

Clause 194 Review of operation of Act

In line with the requirements of the intergovernmental agreement on gene technology, this clause allows the Minister to initiate an independent review of this Act after four years of operation.

Clause 195 Act amended

This clause clarifies that Schedule 2 of this Act sets out the consequential amendments necessitated by this Act.

SCHEDULE 1—REVIEWABLE DECISIONS AND ELIGIBLE PERSONS

This Schedule sets out the reviewable decisions and eligible persons as mentioned in clause 179.

SCHEDULE 2—CONSEQUENTIAL AMENDMENT

This schedule causes amendments to be made to the *Agricultural and Veterinary Chemical (Queensland) Act 1994 (Qld)*. The amendments impose a duty on the National Registration Authority for Agricultural and Veterinary Chemicals to consult with the Gene Technology Regulator in relation to the assessment of genetically modified agricultural or veterinary chemicals.

SCHEDULE 3—DICTIONARY

This Schedule sets out a number of definitions for words and phrases used in the Bill. These definitions determine the meaning that is to be attributed to certain words or phrases whenever they are used in the Bill or regulations. Key definitions, which are essential to defining the scope of the legislation and describing how it will be administered, include:

"deal with", which, in relation to a GMO, is defined to mean:

(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; and

(g) import the GMO;

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

"environment" includes:

(a) ecosystems and their constituent parts; and

(b) natural and physical resources; and

(c) the qualities and characteristics of locations, places and areas.

It is intended that the definition of environment include all animals (including insects, fish and mammals), plants, soils and ecosystems (both aquatic and terrestrial).

"gene technology" is defined to cover any technique for the modification of genes or other genetic material, but does not include:

(a) sexual reproduction;

(b) homologous recombination; or

(c) any other technique specified in the regulations for the purposes of this paragraph.

"genetically modified organism" is defined as:

(a) an organism that has been modified by gene technology;

(b) an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; or

(c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms;

but does not include:

(d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic gene therapy; or

(e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be a genetically modified organisms.

The ability to prescribe things to be genetically modified organisms in regulations (under (c) of the definition of a GMO) ensures there is capacity

to regulate GM products that are not regulated by existing regulatory agencies. An example of such a 'gap' product is GM stockfeed.

Human beings are excluded from the definition of a GMO to ensure that a person who has undergone somatic cell gene therapy (for example, treatment for cancer) is not a GMO (as defined in this legislation), thus requiring the person to be licensed for the rest of their lives because they have been modified by techniques of gene technology. The conduct of human gene therapy will, however, continue to be regulated by the TGA and, in the case of research involving human trials, also overseen by the National Health and Medical Research Council. The Gene Technology Regulator would also be involved if the work involves a live or viable GMO (presenting possible occupational health and safety or environmental risks).

"GM product", which is defined as a thing (other than a GMO) derived or produced from a GMO.

Schedule 3 contains some definitions that refer the reader to regulations for further clarification (specifically the definitions for "exempt dealing", "gene technology" and genetically modified organism"). Although this approach may raise concerns that the fundamental effect of the Act may be amended by the underlying regulations, this approach has been adopted to reflect the fact that gene technology is a relatively young area of scientific endeavour and, as a result, knowledge and expertise in relation to the technology is subject to a change. As the science develops dealings that become common will change, thus altering the understanding of what dealings should be considered "exempt". Similarly, as the science develops new applications may mean the definition of "gene technology" and "genetically modified organism" may require alteration. Further, as the gene technology regulatory scheme is a national system, for Queensland (and other jurisdictions) to ensure legislation is as consistent as possible, the power to alter certain definitions via regulation rather than amendment of an Act was considered appropriate. Finally, the power to change definitions via regulation has been limited to certain key areas so that, in the event of an emergency, necessary change can be made by all jurisdictions expeditiously.