AUSTRALIA

GENE TECHNOLOGY ACT OF 2000*

PART 1. PRELIMINARY

1. *Short title [see footnote]*

This Act may be cited as the Gene Technology Act 2000.

2. *Commencement [see footnnote]*

1) Sections 1 and 2 of this Act commence on the day on which this Act receives the Royal Assent.

2) Subject to subsection 3), the other provisions of this Act commence on a day or days to be fixed by Proclamation.

3) If a provision of this Act does not commence under subsection 2) within 6 months after the day on which this Act receives the Royal Assent, it commences on the first day after the end of that period.

3. *Object of Act*

The object of this 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 GMOs.

4. *Regulatory Framework to Achieve Object*

The object of this Act is to be achieved through a regulatory framework which:

(aa) Provides 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.

(a) Provides an efficient and effective system for the application of gene technologies.

(b) Operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products.

Note: Examples of the schemes mentioned in paragraph (b) are those that regulate food, agricultural and veterinary chemicals, industrial chemicals and therapeutic goods.

5. *Nationally Consistent Scheme*

It is the intention of the Parliament that this Act form a component of a nationally consistent scheme for the regulation of certain dealings with GMOs by the Commonwealth and the States.

* Act to Regulate Activities Involving Gene Technology, and for Related Purposes of 2000.

6. *Act to Bind the Crown*

1) This Act binds the Crown in each of its capacities.

2) Nothing in this Act renders the Crown liable to be prosecuted for an offence.

7. *External Territories*

This Act extends to every external Territory other than Norfolk Island.

8. *Offences*

(1) Chapter 2 of the Criminal Code applies to all offences against this Act.

Note: Chapter 2 of the Criminal Code sets out the general principles of criminal responsibility.

(2) If a maximum penalty is specified:

(a) At the foot of a section of this Act (other than a section that is divided into subsections); or

(b) At the foot of a subsection of this Act; then:

(c) A person who contravenes the section or subsection is guilty of an offence punishable, on conviction, by a penalty not exceeding the specified penalty.

(d) The offence referred to in the section or subsection is punishable, on conviction, by a penalty not exceeding the specified penalty.

PART 2 . INTERPRETATION AND OPERATION OF ACT

Division 1. Simplified Outline

9. *Simplified Outline*

The following is a simplified outline of this Part.

This Part contains the definitions used in this Act.

This Part contains provisions to facilitate the conferral of functions and powers on the Regulator under State legislation, in order to facilitate a nationally consistent regulatory scheme.

This Part contains provisions to enable the concurrent operation of certain State legislation in relation to GMOs, and gives the capacity for this Act to have a more limited operation when corresponding State legislation is in force.

This Part also enables the Ministerial Council to issue policy principles, policy guidelines and codes of practice.

Division 2. Definitions

10. *Definitions*

(1) In this Act, unless the contrary intention appears:

Account means the Gene Technology Account established by section 129.

Accredited organisation means an organisation accredited under Division 3 of Part 7.

Aggravated offence has the meaning given by section 38.

Australian Health Ethics Committee means the Australian Health Ethics Committee established under the National Health and Medical Research Council Act 1992.

Commonwealth authority means the following:

(a) A body corporate established for a public purpose by or under an Act.

(b) A company in which a controlling interest is held by any one of the

following persons, or by 2 or more of the following persons together:

(i) The Commonwealth.

(ii) A body covered by paragraph (a).

(iii) A body covered by either of the above subparagraphs.

Confidential commercial information means information declared by the Regulator to be confidential commercial information under section 185.

Consultative Committee means the Gene Technology Community Consultative Committee established by section 106.

Containment level, in relation to a facility, means the degree of physical confinement of GMOs provided by the facility, having regard to the design of the facility, the equipment located or installed in the facility and the procedures generally used within the facility.

Corresponding State law has the meaning given by section 12.

Deal with, in relation to a GMO, means the following:

(a) Conduct experiments with the GMO.

(b) Make, develop, produce or manufacture the GMO.

(c) Breed the GMO.

(d) Propagate the GMO.

(e) Use the GMO in the course of manufacture of a thing that is not the GMO.

(f) Grow, raise or culture the GMO.

(g) Import the GMO; and 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).

Eligible person, in relation to a reviewable decision, has the meaning given by section 179.

Environment includes:

(a) Ecosystems and their constituent parts.

(b) Natural and physical resources; and

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

Environment Minister means the Minister responsible for environment and conservation.

Ethics Committee means the Gene Technology Ethics Committee established by section 111.

Evidential material means any of the following:

(a) A thing with respect to which an offence against this Act or the regulations has been committed or is suspected, on reasonable grounds, to have been committed.

(b) A thing that there are reasonable grounds for suspecting will afford evidence as to the commission of any such offence.

(c) A thing that there are reasonable grounds for suspecting is intended to be used for the purpose of committing any such offence.

Facility includes, but is not limited to, the following:

(a) A building or part of a building;

(b) A laboratory.

(c) An aviary.

(d) A glasshouse.

(e) An insectary.

(f) An animal house.

(g) An aquarium or tank.

Gene technology means any technique for the modification of genes or other genetic material, but does not include:

(a) Sexual reproduction.

(b) Homologous recombination; or

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

Gene Technology Agreement means the Gene Technology Agreement made for the purposes of this Act between the Commonwealth and at least 4 States, as in force from time to time.

Gene Technology Technical Advisory Committee means the Gene Technology Technical Advisory Committee established by section 100.

Genetically modified organism means:

(a) An organism that has been modified by gene technology.

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

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

But does not include:

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

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

GMO means a genetically modified organism.

GMO licence means a licence issued under section 55.

GMO Register means the GMO Register established by section 76.

GM product means a thing (other than a GMO) derived or produced from a GMO.

Higher education institution means an institution within the meaning of section 4 of the Higher Education Funding Act 1988, but does not include the Australian National University.

Institutional Biosafety Committee means a committee established by an accredited organisation as an Institutional Biosafety Committee.

Jurisdiction means the following:

(a) The Commonwealth.

(b) A State.

Licence holder means the holder of a GMO licence.

Ministerial Council means the Ministerial Council within the meaning of the Gene Technology Agreement.

Notifiable low risk dealing has the meaning given by section 74.

Officer, in relation to the Commonwealth, includes the following:

(a) A minister.

(b) A person who holds:

(i) An office established by or under an Act.

(ii) An appointment made under an Act.

(iii) An appointment made by the governor-general or a minister but not under an Act.

(c) A person who is a member or officer of a Commonwealth authority.

(d) A person who is in the service or employment of the Commonwealth or of a Commonwealth authority, or is employed or engaged under an Act.

Organism means any biological entity that is:

(a) Viable.

(b) Capable of reproduction.

(c) Capable of transferring genetic material.

Person covered by a GMO licence means a person authorised by a GMO licence to deal with a GMO.

Premises includes the following:

(a) A building.

(b) A place (including an area of land).

(c) A vehicle.

(d) A vessel.

(e) An aircraft.

(f) A facility.

(g) Any part of premises [including premises referred to in paragraphs (a) to (f)].

Record means the Record of GMO and GM Product Dealings mentioned in section 138.

Regulator means the Gene Technology Regulator appointed under section 118.

Reviewable decision has the meaning given by section 179.

State includes the Australian Capital Territory and the Northern Territory.

State agency means the following:

(a) The Crown in right of a State.

(b) A minister of a State.

(c) A State Government Department.

(d) An instrumentality of a State, including a body corporate established for a public purpose by or under a law of a State.

(e) A company in which a controlling interest is held by any one of the following persons, or by 2 or more of the following persons together:

(i) The Crown in right of a State.

(ii) A person or body covered by paragraph (b) or (d).

(iii) A person or body covered by either of the above subparagraphs.

Thing includes a substance, and a thing in electronic or magnetic form.

(2) If this Act requires or permits the Ministerial Council to do a thing, the Ministerial Council must do the thing in accordance with any requirements specified in the Gene Technology Agreement.

11. *Meaning of Intentional Release of a GMO into the Environment*

For the purposes of this Act, 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.

12. *Meaning of Corresponding State Law*

(1) For the purposes of this Act, corresponding State law means a State law that is declared by the minister, by notice in the Gazette, to correspond to this Act and the regulations, including such a law as amended from time to time.

(2) The minister may revoke a Gazette notice under subsection (1) in relation to a State law only if:

(a) The minister is requested by the State concerned to revoke the notice.

(b) The State law has been amended otherwise than as agreed by a majority of the members of the Ministerial Council (being a majority that includes the Commonwealth) under the Gene Technology Agreement.

(c) Amendments of the State law have been agreed by a majority of the members of the Ministerial Council (being a majority that includes the Commonwealth) under the Gene Technology Agreement, and the State law has not been amended in accordance with that agreement within a reasonable period after the agreement.

Division 3. Operation of Act

13. *Operation of Act*

(1) This Act applies as follows:

(a) To things done, or omitted to be done, by constitutional corporations.

(b) To things done, or omitted to be done, in the course of constitutional trade or commerce.

(c) To things done, or omitted to be done, by a person that may cause the spread of diseases or pests.

(d) For purposes relating to the collection, compilation, analysis and dissemination of statistics.

(e) To the Commonwealth and Commonwealth authorities.

(f) To things authorised by the legislative power of the Commonwealth under paragraph 51(xxxix) of the Constitution, so far as it relates to the matters mentioned in paragraphs (a) to (e) of this subsection.

(2) In this section:

Constitutional corporation means a trading, foreign or financial corporation within the meaning of paragraph 51(xx) of the Constitution.

Constitutional trade or commerce means trade or commerce:

(a) Between Australia and places outside Australia.

(b) Among the States.

(c) By way of the supply of services to the Commonwealth or to a Commonwealth authority.

14. *Wind-back of Reach of Act*

(1) This section applies to a State (the notifying State) at a particular time if:

(a) A corresponding State law is in force in the notifying State at that time; and

(b) A wind-back notice in relation to that State is in force at that time.

(2) This Act applies as a law of the Commonwealth in the notifying State with the following modifications:

(a) This Act applies as if paragraph 13(1) (c) (which deals with the spread of pests and diseases) had not been enacted.

(b) This Act does not apply to a dealing with a GMO undertaken:

(i) By a higher education institution or a State agency.

(ii) By a person authorised to undertake the dealing by a licence held under the corresponding State law by a higher education institution or a State agency.

(3) In this section:

Wind-back notice, in relation to a State, means a notice given by the State to the minister, under the Gene Technology Agreement, stating that this section is to apply to the State.

15. *Relationship to other Commonwealth Laws*

The provisions of this Act are in addition to, and not in substitution for, the requirements of any other law of the Commonwealth (whether pas-

sed or made before or after the commencement of this section).

Division 4. Provisions to Facilitate a Nationally Consistent Scheme

Subdivision A. General Provisions

16. *State laws may operate concurrently*

(1) This Act is not intended to exclude the operation of any State law, to the extent that the State law is capable of operating concurrently with this Act, other than a State law prescribed by the regulations for the purposes of this section.

(2) The governor-general may prescribe a State law under subsection (1) only if:

(a) There is no corresponding State law in effect in relation to that State; and

(b) Either:

(i) The State law relates specifically to dealings with GMOs; or

(ii) For the purposes of a decision under the State law as to whether or not a licence, authority or approval (however described) is granted under the State law, the State law distinguishes between dealings with GMOs and dealings with other things.

17. *Conferral of Functions on Commonwealth Officers and Bodies*

(1) A corresponding State law may confer functions, powers and duties on the following:

(a) The Regulator or another officer of the Commonwealth.

(b) A Commonwealth authority.

(c) The Consultative Committee.

