GENE TECHNOLOGY BILL 2005

EXPLANATORY MEMORANDUM

Part 1 - Preliminary

Clause 1 - Purpose and Citation

Specifies the short title of the Act as the *Gene Technology Act 2005*, States that the purpose of the Act is "to regulate Activities involving gene technology" and provides that the Act may be referred to as the *Gene Technology Law of Western Australia* or, simply, the *Gene Technology Law*.

Clause 2 - Commencement

The Act will come into operation on a day or days fixed by proclamation.

Clause 3 - Object of Act

This clause States that the object of the Act 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".

The terms "environment", "gene technology", "dealings" and "genetically modified organisms" are defined in clause 10.

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:
Acknowledges the precautionary principle that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation;
Will be based on an efficient and effective system of assessment; and
Operates in conjunction with other Commonwealth and State Regulatory schemes relevant to GMOs and genetically modified (GM) products.

Examples of other Regulatory schemes are:
Foods (including GM foods): regulated under State and Territory food Acts 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;*
Therapeutic goods (including GM therapeutic goods): regulated under the T*herapeutic Goods Act 1989* administered by the Therapeutic Goods Administration;
Agricultural and veterinary chemicals (including GM agricultural and veterinary chemicals): regulated through a national scheme administered, in cooperation with all States and Territories, by the Australian Pesticides and Veterinary Medicines Authority under the A*gricultural and Veterinary Chemicals (Administration) Act 1992* and the A*gricultural and Veterinary Chemicals (Code) Act 1994*; and
Industrial chemicals: regulated through the national industrial chemicals notification and assessment scheme under the *Industrial Chemicals (Notification and Assessment) Act 1989* and accompanying State/Territory legislation.

The Act (and the Commonwealth *Gene Technology Act 2000*) 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 and Territory legislation which may also effect the use of GMOs (for example, general biological control legislation, environment legislation and fisheries legislation).

Clause 5 - Nationally consistent scheme

This clause States that it is intended that the Act form a component of a nationally consistent scheme for the regulation of certain dealings with GMOs. This scheme will consist of the Commonwealth Act, this Act and corresponding Acts of the other States and Territories. An intergovernmental agreement on gene technology has been signed by the Commonwealth, States and Territories to ensure the national system maintains a high degree of consistency over time.

Clause 6 - Act to bind the Crown

Sub-clause 6(1) provides that the Act will bind the Crown in right of Western Australia and so far as the legislative power of the Parliament permits, the Crown in all its other capacities.

Sub-clause 6(2) provides that the Crown may not be prosecuted for an offence.

Clause 7 - External Territories

[The Commonwealth Act has a provision extending that Act to External Territories.]

Clause 8 - Offences

[The Commonwealth Act contains a provision applying chapter 2 of the Commonwealth Criminal Code to offences against that Act and construing penalty provisions in that Act. These are not relevant to the WA Act.]

Clause 8A - Numbering

This clause explains the numbering system used to maintain consistency with the Commonwealth Act. Where that Act contains a provision that is not required in this Act the number and section heading will appear in the WA Act despite the omission of the body of the section. Where the WA Act contains a provision not found in the Commonwealth Act the section is numbered so as to maintain consistency (for example, with an upper-case A, B, C etc, as here).

Clause 8B - Notes

This clause points out that the notes to the Act do not form Part of the Act.

Clause 8C - Outlines

Points out that the simplified outlines at the beginning of Parts 2 to12 are intended only as a general guide to readers.

Part 2 - Interpretation and operation of Act

Division 1 - Simplified outline

Clause 9 - Simplified outline

This clause gives a simplified outline of the Part.

Division 2 - Definitions

Clause 10 - Definitions

This clause 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. 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:
ecosystems and their constituent parts; and
natural and physical resources; and
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:
sexual reproduction;
homologous recombination; or
any other technique specified in the regulations for the purposes of this paragraph.

"genetically modified organism" is defined as:
an organism that has been modified by gene technology;
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
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:
a human being; or
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 organism.

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 product is GM stockfeed.

Human beings are excluded from the definition of a GMO to ensure that a person who has undergone gene therapy and who, for example, has a GM organ inserted in them will not fall within the definition.

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

Clause 11 - Meaning of intentional release of a GMO into the environment

Clause 11 describes the circumstances in which a dealing will be considered to involve an intentional release 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

[The Commonwealth Act contains a provision defining "corresponding State law" for the purposes of that Act. This Act is intended to be a corresponding State law within that definition.]

Clause 12A - Meaning of reckless

This clause explains the meaning of "recklessness" with respect to circumstances and results. These interpretations are required for clauses 32, 33, 34, 35, 38 and 65. This provision is not required in the Commonwealth Act because the term is defined in chapter 2 of the Commonwealth Criminal Code that applies to the relevant offences.

Division 3 - Operation of Act

Clause 13 - Operation of Act

[*The Commonwealth Act includes a provision about the constitutional powers on which that Act is based that is not required in the WA Act.]*

Clause 14 - Wind-back of reach of Act

[*The Commonwealth Act includes a provision for the "wind-back" of the reach of that Act where States or Territories have enacted corresponding State laws and a "wind-back notice" is in force.]*

Clause 15 - Relationship to other Commonwealth laws

This clause makes it clear that the provisions of the Act are in addition to, and not in substitution for, the requirements of any other law of Western Australia.

Division 4 - Provisions to facilitate a nationally consistent scheme

Subdivision A - General provisions

Clause 16 - State laws may operate concurrently

[*The Commonwealth Act includes a provision allowing State laws (apart from State laws prescribed for the purposes of that provision) to operate concurrently with the Commonwealth Act. This is not required in the WA Act.*]

Clause 17 - Conferral of functions on Commonwealth Authorities and officers

[*The Commonwealth Act includes a provision allowing corresponding State laws to confer functions, powers and duties on the Regulator and other officers and Authorities of the Commonwealth and on the committees established under the Commonwealth Act. It then authorises those persons or bodies to perform those functions, powers or duties. It also enables corresponding State laws to empower the Regulator to include or vary matters on the GMO Register and enter information on the Record of GMO and GM product dealings.*]

Clause 18 - No doubling-up of liabilities

This clause provides that if an Act or omission is an offence against the Act 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 WA Act.

A similar provision is made in respect of the imposition of pecuniary penalties.