(d) The Ethics Committee.

(e) The Gene Technology Technical Advisory Committee.

(2) If a function, power or duty is conferred on a person or body under subsection (1), the person or body may perform the function or duty or exercise the power, as the case requires.

(3) If a corresponding State law is expressed to confer on the Regulator the power to determine that dealings be included on the GMO Register, the Regulator may include the dealings on the GMO Register in accordance with the corresponding State law.

(4) If a corresponding State law is expressed to confer on the Regulator the power to vary the GMO Register, the Regulator may vary the GMO Register in accordance with the corresponding State law.

(5) If a corresponding State law is expressed to confer on the Regulator the power to enter information on the Record of GMO and GM Product Dealings, the Regulator may enter the information on the Record in accordance with the corresponding State law.

(6) The Regulator may:

(a) Make any notations in the GMO Register that the Regulator considers necessary to identify entries that relate to dealings included on the Register as mentioned in subsection (3) or (4); and

(b) Make any notations in the Record of GMO and GM Product Dealings that the Regulator considers necessary to identify entries that relate to information entered on the Record as mentioned in subsection (5).

18. *No doubling-up of Liabilities*

(1) If:

(a) An act or omission is an offence against this Act and is also an offence against a corresponding State law; and

(b) The offender has been punished for the offence under the corresponding State law; the offender is not liable to be punished for the offence under this Act.

(2) If a person has been ordered to pay a pecuniary penalty under a corresponding State law, the person is not liable to a pecuniary penalty under this Act in respect of the same conduct.

19. *Review of Certain Decisions*

(1) Application may be made to the Administrative Appeals Tribunal for review of a reviewable State decision.

(2) A decision made by the Regulator in the performance of a function or the exercise of a power conferred by a corresponding State law is a reviewable State decision for the purposes of this section if:

(a) The law under which the decision was made provides for review by the Administrative Appeals Tribunal; and

(b) The decision is declared by the regulations to be a reviewable State decision for the purposes of this section.

(3) For the purposes of this section, the Administrative Appeals Tribunal Act 1975 has effect as if a corresponding State law were an enactment.

20. *Things Done for Multiple Purposes*

The validity of a licence, certificate or other thing issued, given or done for the purposes of this Act is not affected only because it was issued, given or done also for the purposes of a corresponding State law.

Subdivision B. Policy Principles, Policy Guidelines and Codes of Practice

21. *Ministerial Council May Issue Policy Principles*

(1) The Ministerial Council may issue policy principles in relation to the following:

(a) Ethical issues relating to dealings with GMOs.

(aa) recognising areas, if any, designated under State law for the purpose of preserving the identity of one or both of the following:

(i) GM crops.

(ii) Non-GM crops.

for marketing purposes.

(b) Matters relating to dealings with GMOs prescribed by the regulations for the purposes of this paragraph.

Note 1: Section 57 provides that the Regulator must not issue a licence if to do so would be inconsistent with a policy principle.

Note 2: Subsection 33(3) of the Acts Interpretation Act 1901 confers power to revoke or amend an instrument issued under an Act.

(2) Before issuing a policy principle, the Ministerial Council must be satisfied that the policy principle was developed in accordance with section 22.

(3) Regulations for the purposes of paragraph (1)(b) may relate to matters other than the health and safety of people or the environment, but must

not derogate from the health and safety of people or the environment.

(4) Policy principles are disallowable instruments for the purposes of section 46A of the Acts Interpretation Act 1901.

22. *Consultation on Policy Principles*

(1) Policy principles are to be developed in consultation with the following:

(a) The Gene Technology Technical Advisory Committee.

(b) The Regulator.

(c) The Consultative Committee.

(d) The Ethics Committee.

(e) Such Commonwealth and State agencies and such regulatory agencies as the Ministerial Council considers appropriate.

(f) Such industry groups as the Ministerial Council considers appropriate;

(g) Such environmental, consumer and other groups as the Ministerial Council considers appropriate.

(2) Consultation under subsection (1) must be in accordance with guidelines (if any) issued by the Ministerial Council for the purposes of this section.

23. *Ministerial Council May Issue Policy Guidelines*

The Ministerial Council may issue policy guidelines in relation to matters relevant to the functions of the Regulator.

Note 1: Section 56 requires the Regulator to have regard to policy guidelines when deciding an application for a GMO licence. Section 30 provides that the Regulator is not subject to direction in relation to individual decisions.

Note 2: Subsection 33(3) of the Acts Interpretation Act 1901 confers power to revoke or amend an instrument issued under an Act.

24. *Ministerial Council May Issue Codes of Practice*

(1) The Ministerial Council may issue codes of practice in relation to gene technology.

Note: Subsection 33(3) of the Acts Interpretation Act 1901 confers power to revoke or amend an instrument issued under an Act.

(2)The Ministerial Council must not issue a code of practice unless the code of practice was developed by the Regulator in consultation with the following:

(a) The Gene Technology Technical Advisory Committee.

(b) The Consultative Committee.

(c) The Ethics Committee.

(d) Such Commonwealth and State agencies and such regulatory agencies as the Ministerial Council considers appropriate.

(e) Such industry groups as the Ministerial Council considers appropriate.

(f) Such environmental, consumer and other groups as the Ministerial Council considers appropriate.

(3) Codes of practice are disallowable instruments for the purposes of section 46A of the *Acts Interpretation Act 1901*.

PART 3. THE GENE TECHNOLOGY REGULATOR

25. *Simplified Outline*

The following is a simplified outline of this Part:

This Part establishes the office of the Gene Technology Regulator (the *Regulator*), and specifies the Regulator's functions and powers.

26. *The Gene Technology Regulator*

There is to be a Gene Technology Regulator.

27. *Functions of the Regulator*

The Regulator has the following functions:

(a) To perform functions in relation to GMO licences as set out in Part 5.

(b) To develop draft policy principles and policy guidelines, as requested by the Ministerial Council.

(c) To develop codes of practice.

(d) To issue technical and procedural guidelines in relation to GMOs.

(e) To provide information and advice to other regulatory agencies about GMOs and GM products.

(f) To provide information and advice to the public about the regulation of GMOs.

(g) To provide advice to the Ministerial Council about:

(i) The operations of the Regulator and the Gene Technology Technical Advisory Committee; and

(ii) The effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation.

(h) To undertake or commission research in relation to risk assessment and the biosafety of GMOs.

(i) To promote the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies.

(j) To monitor international practice in relation to the regulation of GMOs.

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

(l) Such other functions as are conferred on the Regulator by this Act, the regulations or any other law.

28. *Powers of the Regulator*

Subject to this Act, the Regulator has power to do all things necessary or convenient to be done for or in connection with the performance of the Regulator's functions.

29. *Delegation*

(1) The Regulator may, by instrument in writing, delegate any of the Regulator's powers or functions to any of the following:

(a) An employee of the Department.

(b) An employee of another Department or of a Commonwealth authority, if the functions of the other Department or Commonwealth authority relate, whether directly or indirectly, to GMOs or GM products.

(c) An officer or employee of a State agency, if the functions of the State agency relate, whether directly or indirectly, to GMOs or GM products.

(2) In exercising powers or functions under a delegation, the delegate must comply with any directions of the Regulator.

30. *Independence of the Regulator*

Subject to this Act and to other laws of the Commonwealth, the Regulator has discretion in the performance or exercise of his or her functions or powers. In particular, the Regulator is not subject to direction from anyone in relation to:

(a) Whether or not a particular application for a GMO licence is issued or refused; or

(b) The conditions to which a particular GMO licence is subject.

PART 4. REGULATION OF DEALINGS WITH GMOS

Division 1. Simplified Outline

31. *Simplified Outline*

The following is a simplified outline of this Part:

This Part deals with the regulation of dealings with GMOs.

This Part prohibits dealings with GMOs unless:

(a) The person undertaking the dealing is authorised to do so by a GMO licence; or

(b) The dealing is a notifiable low risk dealing (see Division 2 of Part 6).

(c) The dealing is an exempt dealing; or

(d) The dealing is included in the GMO Register (see Division 3 of Part 6).

This Part imposes heavier penalties on unlawful dealings that cause, or are likely to cause, significant damage to the health and safety of people or to the environment.

Division 2. Dealings with GMOs Must Be Licensed

32. *Person not to Deal with a GMO without a Licence*

(1) A person is guilty of an offence if:

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

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

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

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

(e) The person knows that the dealing is not included on the GMO Register or is reckless as to whether or not the dealing is included on the GMO Register.

Note: Chapter 2 of the Criminal Code sets out the general principles of criminal responsibility.

(2) An offence under subsection (1) is punishable on conviction by whichever of the following applies:

(a) In the case of an aggravated offence-imprisonment for 5 years or 2,000 penalty units.

(b) In any other case-imprisonment for 2 years or 500 penalty units.

Note: Section 38 defines *aggravated offence*.

(3) In this section:

Exempt dealing means a dealing specified by the regulations to be an exempt dealing.

(4) Regulations under subsection (3) may be expressed to exempt:

(a) All dealings with a GMO or with a specified class of GMOs; or

(b) A specified class of dealings with a GMO or with a specified class of GMOs; or

(c) One or more specified dealings with a GMO or with a specified class of GMOs.

33. *Person Not to Deal with a GMO without a Licence Strict Liability Offence*

(1) A person is guilty of an offence if:

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

(b) The dealing with the GMO by the person is not authorised by a GMO licence; and

(c) The dealing is not a notifiable low risk dealing; and

(d) The dealing is not an exempt dealing; and

(e) The dealing is not included on the GMO Register.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

(2) Strict liability applies to paragraphs (1) (b), (c), (d) and (e).

Note: For *strict liability*, see section 6.1 of the *Criminal Code*.

(3) An offence under this section is punishable on conviction by a fine of not more than whichever of the following amounts applies:

(a) In the case of an aggravated offence-200 penalty units.

(b) In any other case—50 penalty units.

Note: Section 38 defines *aggravated offence*.

(4) In this section:

Exempt dealing has the same meaning as in section 32.

34. *Person Must not Breach Conditions of a GMO Licence*

(1) The holder of a GMO licence is guilty of an offence if the holder:

(a) Intentionally takes an action or omits to take an action.

(b) Knows that the action or omission contravenes the licence or is reckless as to whether or not the action or omission contravenes the licence.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

(2) A person covered by a GMO licence is guilty of an offence if:

(a) The person intentionally takes an action or omits to take an action; and

(b) The person knows that the action or omission contravenes the licence or is reckless as to whether or not the action or omission contravenes the licence; and

(c) The person has knowledge of the conditions of the licence.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

(3) An offence under this section is punishable on conviction by whichever of the following applies:

(a) In the case of an aggravated offence-imprisonment for 5 years or 2,000 penalty units.

(b) In any other case-imprisonment for 2 years or 500 penalty units.

Note: Section 38 defines *aggravated offence*.

(4) A person who is guilty of an offence under subsection (1) or (2) is guilty of a separate offence in respect of each day (including the day of a conviction for the offence or any later day) on which the person is guilty of the offence.

35. *Person Must not Breach Conditions of a GMO Licence - Strict Liability Offence*

(1) The holder of a GMO licence is guilty of an offence if the holder:

(a) Takes an action or omits to take an action.

(b) The action or omission contravenes the licence.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

(2) A person covered by a GMO licence is guilty of an offence if:

(a) The person takes an action or omits to take an action.

(b) The action or omission contravenes the licence.

(c) The person has knowledge of the conditions of the licence.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

(3) Strict liability applies to paragraphs (1) (a) and (b) and (2) (a) and (b).

Note: For strict liability, see section 6.1 of the *Criminal Code*.

(4) An offence under this section is punishable on conviction by a fine of not more than whichever of the following amounts applies:

(a) In the case of an aggravated offence 200 penalty units.

(b) In any other case-50 penalty units.

Note: Section 38 defines aggravated offence.

36. *Person Must not Breach Conditions on GMO Register*

(1) A person is guilty of an offence if the person:

(a) Deals with a GMO, knowing that it is a GMO; and

(b) The dealing is on the GMO Register; and

(c) The dealing contravenes a condition relating to the dealing that is specified in the GMO Register.

Maximum penalty: 50 penalty units.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

(2) Strict liability applies to paragraphs (1) (b) and (c).

37. *Offence Relating to Notifiable Low Risk Dealings*

(1) A person is guilty of an offence if:

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

(b) The dealing is a notifiable low risk dealing; and

(c) The dealing by the person was not undertaken in accordance with the regulations.

Maximum penalty: 50 penalty units.

Note 1: Notifiable low risk dealings are specified in the regulations - see Part 6.

Note 2: Chapter 2 of the Criminal Code sets out the general principles of criminal responsibility.

(2) Strict liability applies to paragraphs (1) (b) and (c).

38. *Aggravated offences-Significant Damage to Health or Safety of People or to the Environment*

(1) An offence is an aggravated offence if the commission of the offence causes significant damage, or is likely to cause significant damage, to the health and safety of people or to the environment.

(2) In order to prove an aggravated offence, the prosecution must prove that the person who committed the offence:

(a) Intended his or her conduct to cause significant damage to the health and safety of people or to the environment.

(b) Was reckless as to whether that conduct would cause significant damage to the health and safety of people or to the environment.

PART 5. LICENSING SYSTEM

Division 1. Simplified Outline

39. *Simplified Outline*

The following is a simplified outline of this Part:

This Part provides a licensing system under which a person can apply to the Regulator for a licence authorising dealings with GMOs.

This Part sets out the processes to be followed by the Regulator in relation to applications involving 2 kinds of dealings:

(a) Those that involve the intentional release of a GMO into the environment; and

(b) Those that do not involve the intentional release of a GMO into the environment.

A licence can cover dealings by persons other than the licence holder. The licence holder is required to inform such persons of any conditions of the licence that apply to them.

Division 2. Licence Applications

40. *Person May Apply for a Licence*

(1) A person may apply to the Regulator for a licence authorising specified dealings with one or more specified GMOs by a person or persons.

(2) The application must be in writing, and must contain:

(a) Such information as is prescribed by the regulations (if any); and

(b) Such information as is specified in writing by the Regulator.

(3) The application must specify whether any of the dealings proposed to be authorised by the licence would involve the intentional release of a GMO into the environment.

(4) The dealings in respect of which a person may apply for a licence may be:

(a) All dealings with a GMO, or with a specified class of GMOs; or

(b) A specified class of dealings with a GMO, or with a specified class of GMOs.

(c) One or more specified dealings with a GMO, or with a specified class of GMOs.

(5) The applicant may apply for a licence authorising such dealings by:

(a) A specified person or persons; or

(b) A specified class of person; or

(c) All persons.

(6) The application must be accompanied by the application fee (if any) prescribed by the regulations.

41. *Application may be Withdrawn*

(1) The applicant may withdraw the application at any time before the licence is issued.

(2) The application fee is not refundable if the applicant withdraws the application.

42. *Regulator may Require Applicant to Give Further Information*

(1) The Regulator may, by notice in writing, require an applicant for a licence to give the Regulator such further information in relation to the application as the Regulator requires.

(2) The notice may specify the period within which the information is to be provided.

43. *Regulator Must Consider Applications Except in Certain Circumstances*

(1) The Regulator must consider an application under section 40 for a licence in accordance with this Part.

(2) However, the Regulator is not required to consider the application if:

(a) The application does not contain the information specified by the Regulator or prescribed by the regulations.

(b) The application does not satisfy subsection 40(3).

(c) The application is not accompanied by the application fee (if any) prescribed by the regulations; or

(d) The applicant did not provide further information required by the Regulator by notice under section 42 within the period specified in the notice.

(e) The Regulator is satisfied that to issue the licence would be inconsistent with a policy principle in force under section 21.

(3) The Regulator must issue the licence, or refuse to issue the licence, within the period (if any) prescribed by the regulations.

44. *Regulator May Consult with Applicant*

Before considering an application in accordance with the requirements of this Part, the Regulator may consult the applicant, or another regulatory agency, on any aspect of the application.

45. *Regulator Must Not Use Certain Information in Considering Licence Application*

If:

(a) A person (the first person) applies for a GMO licence; and

(b) The first person provides information to the Regulator for the purposes of the Regulator's consideration of the application; and

(c) The information is confidential commercial information; the Regulator must not take that information into account for the purposes of considering an application by another person for a GMO licence, unless the first person has given written consent for the information to be so taken into account.

Division 3. Initial Consideration of licences for Dealings not Involving Intentional Release of a GMO into the Environment

46. *Applications to which this Division Applies*

This Division applies to an application for a GMO licence if 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.

47. *What the Regulator Must Do in Relation to Application*

(1) Before issuing the licence, the Regulator must prepare a risk assessment and a risk management plan in relation to the dealings proposed to be authorised by the licence.

(2) In preparing the risk assessment, the Regulator must take into account the risks posed by the dealings proposed to be authorised by the licence, including any risks to the health and safety of people or risks to the environment.

(3) In preparing the risk management plan, the Regulator must take into account the means of managing any risks posed by the dealings proposed to be authorised by the licence in such a way as to protect:

(a) The health and safety of people.

(b) The environment.

(4) The Regulator may consult:

(a) The States.

(b) The Gene Technology Technical Advisory Committee.

(c) Relevant Commonwealth authorities or agencies.

(d) Any local council that the Regulator considers appropriate.

(e) Any other person the Regulator considers appropriate; on any aspect of the application.

Division 4. Initial Consideration of licences for Dealings Involving Intentional Release of a GMO into the Environment

48. *Applications to which this Division Applies*

This Division applies to an application for a GMO licence if the Regulator is satisfied that at least one of the dealings proposed to be authorised by the licence would involve the intentional release of a GMO into the environment.

49. *Dealings that may Pose Significant risks to the Health and Safety of People or the Environment*

(1) If the Regulator is satisfied that 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 to the environment, the Regulator must publish a notice in respect of the application:

(a) In the Gazette.

(b) In a newspaper circulating generally in all States.

(c) On the Regulator's website (if any).

(2) For the purpose of satisfying himself or herself as to whether the dealings proposed to be authorised by the licence may pose significant risks to the health and safety of people or

to the environment, the Regulator must have regard to the following:

(a) The properties of the organism to which the dealings relate before it became, or will become, a GMO.

(b) The effect, or the expected effect, of genetic modification that has occurred, or will occur, on the properties of the organism.

(c) Provisions for limiting the dissemination or persistence of the GMO or its genetic material in the environment;

(d) The potential for spread or persistence of the GMO or its genetic material in the environment.

(e) The extent or scale of the proposed dealings.

(f) Any likely impacts of the proposed dealings on the health and safety of people.

(g) Any other matter prescribed by the regulations for the purposes of this paragraph.

(3) The notice mentioned in subsection (1) must:

(a) State that the application has been made.

(b) State that a person may request further information about the application under section 54.

(c) Invite written submissions on whether the licence should be issued, being submissions about matters that the Regulator is required to take into account:

(i) Under paragraph 51(1) (a) in preparing a risk assessment in relation to the dealings proposed to be authorised by the licence; and

(ii) Under paragraph 51(2) (a) in preparing a risk management plan in relation to those dealings.

(d) Specify the closing date for submissions, which must not be earlier than 30 days after the date on which the notice was published.

50. *Regulator must Prepare Risk Assessment and Risk Management Plan*

(1) Before issuing the licence, the Regulator must prepare a risk assessment and a risk management plan in relation to the dealings proposed to be authorised by the licence.

(2) The Regulator must prepare a risk assessment and a risk management plan whether or not the Regulator was required to publish a notice in relation to the application under section 49.

(3) The Regulator must seek advice on matters relevant to the preparation of the risk assessment and the risk management plan from:

(a) The States.

(b) The Gene Technology Technical Advisory Committee.

(c) Each Commonwealth authority or agency prescribed by the regulations for the purposes of this paragraph.

(d) The Environment Minister; and

(e) Any local council that the Regulator considers appropriate.

51. *Matters Regulator Must Take into Account in Preparing Risk Assessment and Risk Management Plan*

(1) In preparing the risk assessment in relation to the dealings proposed to be authorised by the licence, the Regulator must take into account the following:

(a) The risks posed by those dealings, including any risks to the health and safety of people or risks to the en-

vironment, having regard to the matters mentioned in paragraphs 49 (2) (a) to (f).

(b) Any submission made under paragraph 49 (3) (c) in relation to such risks.

(c) Any advice in relation to the risk assessment provided by a State or a local council in response to a request under subsection 50 (3).

(d) Any advice in relation to the risk assessment provided by the Gene Technology Technical Advisory Committee in response to a request under subsection 50 (3).

(e) Any advice in relation to the risk assessment provided by a Commonwealth authority or agency in response to a request under subsection 50 (3).

(f) Any advice in relation to the risk assessment provided by the Environment Minister in response to a request under subsection 50 (3).

(g) Any other matter prescribed by the regulations for the purposes of this paragraph.

(2) In preparing the risk management plan, the Regulator must take into account the following:

(a) The means of managing any risks posed by those dealings in such a way as to protect:

(i) The health and safety of people.

(ii) The environment.

(b) Any submission made under paragraph 49 (3) (c) in relation to the means of managing such risks.

(c) Any advice in relation to the risk management plan provided by a State or a local council in response to a request under subsection 50 (3).

(d) Any advice in relation to the risk management plan provided by the Gene Technology Technical Advisory Committee in response to a request under subsection 50 (3).

(e) Any advice in relation to the risk management plan provided by a Commonwealth authority or agency in response to a request under subsection 50 (3).

(f) Any advice in relation to the risk management plan provided by the Environment Minister in response to a request under subsection 50 (3).

(g) Any other matter prescribed by the regulations for the purposes of this paragraph.

(3) For the avoidance of doubt, in taking into account the means of managing risks as mentioned in paragraph (2) (a), the Regulator:

(a) Is not limited to considering submissions or advice mentioned in paragraphs (2) (b), (c), (d), (e) and (f).

(b) Subject to section 45, may take into account other information, including, but not limited to, relevant independent research.

52. *Public Notification of Risk Assessment and Risk Management Plan*

(1) After taking the steps referred to in sections 49 (if applicable), 50 and 51, the Regulator must publish a notice:

(a) In the Gazette.

(b) In a newspaper circulating generally in all States.

(c) On the Regulator's website (if any).

(2) The notice must:

(a) State that a risk assessment and a risk management plan have been

prepared in respect of dealings proposed to be authorised by the licence; and

(b) State that a person may request further information about the risk assessment and the risk management plan under section 54.

(c) Invite written submissions in relation to the risk assessment and the risk management plan.

(d) Specify the closing date for submissions, which must not be earlier than 30 days after the date on which the notice was published.

(3) The Regulator must also seek advice on the risk assessment and the risk management plan from:

(a) The States.

(b) The Gene Technology Technical Advisory Committee.

(c) Each Commonwealth authority or agency prescribed by the regulations for the purposes of this paragraph.

(d) The Environment Minister; and

(e) Any local council that the Regulator considers appropriate.

53. *Regulator May take Other Actions*

(1) In addition to satisfying the requirements of this Division in relation to an application for a licence to which this Division applies, the Regulator may take any other action the Regulator considers appropriate for the purpose of deciding the application, including holding a public hearing.