Clause 19 - Review of certain decisions

This clause provides for an application to the Administrative Appeals Tribunal under the A*dministrative Appeals Tribunal Act 1975* of the Commonwealth for a review of a "reviewable decision" (see clause 179).

Clause 20 - Things done for multiple purposes

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

Subdivision B - 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:
Ethical issues relating to dealings with GMOs;
recognising designated areas under a law of WA for the purpose of preserving the identity of GM and/or non-GM crops for marketing purposes; and
Other matters relating to dealings with GMOs which are prescribed by the regulations.

(Clause 57 provides that the Regulator must not issue a licence if satisfied that to do so would be inconsistent with a policy principle.)

Sub-clause 21(2) provides that before issuing a policy principle the Ministerial Council must be satisfied that it has been developed in accordance with section 22 of the Commonwealth Act.

Sub-clause 21(3) States that regulations made prescribing issues in relation to which policy principles may be made may relate to matters beyond public health and safety and the environment, but that the principles must not derogate from the health and safety of people or 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 which is the protection of the health and safety of people and the environment.

Clause 22 - Consultation on policy principles

[*Section 22 of the Commonwealth Act describes the consultation process that must be observed before the Ministerial Council may issue a policy principle under clause 21. The clause provides that the policy principles must be developed in consultation with each of the three committees established under the legislation (the Gene Technology Technical Advisory Committee, the Gene Technology Ethics Committee and the gene Technology Community Consultative Committee). The clause also requires consultation with the Regulator and appropriate Commonwealth and State agencies. Consultation must also be undertaken with industry, environmental, consumer and other groups, as determined by the Ministerial Council.*

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. Policy guidelines are distinguishable from policy principles (clause 21) as these guidelines will not be binding on the Regulator. The Regulator will, however, be required to take such guidelines into account when deciding on an application for a licence under the legislation (clause 56).

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. They must be developed in accordance with section 24(2) of the Commonwealth Act which sets out the requirements for consultation. The Regulator must develop the codes of practice in consultation with the three committees established under the legislation (the Gene Technology Technical Advisory Committee, the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee). The Regulator must also consult with such Commonwealth and State agencies, Regulatory agencies and industry, environmental, consumer and other groups as the Ministerial Council considers appropriate.

It is intended that such codes of practice will form the basis for certain conditions imposed on a licence (under section 62).

Part 3 - The Gene Technology Regulator

Clause 25 - Simplified outline

This clause gives a simplified outline of the Part.

Clause 26 - The Gene Technology Regulator

[*The office of Gene Technology Regulator is established by section 26 of the Commonwealth Act.]*

Clause 27 - Functions of the Regulator

This clause sets out the functions of the Regulator. The Regulator will be responsible for:
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 Act);
Developing draft policy principles and policy guidelines as requested by the Ministerial Council;
Developing codes of practice;
Issuing technical and procedural guidelines in relation to GMOs;
Providing information and advice to other Regulatory agencies about GMOs and GM products;
Providing information and advice to the public about the regulation of GMOs;

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;
Undertaking or commissioning research in relation to risk assessment and the biosafety of GMOs;
Promoting the harmonisation of risk assessments relating to GMOs and GM products by Regulatory agencies;
Monitoring international practice in relation to the regulation of GMOs;
Maintaining links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia; and
Performing such other functions as are conferred on the Regulator by the Act, the regulations or any other law.

Clause 28 - Powers of the Regulator

This clause provides 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 a public service officer or an organisation within the meaning of the *Public Sector Management Act 1994* or an employee of a Commonwealth Authority if the functions of the organisation or Authority relate directly or indirectly to GMOs or GM products. This will enable, State and Commonwealth officers or employees to be enlisted to assist the Regulator in, for example, undertaking monitoring activities. While the Regulator will be responsible for assessing applications and issuing licences, the Regulator may need to delegate some functions to, for example, officers of the Australian quarantine and inspection service to enable them to inspect imported GMOs at Australia's border to ensure compliance with any licence issued by the Regulator.

A delegate is required to 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 his or her 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

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

This clause contains the central prohibition in the legislation. It provides that a person commits an offence if:
The person deals with a GMO knowing that it is a GMO; and

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
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
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
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.

This offence is a crime if it is an aggravated offence as defined in clause 38, in which case the maximum penalty is imprisonment for 5 years or a fine of $220 000. For a simple offence the maximum penalty is imprisonment for 2 years or a fine of $55 000.

Sub-clause 32(3) defines “exempt dealing” to be a dealing specified in the regulations as an exempt dealing

Sub-clause 32(4) provides that regulations may exempt all dealings with a GMO, or with a specified class of GMOs, a specified class of dealings with a GMO or with a specified class of GMOs or one or more specified dealings with a GMO or with a specified class of GMOs. A class of dealings or a class of GMOs may be defined by a range of matters. For example, an exempt class of dealings with a GMO may be limited by the type of GMO, who deals with the GMO, how the GMO is dealt with and whether the GMO is regulated under existing legislation.

Clause 33 - Person not to deal with a GMO without a licence - strict liability offence

This clause describes the same offence as clause 32 except that it does not require proof of knowledge that, or recklessness as to whether, the dealing with the GMO is not authorised by a licence, not a notifiable low risk dealing, not an exempt dealing and not included on the GMO Register. A smaller penalty applies in the absence of the fault elements of the offence.

Clause 34 - Person must not breach conditions of a GMO licence

Sub-clause 34(1) provides that a holder of a GMO licence commits an offence if they intentionally do something, or fail to do something, knowing that the action or omission contravenes the licence or being reckless as to whether or not the action or omission will contravene the licence. Sub-clause 34(2) creates a similar offence that applies to a person covered by a licence. In that case the person must have knowledge of the conditions of the licence. (This will be assumed in the case of the holder and will not have to be proved.)

These offences are crimes if they are aggravated offences - as defined in clause 38. The penalties are the same as for offences under clause 32 - knowingly or recklessly dealing with a GMO without a licence - and daily penalties may also be applied for continuing offences.

Clause 35 - Person must not breach conditions of a GMO licence - strict liability offence

This clause describes the same offences as clause 34 without the elements of knowledge or recklessness. Lesser penalties apply.

If a person covered by a licence breaches a condition of licence, provided it can be established that they had knowledge of the conditions of licence, it is not necessary to establish that they breached the condition of licence knowingly or recklessly in order for the penalty to be applied.