(2) If the Regulator holds a public hearing, the Regulator may, having regard to the requirements of this Act in relation to confidential commercial information, direct that any part of the hearing be held in private, and may determine who can attend.

(3) The Regulator may give directions prohibiting or restricting the publication of evidence given, or material contained in documents produced, at a public hearing.

(4) A person must not contravene a direction given under subsection (3).

Maximum penalty: 30 penalty units.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

54. *Person may Request Copies of Certain Documents*

(1) A person may request that the Regulator provide the person with a copy of the following documents:

(a) An application to which this Division applies.

(b) A risk assessment or a risk management plan prepared under section 50.

(2) If a person makes a request under subsection (1), the Regulator must provide to the person a copy of the documents, other than:

(a) Any confidential commercial information contained in the documents.

(b) Any information contained in the documents about relevant convictions (within the meaning of section 58) of the applicant for the licence.

Note 1: In order for information to be confidential commercial information, it must be covered by a declaration under section 185.

Note 2: The Privacy Act 1988 also contains provisions relevant to the disclosure of information.

Division 5. Decision on Licence Etcetera

55. *Regulator Must Make a Decision on Licence and Licence Conditions*

After taking any steps required by Division 3 or 4 of this Part in relation to an application for a GMO licence, the Regulator:

(a) Must decide whether to issue or refuse to issue the licence.

(b) If the Regulator decides to issue the licence may impose conditions to which the licence is subject.

56. *Regulator Must Not Issue the Licence unless Satisfied as to Risk Management*

(1) The Regulator must not issue the licence unless the Regulator is satisfied that any risks posed by the dealings proposed to be authorised by the licence are able to be managed in such a way as to protect:

(a) The health and safety of people.

(b) The environment.

(2) For the purposes of subsection (1), the Regulator must have regard to the following:

(a) If a risk assessment has been prepared under section 50 in relation to those dealings the risk assessment.

(b) If a risk management plan has been prepared under section 50 in relation to those dealings the risk management plan.

(c) Any submissions received under section 52 in relation to the licence.

(d) Any policy guidelines in force under section 23 that relate to:

(i) Risks that may be posed by the dealings proposed to be authorised by the licence.

(ii) Ways of managing such risks so as to protect the health and safety of people or to protect the environment.

57. *Other Circumstances in which Regulator must not Issue the Licence*

(1) The Regulator must not issue the licence if the Regulator is satisfied that issuing the licence would be inconsistent with a policy principle in force under section 21.

(2) The Regulator must not issue the licence unless the Regulator is satisfied that the applicant is a suitable person to hold the licence.

58. *Matters to be Taken into Account in Deciding Whether a Person is Suitable to Hold a Licence*

(1) Without limiting the matters to which the Regulator may have regard in deciding whether a natural person is a suitable person to hold a licence, the Regulator must have regard to:

(a) Any relevant conviction of the person.

(b) Any revocation or suspension of a licence or permit (however described) held by the person under a law of the Commonwealth, a State or a foreign country, being a law relating to the health and safety of people or the environment.

(c) The capacity of the person to meet the conditions of the licence.

(2) Without limiting the matters to which the Regulator may have regard in deciding whether a body corporate is a suitable person to hold a licence, the Regulator must have regard to the following:

(a) Any relevant conviction of the body corporate.

(b) If there is a relevant conviction of the body corporate:

(i) Whether the offence concerned was committed at a time when any person who is presently a director of the body corporate was a director.

(ii) Whether that offence was committed at a time when any officer or shareholder of the body corporate who is presently in a position to influence the management of the body corporate was such an officer or shareholder; and

(c) any revocation or suspension of a licence or permit (however described) held by the body corporate under a law of the Commonwealth, a State or a foreign country, being a law relating to the health and safety of people or the environment.

(d) The capacity of the body corporate to meet the conditions of the licence.

(3) In this section:

Relevant conviction means a conviction for an offence against a law of the Commonwealth, a State or a foreign country, being a law relating to the health and safety of people or the environment, if:

(a) The offence was committed within the period of 10 years immediately before the making of the application for the licence.

(b) The offence was punishable on conviction by a fine of $5,000 or more, or by a term of imprisonment of one year or more.

(4) Nothing in this section affects the operation of Part VIIC of the Crimes Act 1914 (which includes provisions that, in certain circumstances, relieve persons from the requirement to disclose spent convictions and require persons aware of such convictions to disregard them).

59. *Notification of Licence Decision*

The Regulator must notify the applicant in writing of the Regulator's decision (including any conditions imposed by the Regulator, if applicable).

60. *Period of Licence*

(1) A licence continues in force:

(a) If the licence is expressed to be in force for a particular period until the end of that period.

(b) Otherwise-until it is cancelled or surrendered.

(2) A licence is not in force throughout any period of suspension.

Division 6. Conditions of Licences

61. *Licence is Subject to Conditions*

A GMO licence is subject to the following conditions:

(a) The conditions set out in sections 63, 64 and 65.

(b) Any conditions prescribed by the regulations.

(c) Any conditions imposed by the Regulator at the time of issuing the licence.

(d) Any conditions imposed by the Regulator under section 71 after the licence is issued.

62. *Conditions that May be Prescribed or Imposed*

(1) Licence conditions may include conditions that impose obligations in relation to GM products that are deri-

ved from a GMO in respect of which particular dealings are licensed.

(2) Licence conditions may relate to, but are not limited to, the following:

(a) The scope of the dealings authorised by the licence.

(b) The purposes for which the dealings may be undertaken.

(c) Variations to the scope or purposes of the dealings.

(d) Documentation and record-keeping requirements.

(e) The required level of containment in respect of the dealings, including requirements relating to the certification of facilities to specified containment levels.

(f) Waste disposal requirements.

(g) Measures to manage risks posed to the health and safety of people, or to the environment.

(h) Data collection, including studies to be conducted.

(i) Auditing and reporting.

(j) Actions to be taken in case of the release of a GMO from a contained environment.

(k) The geographic area in which the dealings authorised by the licence may occur.

(l) Requiring compliance with a code of practice issued under section 24, or a technical or procedural guideline issued under section 27.

(m) Supervision by, and monitoring by, Institutional Biosafety Committees.

(n) Contingency planning in respect of unintended effects of the dealings authorised by the licence.

(o) Limiting the dissemination or persistence of the GMO or its genetic material in the environment.

(3) Licence conditions may also include conditions requiring the licence 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.

63. *Condition about Informing People of Obligations*

(1) It is a condition of a licence that the licence holder inform any person covered by the licence, to whom a particular condition of the licence applies, of the following:

(a) The particular condition, including any variations of it.

(b) The cancellation or suspension of the licence.

(c) The surrender of the licence.

(2) Requirements in relation to the manner in which information is provided under subsection (1) may be:

(a) Prescribed by the regulations; or

(b) Specified by the Regulator.

(3) Such requirements may include, but are not limited to, measures relating to labelling, packaging, conducting training and providing information.

(4) If such requirements are prescribed or specified, it is a condition of a licence that the licence holder comply with the requirements.

64. *Condition about Monitoring and Audits*

(1) It is a condition of a licence that if:

(a) A person is authorised by the licence to deal with a GMO.

(b) A particular condition of the licence applies to the dealing by the person; the person must allow the Regulator, or a person authorised by the

Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

(2) Subsection (1) does not limit the conditions that may be imposed by the Regulator or prescribed by the regulations.

65. *Condition about Additional Information to be Given to the Regulator*

(1) It is a condition of a licence that the licence holder informs the Regulator if he or she:

(a) 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.

(b) Becomes aware of any contraventions of the licence by a person covered by the licence.

(c) Becomes aware of any unintended effects of the dealings authorised by the licence.

(2) For the purposes of subsection (1):

(a) The licence holder is taken to have become aware of additional information of a kind mentioned in subsection (1) if he or she was reckless as to whether such information existed; and

(b) The licence holder is taken to have become aware of contraventions, or unintended effects, of a kind mentioned in subsection (1) if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.

66. *Person may Give Information to Regulator*

A person covered by a licence may inform the Regulator if he or she:

(a) 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.

(b) Becomes aware of any contraventions of the licence by a person covered by the licence; or

(c) Becomes aware of any unintended effects of the dealings authorised by the licence.

67. *Protection of Persons who Give Information*

A person (the first person) does not incur any civil liability in respect of loss, damage or injury of any kind suffered by another person because the first person gave information to the Regulator under section 65 or 66.

Division 7. Suspension, Cancellation and Variation of Licences

68. *Suspension and Cancellation of Licence*

The Regulator may, by notice in writing given to the holder of a GMO licence, suspend or cancel the licence if:

(a) The Regulator believes on reasonable grounds that a condition of the licence has been breached, whether by the licence holder or by a person covered by the licence.

(b) The Regulator believes on reasonable grounds that the licence holder, or a person covered by the licence, has committed an offence against this Act or the regulations.

(c) Any annual charge payable in respect of the licence remains unpaid after the due date.

(d) The licence was obtained improperly.

(e) The Regulator becomes aware of risks associated with the continuation of the dealings authorised by the licence, and is satisfied that the licence holder has not proposed, or is not in a position to implement, adequate measures to deal with those risks.

(f) The Regulator is satisfied that the licence holder is no longer a suitable person to hold the licence.

69. *Surrender of Licence*

The licence holder may, with the consent of the Regulator, surrender the licence.

70. *Transfer of Licences*

(1) The licence holder and another person (the transferee) may jointly apply to the Regulator for the licence to be transferred from the licence holder to the transferee. *[see note 1]*.

(2) The application must be in writing, and must contain:

(a) Such information as is prescribed by the regulations (if any).

(b) Such information as is specified in writing by the Regulator.

(3) The Regulator must not transfer the licence unless the Regulator is satisfied that, if the licence is transferred, any risks posed by the dealings authorised by the licence will continue to be able to be managed in such a way as to protect:

(a) The health and safety of people.

(b) The environment.

(4) The Regulator must not transfer the licence unless the Regulator is satisfied that the transferee is a suitable person to hold the licence.

(5) The Regulator must give written notice of his or her decision on the application to the licence holder and the transferee.

(6) If the Regulator decides to transfer the licence:

(a) The transfer takes effect on the date specified in the notice.

(b) The licence continues in force as mentioned in section 60.

(c) The licence is subject to the same conditions as those in force immediately before the transfer.

71. *Variation of Licence*

(1) The Regulator may, at any time, by notice in writing given to the licence holder, vary a licence.

(2) However, the Regulator must not vary a licence 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 of this Part.

Note: Applications can only be considered under Division 3 if none of the dealings proposed to be authorised by the licence would involve the intentional release of a GMO into the environment.

(3) Without limiting subsection (1), the Regulator may:

(a) Impose licence conditions or additional licence conditions.

(b) Remove or vary licence conditions that were imposed by the Regulator.

(c) Extend or reduce the authority granted by the licence.

(4) However, the Regulator must not vary the licence unless the Regulator is satisfied that any risks posed by the dealings proposed to be autho-

rised by the licence as varied are able to be managed in such a way as to protect:

(a) The health and safety of people; and

(b) The environment.

72. *Regulator to Notify of Proposed Suspension, Cancellation or Variation*

(1) Before suspending, cancelling or varying a licence under this Division, the Regulator must give written notice of the proposed suspension, cancellation or variation to the licence holder.

(2) The notice:

(a) Must state that the Regulator proposes to suspend, cancel or vary the licence.

(b) May require the licence holder to give to the Regulator any information of a kind specified in the notice that is relevant to the proposed suspension, cancellation or variation.

(c) May invite the licence holder to make a written submission to the Regulator about the proposed suspension, cancellation or variation.

(3) The notice must specify a period within which the licence holder:

(a) Must give the information referred to in paragraph (2) (b).

(b) May make a submission under paragraph (2) (c).

The period must not end earlier than 30 days after the day on which the notice was given.

(4) In considering whether to suspend, cancel or vary a licence, the Regulator must have regard to any submission made under paragraph (2) (c).

(5) This section does not apply to a suspension, cancellation or variation requested by the licence holder.

(6) This section does not apply to a suspension, cancellation or variation of a licence if 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.

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

Division 1. Simplified Outline

73. *Simplified Outline*

The following is a simplified outline of this Part:

Division 2 of this Part establishes a mechanism for the regulations to regulate certain dealings with GMOs that do not involve the intentional release of GMOs into the environment (notifiable low risk dealings).

The regulations may (among other things) require that the Regulator be notified of such dealings.

Division 3 of this Part establishes the GMO Register.

The Regulator may determine that certain dealings previously authorised by a licence be included on the GMO Register.

If a dealing is included on the GMO Register, anyone may undertake the dealing, subject to any specified conditions.

Division 2. Notifiable low Risk Dealings

74. *Notifiable Low Risk Dealings*

(1) The regulations may declare a dealing with a GMO to be a notifiable

low risk dealing for the purposes of this Act.

(2) Before the Governor-General makes regulations declaring a dealing with a GMO to be a notifiable low risk dealing, the Regulator must be satisfied that the dealing would not involve the intentional release of a GMO into the environment.

(3) Before the Governor-General makes regulations declaring a dealing with a GMO to be a notifiable low risk dealing, the Regulator must consider the following matters:

(a) Whether the GMO is biologically contained so that it is not able to survive or reproduce without human intervention.

(b) Whether the dealing with the GMO would involve minimal risk to the health and safety of people and to the environment, taking into account the properties of the GMO as a pathogen or pest and the toxicity of any proteins produced by the GMO.

(c) Whether no conditions, or minimal conditions, would be necessary to be prescribed to manage any risk referred to in paragraph (b).

(4) Regulations under subsection (1) may be expressed to apply to:

(a) All dealings with a GMO or with a specified class of GMOs.

(b) A specified class of dealings with a GMO or with a specified class of GMOs.

(c) One or more specified dealings with a GMO or with a specified class of GMOs.

75. *Regulation of Notifiable Low Risk Dealings*

(1) The regulations may regulate:

(a) A specified notifiable low risk dealing; or

(b) A specified class of notifiable low risk dealings; for the purpose of protecting the health and safety of people or the environment.

(2) The regulations may prescribe different requirements to be complied with in different situations or by different persons, including requirements in relation to the following:

(a) The class of persons who may undertake notifiable low risk dealings.

(b) Notifying the Regulator of notifiable low risk dealings.

(c) Supervision by Institutional Biosafety Committees of notifiable low risk dealings.

(d) The containment level of facilities in which notifiable low risk dealings may be undertaken.

Division 3. The GMO Register

76. *GMO Register*

(1) There is to be a Register known as the GMO Register.

(2) The GMO Register is to be maintained by the Regulator.

(3) The GMO Register may be kept in a computerised form.

77. *Contents of Register*

If the Regulator determines under section 78 that a dealing with a GMO is to be included on the GMO Register, the Regulator must specify in the GMO Register:

(a) A description of the dealing with the GMO.

(b) Any condition to which the dealing is subject.

78. *Regulator may Include Dealings with GMOs on GMO Register*

(1) The Regulator may, by writing, determine that a dealing with a GMO is to be included on the GMO Register if the Regulator is satisfied that:

(a) The dealing is, or has been, authorised by a GMO licence.

(b) The GMO concerned:

(i) Is a GM product.

(ii) Is a genetically modified organism only because of regulations made under paragraph (c) of the definition of genetically modified organism.

(2) A determination under subsection (1) may be made:

(a) On application by the holder of a licence that authorises the dealing; or

(b) On the initiative of the Regulator.

(3) A determination under subsection (1) comes into effect on the day specified in the determination. If the determination was made on application by the holder of a GMO licence that authorises the dealing, the day must not be before the licence ceases to be in force.

(4) A determination under subsection (1) is a disallowable instrument for the purposes of section 46A of the Acts Interpretation Act 1901.

79. *Regulator Not to Make Determination Unless Risks can be Managed*

(1) The Regulator must not make a determination under subsection 78(1) in respect of a dealing with a GMO unless the Regulator is satisfied:

(a) That any risks posed by the dealing are minimal.

(b) That it is not necessary for persons undertaking the dealing to hold, or be covered by a GMO licence, in order to protect the health and safety of people or to protect the environment.

(2) For the purposes of subsection (1), the Regulator must have regard to the following:

(a) Any data available to the Regulator about adverse effects posed by the dealing.

(b) Any other information as to risks associated with the dealing of which the Regulator is aware, including information provided to the Regulator by a licence holder under section 65 or by another person under section 66.

(c) Whether there is a need for the dealing to be subject to conditions.

(d) Any other information in relation to whether the dealing should be authorised by a GMO licence.

(3) The Regulator may have regard to such other matters as the Regulator considers relevant.

80. *Variation of GMO Register*

(1) The Regulator may vary the GMO Register by written determination.

(2) A variation may:

(a) Remove a dealing from the GMO Register.

(b) Revoke or vary conditions to which a dealing on the GMO Register is subject.

(c) Impose additional conditions to which a dealing on the GMO Register is subject.

(3) A determination under subsection (1) is a disallowable instrument for the purposes of section 46A of the Acts Interpretation Act 1901.

81. *Inspection of Register*

The Regulator must permit any person to inspect any part of the GMO Register.

PART 7. CERTIFICATION AND ACCREDITATION

Division 1. Simplified Outline

82. *Simplified Outline*

The following is a simplified outline of this Part:

Division 2 of this Part establishes a system under which the Regulator may certify facilities to specified containment levels in accordance with guidelines issued by the Regulator. Licence conditions can require that facilities be certified to specified containment levels.

Division 3 of this Part enables the Regulator to accredit organisations in accordance with accreditation guidelines issued by the Regulator. Licence conditions can specify that dealings must be supervised by an Institutional Biosafety Committee established by an accredited organisation.

Division 2. Certification

83. *Application for Certification*

(1) A person may apply to the Regulator for certification of a facility to a particular containment level under this Division.

(2) The application must be in writing, and must contain such information as the Regulator requires.

Note: The conditions of a licence may require that a facility be certified under this Division.

(3) The application must be accompanied by the application fee (if any) prescribed by the regulations.

84. *When the Regulator May Certify the Facility*

The Regulator may, by written instrument, certify the facility to a specified containment level if the facility meets the containment requirements specified in guidelines issued by the Regulator under section 90.

85. *Regulator may Require Applicant to Give Further Information*

(1) The Regulator may, by notice in writing, require an applicant for certification of a facility to give the Regulator such further information in relation to the application as the Regulator requires.

(2) The notice may specify the period within which the information is to be provided.

86. *Conditions of Certification*

The certification of a facility is subject to the following conditions:

(a) Any conditions imposed by the Regulator at the time of certification.

(b) Any conditions imposed by the Regulator under section 87 after certification.

(c) Any conditions prescribed by the regulations.

87. *Variation of Certification*

(1) The Regulator may, at any time, by notice in writing given to the holder of the certification, vary the certification of a facility.

(2) Without limiting subsection (1), the Regulator may:

(a) Impose additional conditions; or

(b) Remove or vary conditions that were imposed by the Regulator.

88. *Suspension or Cancellation of Certification*

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

89. *Regulator to Notify of Proposed Suspension, Cancellation or Variation*

(1) Before suspending, cancelling or varying a certification under this Division, the Regulator must give written notice of the proposed suspension, cancellation or variation to the holder of the certification.

(2) The notice:

(a) Must state that the Regulator proposes to suspend, cancel or vary the certification.

(b) May require the holder of the certification to give to the Regulator any information of a kind specified in the notice that is relevant to the proposed suspension, cancellation or variation.

(c) May invite the holder of the certification to make a written submission to the Regulator about the proposed suspension, cancellation or variation.

(3) The notice must specify a period within which the holder of the certification:

(a) Must give the information referred to in paragraph (2)(b).

(b) May make a submission under paragraph (2)(c).

The period must not end earlier than 30 days after the day on which the notice was given.

(4) In considering whether to suspend, cancel or vary a certification, the Regulator must have regard to any submission made under paragraph (2)(c).

(5) This section does not apply to a suspension, cancellation or variation requested by the holder of the certification.

(6) This section does not apply to a suspension, cancellation or variation of a certification if 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.

90. *Guidelines*

(1) The Regulator may, by written instrument, issue technical or procedural guidelines about the requirements for the certification of facilities to specified containment levels.

(2) The Regulator may, by written instrument, vary or revoke the guidelines.

Division 3. Accredited Organisations

91. *Application for Accreditation*

(1) A person may apply to the Regulator for accreditation of an organisation as an accredited organisation under this Division.

Note: The conditions of a licence may require supervision of dealings

by an Institutional Biosafety Committee established by an accredited organisation [see paragraph 62(2)(m)], and the regulations may require such supervision of notifiable low risk dealings [see paragraph 75(2)(c)].

(2) The application must be in writing, and must contain such information as the Regulator requires.

92. *Regulator May Accredit Organisations*

(1) The Regulator may, by written instrument, accredit an organisation as an accredited organisation.

(2) In deciding whether to accredit an organisation, the Regulator must have regard to:

(a) Whether the organisation has established, or proposes to establish, an Institutional Biosafety Committee in accordance with written guidelines issued by the Regulator under section 98.

(b) Whether the organisation will be able to maintain an Institutional Biosafety Committee in accordance with such guidelines.

(c) Whether the organisation has, or will have, appropriate indemnity arrangements for its Institutional Biosafety Committee members.

(d) Any other matters specified in such guidelines.

93. *Regulator May Require Applicant to Give Further Information*

(1) The Regulator may, by notice in writing, require an applicant for accreditation of an organisation to give the Regulator such further information in relation to the application as the Regulator requires.

(2) The notice may specify the period within which the information is to be provided.

94. *Conditions of Accreditation*

The accreditation of an accredited organisation is subject to the following conditions:

(a) Any conditions imposed by the Regulator at the time of accreditation.

(b) Any conditions imposed by the Regulator under section 95 after accreditation.

(c) Any conditions prescribed by the regulations.

95. *Variation of Accreditation*

(1) The Regulator may, at any time, by notice in writing given to an accredited organisation, vary the organisation's accreditation.

(2) Without limiting subsection (1), the Regulator may:

(a) Impose additional conditions; or

(b) Remove or vary conditions that were imposed by the Regulator.

96. *Suspension or Cancellation of Accreditation*

The Regulator may, by notice in writing, suspend or cancel the accreditation of an organisation if the Regulator believes on reasonable grounds that a condition of the accreditation has been breached.

97. *Regulator to Notify of Proposed Suspension, Cancellation or Variation*

(1) Before suspending, cancelling or varying an accreditation under this

Division, the Regulator must give written notice of the proposed suspension, cancellation or variation to the holder of the accreditation.

(2) The notice:

(a) Must state that the Regulator proposes to suspend, cancel or vary the accreditation.

(b) May require the holder of the accreditation to give to the Regulator any information of a kind specified in the notice that is relevant to the proposed suspension, cancellation or variation.

(c) May invite the holder of the accreditation to make a written submission to the Regulator about the proposed suspension, cancellation or variation.