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 relating to the dealing that is specified on the GMO Register (described in Part 6, Division 3). It is not necessary to establish that the person knew the dealing contravened the condition.

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. The maximum penalty is $5 500.

Clause 37 - Offence relating to notifiable low risk dealings

This clause provides that a person commits an offence if they deal with a GMO knowing that it is a GMO if the dealing is a notifiable low risk dealing and it was not undertaken in accordance with the regulations. The maximum penalty is $5 500.

Notifiable low risk dealings are categories of dealings with GMOs that are specified in the regulations along with any conditions that must be complied with in respect of such dealings - see Part 6. For example, research with low risk GMOs occurring within facilities that are entirely contained.

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 referred to 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 Act will be potentially more serious than others (given the possible significant consequences that may flow from an action), and that in the event of such serious consequences 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

This clause gives a simplified outline of the Part.

Division 2 - Licence applications

Clause 40 - Person may apply for a licence

This clause sets out the requirements for applying to the Regulator for a licence to undertake specified 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 and prescribed in the regulations. 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 to be authorised by the licence 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 the application fee (if any) prescribed by 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.

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 (if any); 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 is not required 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 the period (if any) prescribed by the regulations.

Clause 44 - Regulator may consult with applicant

This clause allows the Regulator to consult with the applicant or another Regulatory agency on any aspect of an application before considering that application. This 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 this Division 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. This would include, for example, applications in respect of dealings with GMOs within a contained laboratory.

The term 'intentional release of a GMO into the environment' is defined in clause 11.

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. In preparing the risk assessment the Regulator must take into account any risks posed by the proposed dealing with the GMO, including any risks to the health and safety of people or the environment (47(2)). 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 (47(3)).

Sub-clause 47(4) provides that the Regulator may consult the States, 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 this Division 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. For example, this Division applies to small-scale experimental trials of GM crops conducted in fields or waterways and applications for commercial release of a GMO, for example, large scale growing of GM crops for commercial sale.

The term 'intentional release of a GMO into the environment' is defined in clause 11.

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. For example, the risks posed in relation to an application seeking authorisation to hold two genetically modified cows in a double-fenced holding pen are very different to the risks that may be posed by the extensive growing of genetically modified crops in open fields. While both involve the deliberate release of a GMO into the environment, this clause enables the Regulator to apply a higher level of public scrutiny to applications which pose greater potential risks.

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 via a wide publication of a notice in respect of the application. The Regulator must provide public notification of such applications by notice in the *Gazette*, by advertisement in a newspaper circulating generally in Western Australia and by notice on the Regulator's website. (The Regulator may also choose to notify receipt of such an application through other means, such as direct mailing individuals and organisations who have registered an interest in receiving such information from the Regulator.)

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. The Regulator must, for example, consider the potential for spread of the GMO, the scale of the proposed dealings, and the effects of the genetic modification on the properties of the organism.

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 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.

It is intended that the Regulator will issue detailed guidelines regarding the process for risk assessment and risk management, following extensive public consultation on these matters.

Sub-clause 50(2) clarifies that the Regulator must prepare the risk assessment and risk management plan whether or not the Regulator was required to publish a notice referred to in clause 49. (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, the States, prescribed Commonwealth agencies, the Commonwealth environment minister 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 which must be considered by the Regulator in preparing the risk assessment. These matters include the risks posed by the proposed dealings, submissions made to the Regulator, and any advice provided by the Gene Technology Technical Advisory Committee and Commonwealth, State and local government agencies.

Sub-clause 51(2) details the range of matters which must be considered by the Regulator in preparing the risk management plan. These matters include the means of managing any risks to the health and safety of people and the environment posed by the proposed dealings, submissions made to the Regulator, and any advice provided by the Gene Technology Technical Advisory Committee and Commonwealth, State and local government agencies. Regulations may

also prescribe other matters to be taken into account by the Regulator in preparing the risk assessment or risk management plan.

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 to him or her, and may inform him or herself through other means such as independent research.

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

This clause describes the process the Regulator must follow after having prepared a draft risk assessment and risk management plan. The Regulator must notify the public, stating that a risk assessment and risk management plan has been prepared. The notice must: inform people that they are able to 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).

The Regulator must publish the notice in the *Gazette*, a newspaper circulating generally in Western Australia and on the Regulator's website. (The Regulator may also supplement this notification by, for example, direct mailing all persons who have registered an interest in receiving notification of applications and placing advertisements in the papers of regional areas affected by the application.)

Sub-clause 52(3) also requires the Regulator to seek the views of the Gene Technology Technical Advisory Committee, the 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 provides 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, he or she may impose conditions 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: the 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:
Where the issue of the licence would be inconsistent with a policy principle issued by the Ministerial Council under clause 21; and
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, in relation to a natural person, the Regulator must have regard to any relevant conviction of the person, 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. This may include, for example, a consideration of the person's financial viability, personal skills and experience, and any other matters that may influence the capacity of the applicant to fulfill any conditions of licence imposed by the Regulator.

Sub-clause 58(2) specifies that, for a body corporate, the Regulator must have regard to any relevant conviction of the 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 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. 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) lists 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; limiting the dissemination or persistence of GMO in the environment; and conditions relating to contingency planning in respect of unintended effects of the dealings authorised by the licence (amongst other things).

Under sub-clause 62(3) licence conditions may include conditions requiring the holder to be adequately insured against any loss, damage or injury that may be caused to human health, property or the environment by the licensed dealing

Clause 63 - Condition about informing people of obligations

Sub-clause 63(1) 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 several matters. These are: the particular conditions applying to the person (including any variations of conditions); the cancellation or suspension of the licence; and the licence-holder's surrender of the licence.

Sub-clause 63(2) allows the Regulator or the regulations to specify particular requirements for the way that people covered by a licence must be informed of their obligations by the licence holder.

Sub-clause 63(3) notes that such requirements may include measures relating to labelling, packaging, conducting training and providing information.

Sub-clause 63(4) makes it a condition of licence that where requirements for informing people covered by a licence have been prescribed or specified the licence holder must comply with those requirements.

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 condition 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 with and that the Activity with the GMO is being conducted safely. The auditing and

monitoring powers of the Regulator (provided for by this clause) are also supplemented by the inspection powers of inspectors in the case of a possible breach of the legislation. Part 11 of the Bill describes these additional powers of inspection.