(3) The notice must specify a period within which the holder of the accreditation:

(a) Must give the information referred to in paragraph (2)(b).

(b) May make a submission under paragraph (2)(c).

The period must not end earlier than 30 days after the day on which the notice was given.

(4) In considering whether to suspend, cancel or vary an accreditation, the Regulator must have regard to any submission made under paragraph (2)(c).

(5) This section does not apply to a suspension, cancellation or variation requested by the holder of the accreditation.

(6) This section does not apply to a suspension, cancellation or variation of an accreditation if 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.

98. *Guidelines*

(1) The Regulator may, by written instrument, issue technical or procedural guidelines in relation to requirements that must be met in order for an organisation to be accredited under this Division.

(2) The guidelines may relate to, but are not limited to, matters concerning the establishment and maintenance of Institutional Biosafety Committees.

(3) The Regulator may, by written instrument, vary or revoke the guidelines.

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

Division 1. Simplified Outline

99. *Simplified Outline*

The following is a simplified outline of this Part:

This Part provides for the establishment of the Gene Technology Technical Advisory Committee, the Gene Technology Community Consultative Committee and the Gene Technology Ethics Committee.

The Part sets out the membership of these bodies, and their functions.

Division 2. The Gene Technology Technical Advisory Committee

100. *The Gene Technology Technical Advisory Committee*

(1) The Gene Technology Technical Advisory Committee is established.

(2) The minister is to appoint up to 20 members of the Committee, and must appoint one of the members to chair the Committee.

(3) The members hold office on a part-time basis.

(4) Before appointing a member of the Committee, the Minister must consult the following:

(a) The States.

(b) The Regulator.

(c) Such scientific, consumer, health, environmental and industry groups as the Minister considers appropriate.

(d) Such other Ministers as the Minister considers appropriate.

(5) Subject to subsection (6), the minister must not appoint a person as a member of the Committee unless the minister is satisfied that the person has skills or experience in one or more of the following areas:

(a) Molecular biology.

(b) Ecology.

(c) Plant, microbial, animal or human genetics.

(d) Virology.

(e) Entomology.

(f) Agricultural or aquacultural systems.

(g) Biosafety engineering.

(h) Public health.

(i) Occupational health and safety.

(j) Risk assessment.

(k) Clinical medicine.

(l) Biochemistry.

(m) Pharmacology.

(n) Plant or animal pathology.

(o) Botany.

(p) Microbiology.

(q) Animal biology.

(r) Immunology.

(s) Toxicology.

(t) An area specified by the regulations for the purposes of this paragraph.

(6) The minister must appoint a layperson as a member of the Committee. The minister is not required to be satisfied that the person has skills or experience in an area mentioned in subsection (5).

(7) In appointing the members of the Committee, the minister must ensure, as far as practicable, that among the members as a whole there is a broad range of skills and experience in the areas mentioned in subsection (5).

(7A) The minister must ensure that the Committee includes the following members:

(a) A person who is a member of the Consultative Committee.

(b) A person who is a member of the Ethics Committee.

The minister is not required to be satisfied that these persons have skills or experience in an area mentioned in subsection (5).

(8) The minister must not appoint a member to chair the Committee unless a majority of jurisdictions agree to the appointment.

101. *Function of the Gene Technology Technical Advisory Committee*

The function of the Gene Technology Technical Advisory Committee is to provide scientific and technical

advice, on the request of the Regulator or the Ministerial Council, on the following:

(a) Gene technology, GMOs and GM products.

(b) Applications made under this Act;

(c) The biosafety aspects of gene technology.

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

102. *Expert Advisers*

(1) The minister may appoint one or more persons (expert advisers) to give expert advice to the Gene Technology Technical Advisory Committee to assist it in the performance of its functions. Expert advisers may be appointed on a continuing or an ad hoc basis.

(2) For the avoidance of doubt, expert advisers are not Committee members.

103. *Remuneration*

(1) A person who is a member of the Gene Technology Technical Advisory Committee or an expert adviser is to be paid the remuneration that is determined by the Remuneration Tribunal. If no determination of that remuneration by the Tribunal is in operation, the member is to be paid the remuneration that is prescribed by the regulations.

(2) A person who is a member of the Gene Technology Technical Advisory Committee or an expert adviser is to be paid the allowances that are prescribed by the regulations.

(3) This section has effect subject to the Remuneration Tribunal Act 1973.

104. *Members and Procedures*

(1) The regulations may prescribe matters relating to the members of the Gene Technology Technical Advisory Committee and expert advisers, including, but not limited to, the following:

(a) Term of appointment.

(b) Resignation.

(c) Disclosure of interests.

(d) Termination of appointment.

(e) Leave of absence.

(2) The regulations may prescribe matters relating to the operation of the Gene Technology Technical Advisory Committee, including, but not limited to:

(a) Procedures for convening meetings of the Committee.

(b) The constitution of a quorum for a meeting of the Committee.

(c) The way in which matters are to be resolved by the Committee; and

(d) Committee records.

(e) Reporting requirements, including, but not limited to, reports to the Regulator and to the public.

(3) If no regulations are in force under subsection (2), the Committee must operate in the way determined by the Regulator in writing.

(4) If no regulations are in force under subsection (2) and no determination is in force under subsection (3), the Committee may operate in the way it determines.

105. *Subcommittees*

(1) The Gene Technology Technical Advisory Committee may, with

the Regulator's consent, establish subcommittees to assist in the performance of its functions.

(2) The regulations may prescribe matters relating to the constitution and operation of subcommittees.

Division 3. The Gene Technology Community Consultative Committee

106. *The Gene Technology Community Consultative Committee*

The Gene Technology Community Consultative Committee (the Consultative Committee) is established.

107. *Function of Consultative Committee*

The function of the Consultative Committee is to provide advice, on the request of the Regulator or the Ministerial Council, on the following:

(aa) Matters of general concern identified by the Regulator in relation to applications made under this Act.

(a) Matters of general concern in relation to GMOs.

(b) 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.

108. *Membership*

(1) The minister is to appoint up to 12 members of the Consultative Committee, and must appoint one of the members to chair the Consultative Committee.

(2) Before appointing a member of the Consultative Committee, the Minister must consult the following:

(a) The States.

(b) The Regulator.

(c) Such scientific, consumer, health, environmental and industry groups as the Minister considers appropriate.

(d) Such other ministers as the Minister considers appropriate.

(3) The minister must not appoint a person as a member of the Consultative Committee (other than as a member mentioned in subsection (4)) unless the minister is satisfied that the person has skills or experience of relevance to gene technology in relation to one or more of the following:

(a) Environmental issues.

(b) Consumer issues.

(c) The impact of gene technology on the community.

(d) Issues relevant to the biotechnology industry.

(e) Issues relevant to gene technology research.

(f) Public health issues.

(g) Issues relevant to primary production.

(h) Issues relevant to local government.

(i) Issues specified by the regulations for the purposes of this paragraph.

(4) The minister must ensure that the Consultative Committee includes the following members:

(a) A person who is a member of the Gene Technology Technical Advisory Committee.

(b) A person who is a member of the Ethics Committee.

(5) The members of the Consultative Committee hold office on a part-time basis.

(6) The Minister must not appoint a member to chair the Consultative

Committee unless a majority of jurisdictions agree to the appointment.

109. *Remuneration*

(1) A person who is a member of the Consultative Committee is to be paid the remuneration that is determined by the Remuneration Tribunal. If no determination of that remuneration by the Tribunal is in operation, the member is to be paid the remuneration that is prescribed by the regulations.

(2) A person who is a member of the Consultative Committee is to be paid the allowances that are prescribed by the regulations.

(3) This section has effect subject to the Remuneration Tribunal Act 1973.

110. *Regulations*

(1) The regulations may prescribe matters relating to the members of the Consultative Committee, including, but not limited to, the following:

(a) Term of appointment.

(b) Resignation.

(c) Disclosure of interests.

(d) Termination of appointment.

(e) Leave of absence.

(2) The regulations may prescribe matters relating to the operation of the Consultative Committee, including:

(a) Procedures for convening meetings of the Consultative Committee; and

(b) The constitution of a quorum for a meeting of the Consultative Committee.

(c) The way in which matters are to be resolved by the Consultative Committee.

(d) Consultative Committee records.

(e) Reporting requirements, including, but not limited to, reports to the Regulator and to the public.

(3) If no regulations are in force under subsection (2), the Consultative Committee must operate in the way determined by the Regulator in writing.

(4) If no regulations are in force under subsection (2) and no determination is in force under subsection (3), the Consultative Committee may operate in the way it determines.

110.A *Subcommittees*

(1) The Consultative Committee may, with the Regulator's consent, establish subcommittees to assist in the performance of its functions.

(2) The regulations may prescribe matters relating to the constitution and operation of subcommittees.

Division 4. The Gene Technology Ethics Committee

111. *The Gene Technology Ethics Committee*

(1) The Gene Technology Ethics Committee (the Ethics Committee) is established.

(2) The minister is to appoint up to 12 members of the Ethics Committee, and must appoint one of the members to chair the Committee.

(3) The members hold office on a part-time basis.

(4) Before appointing a member of the Ethics Committee, the minister must consult the following:

(a) The States.

(b) The Regulator.

(c) Such scientific, consumer, health, environmental and industry groups as the minister considers appropriate.

(d) Such other ministers as the minister considers appropriate.

(5) The minister must not appoint a person as a member of the Ethics Committee (other than as a member mentioned in subsection (6)) unless the minister is satisfied that the person has skills or experience in one or more of the following areas:

(a) Ethics and the environment.

(b) Health ethics.

(c) Applied ethics.

(d) Law.

(e) Religious practices.

(f) Population health.

(g) Agricultural practices.

(h) Animal health and welfare.

(i) Issues of concern to consumers in relation to gene technology.

(j) Environmental systems.

(6) The minister must ensure that the Ethics Committee includes the following members:

(a) A person who is a member of the Gene Technology Technical Advisory Committee.

(b) A person who is a member of the Australian Health Ethics Committee and who has expertise in medical research.

(7) The minister must not appoint a member to chair the Ethics Committee unless a majority of jurisdictions agree to the appointment.

112. *Function of the Gene Technology Ethics Committee*

The function of the Ethics Committee is to provide advice, on the request of the Regulator or the Ministerial Council, on the following:

(a) Ethical issues relating to gene technology.

(b) The need for, and content of, codes of practice in relation to ethics in respect of conducting dealings with GMOs.

(c) The need for, and content of, policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons.

113. *Expert Advisers*

(1) The minister may appoint one or more persons (expert advisers) to give expert advice to the Ethics Committee to assist it in the performance of its functions. Expert advisers may be appointed on a continuing or an ad hoc basis.

(2) For the avoidance of doubt, expert advisers are not Committee members.

114. *Remuneration*

(1) A person who is a member of the Ethics Committee or an expert adviser is to be paid the remuneration that is determined by the Remuneration Tribunal. If no determination of that remuneration by the Tribunal is in operation, the member is to be paid the remuneration that is prescribed by the regulations.

(2) A person who is a member of the Ethics Committee or an expert adviser is to be paid the allowances that are prescribed by the regulations.

(3) This section has effect subject to the Remuneration Tribunal Act 1973.

115. *Members and Procedures*

(1) The regulations may prescribe matters relating to the members of the Ethics Committee and expert advisers, including, but not limited to, the following:

(a) Term of appointment.

(b) Resignation.

(c) Disclosure of interests.

(d) Termination of appointment.

(e) Leave of absence.

(2) The regulations may prescribe matters relating to the operation of the Ethics Committee, including, but not limited to:

(a) Procedures for convening meetings of the Committee.

(b) The constitution of a quorum for a meeting of the Committee.

(c) The way in which matters are to be resolved by the Committee.

(d) Committee records.

(e) Reporting requirements, including but not limited to reports to the Regulator and to the public.

(3) If no regulations are in force under subsection (2), the Ethics Committee must operate in the way determined by the Regulator in writing.

(4) If no regulations are in force under subsection (2) and no determination is in force under subsection (3), the Ethics Committee may operate in the way it determines.

116. *Subcommittees*

(1) The Ethics Committee may, with the Regulator's consent, establish subcommittees to assist in the performance of its functions.

(2) The regulations may prescribe matters relating to the constitution and operation of subcommittees.

PART 9. ADMINISTRATION

Division 1. Simplified Outline

117. *Simplified Outline*

The following is a simplified outline of this Part:

This Part provides for various administrative matters.

Division 2 sets out matters relating to the appointment, conditions and remuneration of the Regulator.

Division 3 provides for financial matters, including the establishment of a Special Account, called the Gene Technology Account.

Division 4 provides for matters relating to staffing.

Division 5 sets out reporting requirements.

Division 6 requires the Regulator to maintain a record of GMOs and GM products.

Division 7 permits the Regulator to review notifiable low risk dealings and exemptions.

Division 2. Appointment and Conditions of Regulator

118. *Appointment of the Regulator*

(1) The Regulator is to be appointed by the governor-general by written instrument.

(2) The Regulator holds office for the period specified in the instrument of appointment. The period specified must not be less than 3 years or more than 5 years.

(3) The Regulator holds office on a full-time basis.

(4) The governor-general must not appoint a person as the Regulator un-

less a majority of jurisdictions agree to the appointment.

(5) The governor-general must not appoint a person as the Regulator if, at any time during the period of 2 years immediately before the proposed period of appointment, the person was employed by a body corporate whose primary commercial activity relates directly to the development and implementation of gene technologies.

(6) The governor-general must not appoint a person as the Regulator if the person has a pecuniary interest in a body corporate whose primary commercial activity relates directly to the development and implementation of gene technologies.

119. *Termination of Appointment*

(1) The governor-general may terminate the appointment of the Regulator for misbehaviour or physical or mental incapacity.

(2) If the Regulator:

(a) becomes bankrupt, applies to take the benefit of any law for the relief of bankrupt or insolvent debtors, compounds with his or her creditors or makes an assignment of his or her remuneration for their benefit.

(b) Fails to comply with his or her obligations under section 120.

(c) Without the consent of the minister, engages in any paid employment outside the duties of his or her office; or

(d) Is absent from duty, except on leave of absence, for 14 consecutive days or for 28 days in any 12 months; the governor-general must terminate his or her appointment.

(3) The governor-general must not terminate the appointment of the Regulator under subsection (1) unless a majority of jurisdictions agree to the termination of the appointment.

(4) If the Regulator is:

(a) An eligible employee for the purposes of the Superannuation Act 1976.

(b) A member of the superannuation scheme established by deed under the Superannuation Act 1990; the governor-general may, with the consent of the Regulator, retire the Regulator from office on the grounds of physical or mental incapacity.

(5) For the purposes of the Superannuation Act 1976, the Regulator is taken to have been retired from office on the grounds of invalidity if:

(a) The Regulator is removed or retired from office on the grounds of physical or mental incapacity.

(b) The Commonwealth Superannuation Board of Trustees No. 2 gives a certificate under section 54C of the Superannuation Act 1976.

(6) For the purposes of the Superannuation Act 1990, the Regulator is taken to have been retired from office on the grounds of invalidity if:

(a) The Regulator is removed or retired from office on the grounds of physical or mental incapacity.

(b) The Commonwealth Superannuation Board of Trustees num. 1 gives a certificate under section 13 of the Superannuation Act 1990.

120. *Disclosure of Interests*

The Regulator must give written notice to the Minister of all interests, pecuniary or otherwise, that the Regulator has or acquires and that could conflict with the proper performance of the Regulator's functions.

121. *Acting Appointment*

(1) The minister may appoint a person to act as the Regulator:

(a) During a vacancy in the office of Regulator, (whether or not an appointment has previously been made to the office).

(b) During any period, or during all periods, when the Regulator is absent from duty or from Australia, or is, for any reason, unable to perform the duties of the office.

(2) Anything done by or in relation to a person purporting to act under an appointment is not invalid merely because:

(a) The occasion for the appointment had not arisen.

(b) There was a defect or irregularity in connection with the appointment; or

(c) The appointment had ceased to have effect.

(d) The occasion to act had not arisen or had ceased.

122. *Terms and Conditions*

The Regulator holds office on the terms and conditions (if any) in relation to matters not covered by this Act that are determined by the Governor-General.

123. *Outside Employment*

The Regulator must not engage in paid employment outside the duties of the Regulator's office without the approval of the minister.

124. *Remuneration*

(1) The Regulator is to be paid the remuneration that is determined by the Remuneration Tribunal. If no determination of that remuneration by the Tribunal is in operation, the Regulator is to be paid the remuneration that is prescribed by the regulations.

(2) The Regulator is to be paid the allowances that are prescribed by the regulations.

(3) This section has effect subject to the Remuneration Tribunal Act 1973.

125. *Leave of Absence*

(1) The Regulator has the recreation leave entitlements that are determined by the Remuneration Tribunal.

(2) The minister may grant the Regulator leave of absence, other than recreation leave, on the terms and conditions as to remuneration or otherwise that the minister determines.

126. *Resignation*

The Regulator may resign his or her appointment by giving the governor-general a written resignation.

Division 3. Money

127. *Regulator May Charge for Services*

The Regulator may charge for services provided by, or on behalf of, the Regulator in the performance of the Regulator's functions.

128. *Notional Payments by the Commonwealth*

(1) The purpose of this section is to ensure that fees and charges under this Act and the regulations, and charges under the Gene Technology (Li-

cence Charges) Act 2000, are notionally payable by the Commonwealth (or parts of the Commonwealth).

(2) The minister responsible for administering the Financial Management and Accountability Act 1997 may give written directions for the purpose of this section, including directions relating to the transfer of amounts within, or between, accounts operated by the Commonwealth.

129. *Gene Technology Account*

(1) The Gene Technology Account is established.

(2) The Account is a Special Account for the purposes of the Financial Management and Accountability Act 1997.

130. *Credits to Account*

(1) There must be credited to the Account the following:

(a) All money appropriated by the Parliament for the purposes of the Account.

(b) Amounts equal to money from time to time received by the Commonwealth under the Gene Technology (Licence Charges) Act 2000.

(c) Amounts equal to fees received by the Commonwealth under subsections 40(6) and 83(3).

(d) Amounts equal to amounts received by the Commonwealth in connection with the performance of the Regulator's functions under this Act, the regulations or a corresponding State law.

(e) Amounts equal to interest received by the Commonwealth from the investment of money from the Account.

(f) Amounts equal to money received by the Commonwealth in relation to property paid for with money from the Account.

(g) Amounts equal to amounts recovered by the Commonwealth under subsection 146(5) or 158(4), to the extent that they are referable to amounts paid out of the Account.

(h) Amounts equal to amounts of any gifts given or bequests made for the purposes of the Account.

(2) The purposes of the Account are to make payments:

(a) To further the object of this Act (as set out in section 3).

(b) Otherwise in connection with the performance of the Regulator's functions under this Act, the regulations or a corresponding State law.

131. *Recovery of Amounts*

The following amounts may be recovered in a court of competent jurisdiction as debts due to the Commonwealth:

(a) Amounts payable to the Commonwealth under the Gene Technology (Licence Charges) Act 2000.

(b) Fees payable to the Commonwealth under this Act, the regulations or a corresponding State law.

(c) Amounts payable to the Commonwealth in connection with the performance of the Regulator's functions.

132. *Purposes of Account*

Amounts standing to the credit of the Account may be expended:

(a) In payment or discharge of the costs, expenses and other obligations incurred:

(i) By the Regulator in the performance of the Regulator's functions or in the exercise of the Regulator's powers under this Act, the regulations or a corresponding State law.

(ii) By an inspector under paragraph 158(2)(e) or under a corresponding State law.

(b) In payment of any remuneration and allowances payable to any person under this Act or the regulations.

Division 4. Staffing

133. *Staff assisting the Regulator*

The staff assisting the Regulator are to be persons engaged under the Public Service Act 1999 and made available for the purpose by the secretary of the Department.

134. *Consultants*

(1) The Regulator may engage persons with suitable qualifications and experience as consultants to the Regulator.

(2) The terms and conditions of engagement of consultants are such as the Regulator determines.

135. *Seconded Officers*

The Regulator may be assisted by the following:

(a) Persons engaged under the Public Service Act 1999.

(b) Officers and employees of Commonwealth authorities.

(c) Officers and employees of State agencies; whose services are made available to the Regulator in connection with the performance or exercise of any of the Regulator's functions or powers.

Division 5. Reporting Requirements

136. *Annual Report*

(1) As soon as practicable after the end of each financial year, the Regulator must prepare and give to the minister a report on the operations of the Regulator during that year.

(2) The minister must cause a copy of the report to be laid before each House of the Parliament within 15 sitting days of the day on which the report was given to the minister.

(3) The Regulator must give a copy of the report to each State.

136. A *Quarterly Reports*

(1) 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.

(2) The report must include information about the following:

(a) GMO licences issued during the quarter.

(b) Any breaches of conditions of a GMO licence that have come to the Regulator's attention during the quarter.

(c) Auditing and monitoring of dealings with GMOs under this Act by the Regulator or an inspector during the quarter.

Note: Auditing and monitoring may include spot checks.

(3) The minister must cause a copy of the report to be laid before each House of the Parliament within 15 sitting days of the day on which the report was given to the minister.

(4) In this section:

Quarter means a period of 3 months beginning on 1 january, 1 april, 1 july or 1 october of any year.

137. *Reports to Parliament*

(1) The Regulator may at any time cause a report about matters relating to the Regulator's functions to be tabled in either House of the Parliament.

(2) The Regulator must give a copy of the report to the minister and to each State.

Division 6. Record of GMO and GM Product Dealings

138. *Record of GMO and GM Product Dealings*

(1) The Regulator must maintain a Record of GMO and GM Product Dealings (the Record).

(2) The purpose of the Record is to maintain a comprehensive record of all dealings in Australia that involve GMOs or GM products.

(3) The Record must contain the following information, other than confidential commercial information, in relation to each licence issued under section 55:

(a) The name of the licence holder.

(b) The persons covered by the licence.

(c) The dealings authorised by the licence and the GMO to which those dealings relate.

(d) Any licence conditions.

(e) The date on which the licence was issued, and its expiry date (if any).

(4) The Record must contain the following information, other than confidential commercial information, in relation to each notifiable low risk dealing that is notified to the Regulator in accordance with regulations under section 75:

(a) The name of the person who notified the dealing.

(b) Such particulars of the dealing as are prescribed by the regulations for the purposes of this paragraph.

(5) 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 given to the Regulator under the following Acts:

(a) The Agricultural and Veterinary Chemicals (Administration) Act 1992.

(b) The Food Standards Australia New Zealand Act 1991.

(c) The Industrial Chemicals (Notification and Assessment) Act 1989.

(d) The Therapeutic Goods Act 1989.

(6) The Record must also contain:

(a) A description of each dealing on the GMO Register; and

(b) Any condition to which the dealing is subject.

(7) The Record may be kept in a computerised form.

(8) The Regulator must ensure that information mentioned in subsection (3), (4), (5) Or (6) is entered on the Record as soon as reasonably practicable.

(9) In this section:

Designated notification means a notification required because of the amendments made by the Gene Technology (Consequential Amendments) Act 2000.