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

This clause makes it a condition of a licence that the licence holder informs the Regulator if the licence holder:

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
Becomes aware of any contraventions of the licence by a person covered by the licence; or
Becomes aware of any unintended effects of the dealings authorised by the licence.

Sub-clause 65(2) specifies that the licence holder is taken to have become aware of additional information as to risks if the licence holder was reckless as to whether such information existed. The licence holder is also taken to have become aware of contraventions or unintended effects of the licence if they were reckless as to whether such contraventions had occurred or unintended effects existed.

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.

Clause 67 - Protection of persons who give information

This clause provides that civil liability for loss, damage or injury suffered by another person is not incurred by a person who has given information to the Regulator under section 65 or 66. This clause would not affect any rights a person may have against a person who published the information more broadly than just to the Regulator - it only provides protection in respect of civil liability for the disclosure of 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. This power may be exercised by the Regulator by giving written notice to the licence holder. The grounds for the exercise of this power are listed in this clause and include: suspected breach of a licence condition; suspicion that an offence has been committed; or where the Regulator becomes aware of new information about the risks associated with the licensee's dealings, and is satisfied that the licensee does not have adequate measures to deal with those risks.

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 person to whom it is proposed that the licence be transferred (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) 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.

Sub-clause 71(2) provides that the Regulator's discretion to vary the licence is limited. The Regulator must not vary a licence so as to authorise dealings involving the intentional release of a GMO into the environment if the application for the licence was originally considered under Division 3 (which deals with licence applications where there is to be no release of the GMO into the environment).

Sub-clause 71(3) allows the Regulator to vary a licence in a number of ways, including: by imposing additional licence conditions; removing or varying conditions; or by extending or reducing the authority granted by the licence.

Sub-clause 71(4) provides that the Regulator must not vary a licence if to do so would mean that any risks posed by a dealing authorised by the licence could not be properly managed so as to ensure the continued protection of the health and safety of people and the environment.

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 Regulator's 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.

Division 8 - Annual charge

Clause 72A - GMO licence - annual charge

This clause provides for an annual licence charge as prescribed in the regulations.

[*Charges relating to the Commonwealth Act are imposed under a separate Act the Gene Technology (Licensing Charges) Act 2000*.]

Part 6 - Regulation of notifiable low risk dealings and dealings on the GMO Register

Division 1 - Simplified outline

Clause 73 - Simplified outline

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 the Act. 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.

Sub-clause 74(2) provides that a notifiable low risk dealing can never involve the intentional release of the GMO into the environment. That is, dealings with GMOs may only be prescribed in the regulations as notifiable low risk dealings if the dealings are carried out within contained facilities.

Sub-clauses 74(3) specifies the matters to be considered by the Regulator before regulations are made prescribing notifiable low risk dealings. Relevant considerations include: whether the GMO is 'biologically contained' (because it is not able to survive or reproduce without human intervention); whether the dealing involves minimal risk (taking into account the properties of the GMO as a pathogen or pest and its capacity to produce toxic proteins); and whether proposed conditions will be adequate to manage any risk associated with the proposed dealing.

Sub-clause 74(4) provides that where regulations are made prescribing certain dealings as notifiable low risk dealings, the regulations may be expressed to apply to a single dealing, a class of dealings or all dealings with a GMO or a class of GMOs.

Clause 75 - Regulation of notifiable low risk dealings

Sub-clause 75(1) allows regulations to be made which regulate one notifiable low risk dealing, or a specified class of notifiable low risk dealings.

Sub-clause 75(2) specifies that the regulations may contain certain conditions which must be complied with by persons undertaking notifiable low risk dealings, including requirements in relation to: the class of person who may undertake notifiable low risk dealings; notification of the dealings to the Regulator; the need for supervision by an institutional biosafety committee; and the containment level of facilities in which such dealings are undertaken. The role of institutional biosafety committees, set up within accredited organisations, is explained in more detail in Part 7, Division 3.

Division 3--The GMO Register

Clause 76 - GMO Register

[*Section 76 of the Commonwealth Act provides for the establishment and maintenance of the GMO Register.*]

[*The purpose of the GMO Register is to enable certain dealings with GMOs to be undertaken without the requirement for a licence to be held by a named individual or organisation. Dealings with GMOs may be entered on the GMO Register once they have been licensed for a certain period of time, and once the Regulator is satisfied that the dealings with the GMO are sufficiently safe that they can be undertaken by anyone without the GMO being dependent on oversight by a licence holder.*

For example, a company that wished to market a flower that had been genetically modified to extend vase life, would initially apply for a licence to do so. If any risks posed by the flower could be managed, the Regulator would grant the applicant a licence subject to, as a minimum, conditions requiring provision of any further information about risks or unintended effects by the licence holder and a requirement that the Regulator be allowed to enter premises to undertake auditing and monitoring. After a period of time (for example, 5 years), the Regulator could re-examine the licence and determine that, on the basis of the absence of risks posed by the flower, it is no longer appropriate for the flower to be subject to the licensing regime and that the flower should be entered on the Register, enabling unrestricted use.]

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 to which the dealing is subject.

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

Sub-clause 78(1) provides that the Regulator may determine to include a dealing with a GMO on the GMO Register where:
The dealing with the GMO is, or has previously been, authorised by a GMO licence; or
The GMO concerned is a GM product and is a GM organism only because of regulations made under paragraph (c) of the definition of “genetically modified organism”.

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. Where a licence holder has applied to have a dealing 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.

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.

In making a determination to place a dealing on the GMO Register, the Regulator must have regard to all available information about the possible need for a licence, including: any data about adverse effects posed by the dealing; any other information as to risks associated with the dealing of which the Regulator is aware; and whether there is a need for the dealing to be subject to conditions. The Regulator may also have regard to any other matters the Regulator considers relevant.

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.

Clause 81 - Inspection of Register

[*Section 81 of the Commonwealth Act 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

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, and be accompanied by the appropriate application fee (as prescribed by the regulations).

Certification of a facility to a certain containment level 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.

The containment levels to which the Regulator may certify a facility will be documented in guidelines issued by the Regulator (as described in clause 90).

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, on reasonable grounds, that a condition of the certification has been breached.

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

Sub-clause 89(1) 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-clause 89(2), and include the requirement that (within a designated period) any relevant information be provided by the holder of the certification to the Regulator, and a requirement to invite the holder of the certification to make a written submission concerning the proposed suspension, cancellation or variation.

Sub-clause 89(3) requires that the notice provided to the holder of the certification must specify the period in which the holder of certification must give information or make submission. The period must not be less than 30 days.

Sub-clause 89(4) provides that the Regulator must consider any written submissions made to him or her.

Sub-clauses 89(5) and (6) exclude the requirements of this clause where the suspension or variation is requested by the holder of the certification, or where the Regulator considers that the Action is necessary to avoid an imminent risk of death, serious illness, serious injury or serious damage to the environment.

Clause 90 - Guidelines

This clause allows the Regulator to issue technical or procedural guidelines about the requirements for the certification of facilities to specified containment levels and to vary or revoke those guidelines.

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.

The Regulator may impose as a condition of licence a requirement that the work be conducted within an accredited organisation. As described in this Division, an organisation will be accredited if it can establish to the satisfaction of the Regulator that it has a properly constituted institutional biosafety committee (operating in accordance with guidelines issued by the Regulator).

The role of institutional biosafety committees will be to provide day to day advice and assistance to, and oversight of, people undertaking dealings with GMOs within organisations. Regulatory responsibility will continue to rest with the Regulator (including responsibility for independent monitoring and auditing of the dealings with GMOs). The institutional biosafety committee will, however, play an important role in ensuring the safety of dealings with GMOs and in providing assistance and advice both to applicants and licence holders and also to the Regulator.

Clause 92 - Regulator may accredit organisations

Sub-clause 92(1) enables the Regulator to accredit an organisation (by written instrument).

Sub-clause 92(2) provides that in making the decision whether to accredit the organisation, the Regulator must have regard to matters such as: whether the organisation has established, or proposes to establish, and whether it will be able to maintain, an institutional biosafety committee and; whether the organisation has, or will have, appropriate indemnity arrangements for institutional biosafety committee members. The Regulator may also take into account any other matters specified in guidelines issued by the Regulator.

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 specified 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.

Sub-clause 95(2) allows the Regulator to impose additional conditions or remove or vary conditions that were originally imposed.

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 specified time. The Regulator must consider any written submissions made to him or her.

Sub-clauses 97(5) and (6) exclude the requirements of the clause where the suspension, cancellation or variation is requested by the holder of the accreditation, or where the Regulator considers that the Action is necessary to avoid an imminent risk of death, serious illness, serious injury or serious damage to the environment.

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

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

[*Section 100 of the Commonwealth Act provides for the establishment and maintenance of the Gene Technology Technical Advisory Committee. The committee comprises up to 20 part-time members appointed by the minister with skills and experience in various specified scientific areas. It must also include a layperson and the appointment of the chairperson must be agreed by a majority of the jurisdictions. The minister must consult with the States, the Regulator and other groups before appointing committee members.]*

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 which include:
Gene technology, GMOs and GM products;
Applications made under the Act;
The biosafety aspects of gene technology; and
The need for policy principles, policy guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products and the content of such principles, guidelines and codes.

Clause 102 - Expert advisers

[*Section 102 of the Commonwealth Act provides for the appointment of expert advisors to the Gene Technology Technical Advisory Committee.]*

Clause 103 - Remuneration

[*Section 103 of the Commonwealth Act provides for the payment of remuneration and allowances to members of, and expert advisors to, the committee*.]

Clause 104 - Members and procedures

[*Section 104 of the Commonwealth Act enables regulations to be made prescribing a range of matters relating to the members of the Gene Technology Technical Advisory Committee, and to expert advisers, such as: terms of appointment; resignation; disclosure of interests; termination of appointment; and leave of absence.]*

Clause 105 - Subcommittees

[*Section 105 of the Commonwealth Act allows the formation of subcommittees to assist in the performance of the committee's functions, and provides for the making of regulations to deal with the constitution and operation of such subcommittees*.]

Division 3 - The Gene Technology community consultative Committee

Clause 106 - The Gene Technology community consultative Committee

[*Section 106 of the Commonwealth Act establishes the Gene Technology Community Consultative Committee*.]

Clause 107 - Function of consultative committee

This clause provides that the function of the consultative committees 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 GM products.

Clause 108 - Membership

[*Section 108 of the Commonwealth Act provides for the membership of the consultative committee*.]

Clause 109 - Remuneration

[*Section 109 of the Commonwealth Act provides for the payment of remuneration and allowances to members of the consultative committee*.]

Clause 110 - Regulations

[*Section 110 of the Commonwealth Act empowers the making of regulations relating to the membership and operation of the consultative committee*.]

Clause 110A - Subcommittees

[Section 110A of the Commonwealth Act deals with the establishment of subcommittees by the consultative committee.]

Division 4 - The Gene Technology Ethics Committee

Clause 111 - The Gene Technology Ethics Committee

[*Section 111 of the Commonwealth Act provides for the establishment and membership of the Gene Technology Ethics Committee (the ethics committee).]*

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 ethical guidelines for the conduct of dealings with GMOs; and the development of guidelines in relation to dealings with GMOs that should not be conducted for ethical reasons.

Clause 113 - Expert advisers

[*As for other committees*.]

Clause 114 - Remuneration

[*As for other committees*.]

Clause 115 - Members and procedures

[*As for other committees*.]

Clause 116 - Subcommittees

[*As for other committees.*]

Part 9 - Administration

Division 1 - Simplified outline

Clause 117 - Simplified outline

This clause gives a simplified outline of the Part.

Division 2 - Appointment and conditions of Regulator

[*Sections 118 - 126 of the Commonwealth Act deal with various matters relating to the appointment and conditions of the Regulator.*]

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 State

As the Act binds the Crown in right of the State, the purpose of this clause is to ensure that fees and charges under the Act and regulations are notionally payable by the State and bodies representing the State.

Sub-clause 128(2) provides that the minister responsible for administering the *financial administration and audit Act 1985* may give written directions for the purpose of this clause, including directions relating to the transfer of amounts within, or between, accounts operated by the State.

Clause 129 - Gene technology account

[*Section 129 of the Commonwealth Act provides for the establishment of the gene technology account, which is a special account for the purposes of the Financial Management and Accountability Act 1997 of the Commonwealth.*]

Clause 130 - Credits to account

Sub-clause 130(1) sets out the amounts that must be paid to the Commonwealth for crediting to the gene technology account. These include:
Amounts equal to money received by WA under Part 5 Division 8 (annual licence charge);
Amounts equal to fees received by WA under sections 40(6) and 83(3);
Amounts equal to amounts received by WA in connection with the performance of the Regulator's functions under this Act or the regulations;
Amounts equal to amounts recovered by the WA to the extent that they are referrable to costs paid out of the gene technology account monies appropriated by the parliament for the purposes of the account.

Sub-clause 130(2) appropriates the consolidated fund to the extent necessary to enable these amounts to be paid to the Commonwealth.

Clause 131 - Recovery of amounts

This clause provides that the following amounts may be recovered in a court as debts due to WA:
Amounts payable to WA under Part 5 Division 8;
Fees payable to WA under the Act or the regulations; and
Amounts payable to WA in connection with the performance of the Regulator's functions.

Clause 132 - Purposes of account

[*Section 132 of the Commonwealth Act sets out the purposes for which money in the account may be expended*.]

Division 4 - Staffing

Clause 133 - Staff assisting the Regulator

[Commonwealth Act provides for staff to be made available to assist the Regulator.]

Clause 134 - Consultants

[*Commonwealth Act enables the Regulator to appoint suitably qualified and experienced consultants to assist the Regulator*.]

Clause 135 - Seconded officers

[*Commonwealth Act provides for staff to be seconded to the Regulator*.]

Division 5 - Reporting requirements

Clause 136 - Annual report

As soon as practicable after the end of each financial year the Regulator must prepare and give to the minister an annual report on the operations of the Regulator during the year. This must be tabled before each house of parliament within 15 sitting days of the day on which the report was given to the minister.

[*The Commonwealth Act requires the Regulator to provide a copy of the annual report under that Act to each State*.]

Clause 136A - Quarterly reports

As soon as practicable after the end of each quarter the Regulator must prepare and give to the minister a report on the operations of the Regulator during that quarter. The report must include information about: GMO licences issued during the quarter; any breaches of condition of a licence that have come to the Regulator's attention; auditing and monitoring of dealings with GMOs by the Regulator or an inspector. Quarterly reports must be tabled in parliament just as the annual report must.

Clause 137 - Reports to parliament

The Regulator may, at any time, cause a report about matters relating to the Regulator's functions to be tabled in either house of parliament. The Regulator must give a copy of such a report to the minister.

[*The Commonwealth Act requires a report tabled under the equivalent section of that Act to be given to each State*.]

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 record of GMO and GM product dealings, to be known as 'the Record'. The purpose of the Record is to maintain a comprehensive record of all dealings in Australia that involve GMOs or GM products.

In relation to GMO licences, sub-clause 138(3) requires that the Record contain certain information (other than confidential commercial information) in relation to every GMO licence which has been issued. That information includes details such as: name of licence holder; persons covered by the licence; and any licence conditions.

In relation to notifiable low risk dealings, sub-clause 138(4) requires that the Record contain the following information (other than confidential commercial information): the name of the person who notified the dealing; and relevant particulars of the dealing as prescribed in regulations.

As far as GM products are concerned, the Record must contain such information as is prescribed by the regulations (other than confidential commercial information) in relation to GM products mentioned in designated notifications. "Designated notifications" are notifications required to be given to the Regulator under an Act, or any law applying as a law of WA by force of an Act.

[*Section 138(5) of the Commonwealth Act refers to designated notifications under*:
The Agricultural and V eterinary Chemicals (Administration) Act 1992;
The Australia New Zealand Food Authority Act 1991;
The Industrial Chemicals (Notification and Assessment) Act 1989;
The Therapeutic Goods Act 1989.]

The Record must also include a description of each dealing on the GMO Register, including any conditions to which the dealing is subject.

Clause 139 - Inspection of Record

[*The Commonwealth Act requires the Regulator to permit any person to inspect any part of the Record*.]

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.

Sub-clause 140(2) requires that, in making these decisions, the Regulator must consider the matters in sub-clause 74(2) and sub-clause 74(3). These sub-clauses require the Regulator to consider matters such as: whether the proposed dealings involve an intentional release into the environment; whether the GMO can be biologically contained; whether the GMO is a pathogen or pest; and whether any risks can be managed with minimal, or no, conditions.

Clause 141 - Regulator may review exemptions

This clause allows the Regulator, at any time, to consider whether an exempt dealing should no longer be an exempt dealing and whether a dealing with a GMO (that is not an exempt dealing) should be an exempt dealing.

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, including submissions on any reasons for the proposed change. This clause also sets out the matters that the Regulator must include in a public notice, and requires the Regulator to specifically notify the States, the Gene Technology Technical Advisory Committee, and prescribed Commonwealth agencies.

Clause 143 - What Regulator may do after consideration

This clause allows the Regulator, after completion of the process outlined above, to recommend to the Ministerial Council that:
A dealing be declared a notifiable low risk dealing, or
An existing declaration under regulations be withdrawn where the dealing should no longer be a notifiable low risk dealing; or
A dealing be exempted; or
An existing exemption be retained or removed.

The Regulator is required to advise the Ministerial Council because it will be the Ministerial Council who agree any changes to the national legislative scheme, and who make recommendations to each of the parliaments to adopt such changes.

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

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 it is necessary to do so in order to protect 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 with the legislation. If the person does not take the necessary action within the period of time specified by the Regulator, the Regulator may arrange for the necessary steps to be taken, to ensure compliance with the legislation.

This provision effectively enables a “clean-up” or remediation to be undertaken, at the direction of the Regulator, where, for example, a condition of licence has been breached resulting in the accidental release of a GMO, and there is a need to re-contain the GMO.

The clause further provides that if costs are incurred by the Regulator because of arrangements made to bring the activity back into compliance with the legislation, such costs may be recovered from the licence holder or the person covered by the licence (as applicable).

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. In such circumstances, the inspector can take such steps as are necessary without first giving written notice to the licence holder or applicant requiring them to take the necessary steps. Such action, by the inspector or others, is also cost recoverable from the offending party.

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 Act or regulations, the Supreme Court, on the application of the

Regulator or any other aggrieved person, may grant an injunction, restraining that person from engaging in that conduct.

Likewise, if a person has refused or failed, or is refusing or failing, or is proposing to refuse or fail, to do any thing, and such a refusal or failure is or would constitute an offence against the legislation, then the Supreme Court may, on application by the Regulator or any other aggrieved person, grant an injunction requiring the person to do the thing.

The court's powers to grant injunctions under this section may be exercised whether or not it appears to the court that the person intends to engage, or to continue to engage, in conduct of that kind, and whether or not the person has previously engaged in conduct of that kind (sub-clause 147(3)).

Injunctions may be discharged or varied, interim injunctions may be granted, and the court's powers under these provisions are in addition to, and not in derogation of, any other powers of the court. (sub-clauses 147(4), (5) and (6)).

[*The Commonwealth Act confers on the Federal Court a similar power to grant injunctions.]*

Clause 148 - Forfeiture

Sub-clause 148(1) States that if a court convicts a person of an offence against the Act or regulations, then the court may order forfeiture of the thing used, or otherwise involved in the commission of the offence.

A thing ordered by a court to be forfeited becomes the property of the State and may be sold or otherwise dealt with in accordance with the directions of the Regulator (148(2)).

Until the Regulator gives such a direction, the thing must be kept in such custody as the Regulator directs (148(3)). “Thing” is widely defined in clause 10 to include a substance, and a thing in electronic or magnetic form.

Part 11 - Powers of inspection

Division 1 - Simplified outline

Clause 149 - Simplified outline

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 as inspectors any employee or class of employee employed under Part 3 of the *Public Sector Management Act 1994* or a person who is appointed or employed by the Commonwealth.

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

Sub-clauses 151(1) and 151(2) require the Regulator to issue an identity card, in a form prescribed by the regulations, to every person appointed as an inspector. The identity card must have a recent photograph of the inspector.

Sub-clause 151(3) provides that it is an offence for a person who ceases to be appointed as an inspector to fail to return his or her identity card to the Regulator, as soon as practicable. The offence attracts a maximum penalty of $110.

Sub-clause 151(4) requires the inspector to carry his or her identity 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

Sub-clause 152(1) 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 Act or regulations are being complied with.

Sub-clause 152(2) provides that an inspector may only enter premises under this provision if: the occupier of the premises has consented; the inspector has obtained a warrant under clause 172; or the occupier of the premises is a licence holder, or a person covered by a licence, and the entry is at a reasonable time.

Clause 153 - Monitoring powers

This clause describes the monitoring powers that an inspector may exercise for the purposes of finding out whether the Act 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.

Sub-clause 154(1) States that the powers may be exercised if an inspector has reasonable grounds for suspecting that there may be evidential material on any premises.

Sub-clause 154(2) provides that an inspector may enter premises, either with the consent of the occupier or under a warrant issued under clause 173, to do any of the things described in sub-clause 154(3) and clause 155, including, if the entry is under a warrant, seizing the evidential material if the inspector finds it on the premises.

Sub-clause 154(3) provides that if, in the course of searching for a particular thing at premises in accordance with a warrant, an inspector finds something else that he or she believes on reasonable grounds to be evidential material which the inspector also reasonably believes must be seized to prevent its concealment, loss or destruction or use in the commission or continuation of an offence against the legislation, then the warrant is taken to authorise the inspector to seize that thing.

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; 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 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.

Sub-clause 156(2) provides that, if evidential material is so accessible, the inspector may seize the equipment and any disk, tape or other associated device, or operate the equipment, in order to obtain the evidential material, or to copy such evidential material to another storage device, and remove it from the premises.

Sub-clause 156(3) is intended to facilitate the seizure of printouts or duplicate discs wherever possible, rather than the original material. It provides that an inspector may seize equipment under paragraph 156(2)(a) only if it is not practicable to put the material into documentary form or to copy it to a storage device, or if possession by the occupier of the equipment could constitute an offence.

Sub-clause 156(4) provides that an inspector may seize equipment under paragraph 156(2)(a) or documents under paragraph 156(2)(b), only if the inspector entered the premises under a warrant.

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.

Sub-clause 157(3) allows the thing to be secured for either 24 hours or until the thing is operated by an expert, whichever happens first.

Sub-clause 157(4) allows an inspector to apply to a magistrate for an extension of the time needed for securing the equipment if he or she believes, on reasonable grounds, that the expert assistance will not be available within the 24 hour period. The occupier must be given notice under sub-clause 157(5) that the inspector intends to apply for an extension, and the occupier has a right to be heard in relation to the application.

Division 6 - Emergency powers

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

Sub-clause 158(1) describes the circumstances in which an inspector may exercise powers under this clause. These are where 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 Act 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.

Sub-clause 158(2) provides that, in such circumstances, an inspector may, without a warrant or the consent of an occupier: enter premises; search the premises for the thing; secure the thing if the inspector finds it on the premises until a warrant is obtained to seize the thing; if the inspector believes on reasonable grounds that a person has failed to comply with any requirements of the Act or regulations in relation to the thing, require the person to take such steps, or arrange for such steps to be taken, as the inspector considers necessary for the person to comply with the legislation; and take such steps in relation to the thing as the inspector considers appropriate.

Sub-clause 158(3) requires the inspector to exercise his or her powers under sub-clause 158(2) only to the extent necessary for the purposes of avoiding an imminent risk of death, serious illness, serious injury or serious damage to the environment.

Sub-clause 158(4) provides that, where the Regulator incurs costs as the result of the inspector taking steps, or arranging for steps to be taken, these may be recovered from the person who failed to comply with the legislation.

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.

Sub-clause 160(2) clarifies that any consent given by a person to enable entry to premises by the inspector must be voluntary.

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. Sub-clause 161(3) provides that the copy need not include the signature of the magistrate who issued the warrant.

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 as mentioned in clauses 153 or 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 to the owner.

In determining the amount payable, regard is to be had as to whether the occupier (or his or her employees and agents) had provided any warning or guidance as to the operation of the thing. This is to minimize compensation in cases where there has been a deliberate programming of software to destroy or cause damage if not accessed in a particular manner, or where the occupier failed to mitigate damage by providing warning or guidance.

[*The Commonwealth Act provides for compensation to be payable out of money appropriated by the Parliament*.]

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. Failure or refusal to answer a question relating to such goods or baggage is punishable by a fine up to $3,300 for individuals.

This clause has been included to 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 are evidential material.

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 the clause does not apply where the thing seized was seized under paragraphs 156(2)(b) or (c) (where a copy was taken, not the original), 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 observe 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 a number of items to be listed on the same receipt.

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 the thing is forfeited or forfeitable, 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 - Magistrate may permit a thing to be retained

This clause describes how an inspector may apply to a magistrate 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 a magistrate) where proceedings in respect of which the thing may afford evidence have not commenced.

Sub-clause 170(2) provides that if the magistrate 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 Act or to enable the evidence to be secured for the purposes of a prosecution, the magistrate 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 Act 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 he or she is 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, fax 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 section, 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 $13 200, if an inspector makes a statement, when applying for a warrant, that the inspector knows to be false or misleading in a material particular.

Sub-clause 175(2) prohibits certain other actions in relation to warrants that attract the same penalties. These include:

(a) 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;

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 do not 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

This clause gives a simplified outline of the Part.

Division 2 - Review of decisions

Clause 179 - Meaning of terms

This clause specifies those decisions under the Act that will be “reviewable decisions” under the Act. It uses a table listing the decision, the provision under which the decision will be made and the person eligible to seek the review.

Clause 180 - Notification of decisions and review rights

This clause provides that as soon as practicable after making a reviewable decision 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 to make a reviewable decision, a period is specified for giving notice of that decision to the applicant, and the Regulator has not notified the applicant of the Regulator's decision within that period then the Regulator is taken to have made a decision to reject the application. (Thus there is taken to be a decision that can be reviewed and the applicant is not left waiting indefinitely.)

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

[*The Commonwealth Act provides that a State is taken to be a person aggrieved for the purpose of the application of the Administrative Decisions (Judicial Review) Act 1977 of the Commonwealth in relation to decisions, failure to make decisions and conduct engaged in for the purpose of making decisions under the Act and regulations*.]

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 the Act relates is confidential commercial information for the purposes of the Act. 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 Act.

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-clause 185(2a) requires the Regulator to refuse to declare that information is confidential commercial information if the information relates to one or more locations at which field trials involving GMOs are occurring or are proposed to occur, unless the Regulator is satisfied that significant damage to the health and safety of people, the environment or property would be likely to occur if the locations were disclosed.

This means that in general, information about sites where dealings with GMOs are occurring will be required to be disclosed under sections 38 and 154.

Sub-clause 185(3) provides that the Regulator must give the applicant written notice of his or her decision about the application.

Sub-clause 185(3a) provides that if the Regulator does declare that information relating to site locations is confidential commercial information the Regulator must make publicly available a statement of the reasons for making the declaration, including, but not limited to: the reasons the Regulator was satisfied as mentioned in 185(1); the reasons the Regulator was not satisfied under 185(2) that the public interest in disclosure outweighed the prejudice that disclosure would cause; and the reasons why the Regulator was satisfied under 185(2a) that significant damage would occur if the locations were disclosed.

Sub-clause 185(4) provides 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 (in sub-clause 187(1)) that a person who has access to confidential commercial information because of performing duties or functions under the Act, the Commonwealth Act or a corresponding law of another State, must not disclose that information except: (in the course of carrying out those duties or functions) to a State agency, the Commonwealth or a Commonwealth Authority or the Gene Technology Technical Advisory Committee; by order of a court; or with the consent of the person who applied to have the information declared as confidential commercial information.

By sub-clause (2), the same restrictions on disclosure will apply to a person to whom the information is disclosed under sub-clause (1) or this sub-clause.

These provisions enable 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 or an employee or agent of a person.

Clause 189 - Meaning of terms

This clause defines terms used in clause 188 including “the state of mind of a person”, “a director of a body corporate”, “engaging in conduct” and “an ancillary offence”.

Division 5 - Transitional provisions

Clause 190 - Transitional provision - dealings covered by genetic manipulation advisory committee advice to proceed

This clause provides for transitional arrangements in relation to dealings with GMOs approved prior to the commencement of the Bill. It covers matters in relation to which an “advice to proceed” was issued by the Genetic Manipulation Advisory Committee before the commencement of Part 4 (regulation of dealings with GMOs, which include the licensing provisions).

If the dealing is in accordance with the advice to proceed then the advice to proceed is taken to be a licence and the licence is taken to be subject to any conditions to which the advice to proceed was subject.

Such a licence is taken to continue in force until the advice to proceed expires, until the end of the transition period (the period not exceeding 2 years prescribed for the purposes of this section), or until the licence is cancelled or surrendered, whichever is the earliest.

If, at the time when the licence ceases to be in force, the licence holder wishes to continue the dealings with the GMO, the licence holder will need to apply to the Regulator for another licence.

Clause 191 - Regulations may relate to transitional matters

This clause provides that regulations may be made in relation to transitional matters arising from the enactment of the Act.

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 or in compliance or purported compliance with the legislation. The penalty for an offence against this provision is imprisonment of 1 year or $6,600.

Clause 192A - Interference with dealings with GMOs

This clause makes it an offence to engage in conduct that results in damage to, or destruction of or interference with premises, or a thing in premises at which dealings with GMOs are being undertaken. The offence is committed if the owner or occupier of the premises or thing has not consented to the conduct and the person engaging in the conduct intends to prevent or hinder authorised GMO dealings and knows, or is reckless as to, the damage that results.

Clause 192A -Ancillary offences (parties to offences, attempts, incitement or conspiracy)

This clause provides for these ancillary matters to be covered by reference to the criminal code.

Clause 193 - Regulations: general

This clause empowers the making of regulations prescribing matters required or permitted to be prescribed or necessary or convenient to be prescribed for carrying out or giving effect to the Act. Without limiting that general power, it is specifically provided that regulations may be made requiring a person to comply with codes of practice or guidelines issued under the Act, as in force at a particular time or from time to time.

Clause 194 - Review of operation of Act

The minister is to cause an independent review of the Act to be undertaken as soon as possible after the fourth anniversary of its commencement. A written report is to be given to the minister and tabled in parliament within 12 months of the fourth anniversary of the Act.

"Independent review" means a review undertaken by persons who possess appropriate qualifications to undertake the review and include one or more who are not employed by the State or Commonwealth governments.

Part 13 - Consequential amendments

Clause 195 - *Agricultural and Veterinary Chemicals (Western Australia) Act 1995* amended

The *Gene Technology (Consequential Amendments) Act 2000* of the Commonwealth inserts section 8A into the *Agricultural and Veterinary Chemicals (Administration) Act 1992* of the Commonwealth. That section requires the Australian Pesticides and Veterinary Medicines Authority to consult with the Regulator in relation to agricultural and veterinary chemical products containing GM products. This amendment to the WA Act ensures that this provision applies in relation to the WA agricultural and veterinary chemicals legislation.