139. *Inspection of Record*

The Regulator must permit any person to inspect any part of the Record.

Division 7. Reviews of Notifiable Low Risk Dealings and Exemptions

140. *Regulator May Review Notifiable Low Risk Dealings*

(1) The Regulator may, at any time, in accordance with this Division, consider the following matters:

(a) Whether a dealing with a GMO should be a notifiable low risk dealing.

(b) Whether an existing notifiable low risk dealing should no longer be a notifiable low risk dealing.

(2) The basis of the Regulator's consideration must relate to:

(a) The matters of which the Regulator must be satisfied under subsection 74(2).

(b) The matters the Regulator must consider under subsection 74(3).

141. *Regulator May Review Exemptions*

The Regulator may, at any time, in accordance with this Division, consider the following matters:

(a) Whether a dealing that is an exempt dealing within the meaning of subsection 32(3) should not be an exempt dealing.

(b) Whether a dealing should be an exempt dealing within the meaning of that subsection.

142. *Regulator May Give Notice of Consideration*

(1) The Regulator may publish a notice inviting written submissions in relation to any matter that the Regulator may consider under section 140 or 141. The notice must:

(a) Specify the matters to which submissions are to relate.

(b) Specify the closing date for submissions, which must not be earlier than 30 days after the date on which the notice was published.

(2) If the Regulator publishes a notice under subsection (1), the Regulator must also give written notice, stating the matters mentioned in subsection (1), to:

(a) The States.

(b) The Gene Technology Technical Advisory Committee.

(c) Each Commonwealth authority or agency prescribed by the regulations for the purposes of this paragraph.

(3) A notice under this section may relate to a single matter or to a class of matters.

143. *What Regulator May do After Consideration*

(1) If:

(a) The matter relates to whether a dealing should be a notifiable low risk dealing.

(b) The Regulator is satisfied as mentioned in subsection 74(2); and

(c) The Regulator has considered the matters mentioned in subsection 74(3); the Regulator may recommend to the Ministerial Council that the dealing be declared to be a notifiable low risk dealing.

(2) If:

(a) The matter relates to whether an existing notifiable low risk dealing be reconsidered.

(b) After having had regard to the matters mentioned in section 74, the Regulator considers that the dealing should not be a notifiable low risk dealing; the Regulator may recom-

mend to the Ministerial Council that the regulations be amended accordingly.

(3) If the matter relates to whether a dealing:

(a) Should be an exempt dealing; or

(b) Should cease to be an exempt dealing; the Regulator may recommend to the Ministerial Council that the regulations be amended accordingly.

144. *Regulator not Required to Review Matters*

Nothing in this Division requires the Regulator to consider a matter under section 140 or 141.

PART 10. ENFORCEMENT

145. *Simplified Outline*

The following is a simplified outline of this Part:

This Part enables the Regulator to give directions to a licence holder or to a person covered by a licence, if:

(a) The Regulator believes that the person is not complying with this Act or the regulations.

(b) The Regulator believes that it is necessary to do so in order to protect the health and safety of people or to protect the environment.

The Part also empowers the Federal Court to issue injunctions, and contains a forfeiture provision.

146. *Regulator May Give Directions*

(1) If the Regulator believes, on reasonable grounds, that:

(a) A licence holder is not complying with this Act or the regulations in respect of a thing.

(b) It is necessary to exercise powers under this section in order to protect the health and safety of people or to protect the environment; the Regulator may give directions to the licence holder, by written notice, requiring the licence holder, within the time specified in the notice, to take such steps in relation to the thing as are reasonable in the circumstances for the licence holder to comply with this Act or the regulations.

(2) If the Regulator believes on reasonable grounds that:

(a) A person covered by a GMO licence is not complying with this Act or the regulations in respect of a thing.

(b) It is necessary to exercise powers under this section in order to protect the health and safety of people or to protect the environment; the Regulator may give directions to the person, by written notice, requiring the person, within the time specified in the notice, to take such steps in relation to the thing as are reasonable in the circumstances for the person to comply with this Act or the regulations.

(3) A person commits an offence if he or she does not take the steps specified in a notice under subsection (1) or (2) within the time specified in the notice.

Maximum penalty:

(a) In the case of an aggravated offence - 2,000 penalty units.

(b) In any other case 500 penalty units.

Note 1: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

Note 2: Aggravated offence is defined in section 38.

(4) If the licence holder or the person, as the case requires, does not take the steps specified in the notice within the time specified in the notice, the Regulator may arrange for those steps to be taken.

(5) If the Regulator incurs costs because of arrangements made by the Regulator under subsection (4), the licence holder or the person, as the case requires, is liable to pay to the Commonwealth an amount equal to the cost, and the amount may be recovered by the Commonwealth as a debt due to the Commonwealth in a court of competent jurisdiction.

(6) Section 4K of the Crimes Act 1914 does not apply to an offence against subsection (3).

(7) A time specified in a notice under subsection (1) or (2) must be reasonable having regard to the circumstances.

147. *Injunctions*

(1) If a person has engaged, is engaging, or is about to engage in any conduct that is or would be an offence against this Act or the regulations, the Federal Court of Australia (the Court) may, on the application of the Regulator or any other aggrieved person, grant an injunction restraining the person from engaging in the conduct.

(2) If:

(a) A person has refused or failed, is refusing or failing, or is about to refuse or fail, to do a thing.

(b) The refusal or failure is, or would be, an offence against this Act or the regulations; the Court may, on the application of the Regulator or any other aggrieved person, grant an injunction requiring the person to do the thing.

(3) The power of the Court to grant an injunction may be exercised:

(a) Whether or not it appears to the Court that the person intends to engage, or to continue to engage, in conduct of that kind.

(b) Whether or not the person has previously engaged in conduct of that kind.

(4) The Court may discharge or vary an injunction granted under this section.

(5) The Court may grant an interim injunction pending a determination of an application under subsection (1).

(6) The powers granted by this section are in addition to, and not in derogation of, any other powers of the Court.

148. *Forfeiture*

(1) If a court:

(a) Convicts a person of an offence against this Act or the regulations; or

(b) Makes an order under section 19B of the Crimes Act 1914 in respect of a person charged with an offence against this Act or the regulations; the court may order forfeiture to the Commonwealth of any thing used or otherwise involved in the commission of the offence.

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

(3) Until the Regulator gives a direction, the thing must be kept in such custody as the Regulator directs.

PART 11. POWERS OF INSPECTION

Division 1. Simplified Outline

149. *Simplified Outline*

The following is a simplified outline of this Part:

This Part provides for powers of inspection in relation to monitoring and offences.

Division 2 provides for the appointment of inspectors.

Divisions 3 to 9 deal with the powers and obligations of inspectors, and the rights and responsibilities of an occupier of premises when an inspector seeks to exercise powers.

Division 10 sets out procedures relating to monitoring warrants and offence-related warrants.

This Part does not limit the conditions to which a licence can be subject, and section 64 imposes a condition in relation to monitoring dealings with GMOs.

Division 2. Appointment of Inspectors and Identity Cards

150. *Appointment of Inspectors*

(1) The Regulator may, by instrument in writing, appoint any of the following persons as inspectors:

(a) A person who is appointed or employed by the Commonwealth.

(b) A person who is appointed or employed by a State.

(2) In exercising powers or performing functions as an inspector, an inspector must comply with any directions of the Regulator.

151. *Identity Card*

(1) The Regulator must issue an identity card to an inspector.

(2) The identity card:

(a) Must be in the form prescribed by the regulations.

(b) Must contain a recent photograph of the inspector.

(3) If a person to whom an identity card has been issued ceases to be an inspector, the person must return the identity card to the Regulator as soon as practicable.

Maximum penalty: 1 penalty unit.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

(4) An inspector must carry his or her identity card at all times when exercising powers or performing functions as an inspector.

Division 3. Monitoring Powers

152. *Powers Available to Inspectors for Monitoring Compliance*

(1) For the purpose of finding out whether this Act or the regulations have been complied with, an inspector may:

(a) Enter any premises.

(b) Exercise the monitoring powers set out in section 153.

(2) An inspector is not authorised to enter premises under subsection (1) unless:

(a) The occupier of the premises has consented to the entry.

(b) The entry is made under a warrant under section 172.

(c) The occupier of the premises is a licence holder, or a person covered by a licence, and the entry is at a reasonable time.

153. *Monitoring Powers*

(1) The monitoring powers that an inspector may exercise under paragraph 152(1) (b) are as follows:

(a) To search the premises and any thing on the premises.

(b) To inspect, examine, take measurements of, conduct tests on, or take samples of, any thing on the premises that relates to a GMO.

(c) To take photographs, make video or audio recordings or make sketches of the premises or any thing on the premises.

(d) If the inspector was authorised to enter the premises by a warrant under section 172 to require any person in or on the premises to:

(i) Answer any questions put by the inspector; and

(ii) Produce any book, record or document requested by the inspector.

(e) To inspect any book, record or document on the premises.

(f) To take extracts from or make copies of any such book, record or document.

(g) To take onto the premises such equipment and materials as the inspector requires for the purpose of exercising powers in relation to the premises.

(h) To secure a thing, until a warrant is obtained to seize it, being a thing:

(i) That the inspector finds during the exercise of monitoring powers on the premises.

(ii) That the inspector believes on reasonable grounds is evidential material; and

(iii) That the inspector believes on reasonable grounds would be lost, destroyed or tampered with before the warrant can be obtained.

(2) For the purposes of this Part, monitoring powers include the power to operate equipment at premises to see whether:

(a) The equipment.

(b) A disk, tape or other storage device that:

(i) Is at the premises.

(ii) Can be used with the equipment or is associated with it; contains information that is relevant to determining whether there has been compliance with the Act or the regulations.

(3) If the inspector, after operating equipment at the premises, finds that the equipment, or that a tape, disk or other storage device at the premises, contains information mentioned in subsection (2), the inspector may:

(a) Operate facilities at the premises to put the information in documentary form and copy the document so produced.

(b) If the information can be transferred to a tape, disk or other storage device that:

(i) Is brought to the premises.

(ii) Is at the premises and the use of which for the purpose has been agreed to in writing by the occupier of the premises; operate the equipment or other facilities to copy the information to the storage device, and remove the storage device from the premises.

Division 4. Offence-related Powers

154. *Searches and Seizures Related to Offences*

(1) This section applies if an inspector has reasonable grounds for suspecting that there may be evidential material on any premises.

(2) The inspector may:

(a) Enter the premises, with the consent of the occupier or under a warrant issued under section 173.

(b) Exercise the powers set out in subsection (3) and section 155.

(c) If the entry is under a warrant-seize the evidential material, if the inspector finds it on the premises.

(3) If:

(a) In the course of searching, in accordance with a warrant, for a particular thing, an inspector finds another thing that the inspector believes on reasonable grounds to be evidential material.

(b) The inspector believes, on reasonable grounds, that it is necessary to seize that other thing in order to prevent its concealment, loss or destruction, or its use in committing, continuing or repeating an offence against this Act or the regulations; the warrant is taken to authorise the inspector to seize that other thing.

155. *Offence-related Powers of Inspectors in Relation to Premises*

The powers an inspector may exercise under paragraph 154(2)(b) are as follows:

(a) To search the premises and any thing on the premises for the evidential material.

(b) To inspect, examine, take measurements of, conduct tests on, or take samples of the evidential material.

(c) To take photographs, make video or audio recordings or make sketches of the premises or the evidential material.

(d) To take onto the premises such equipment and materials as the inspector requires for the purpose of exercising powers in relation to the premises.

156. *Use of Equipment at Premises*

(1) The inspector may operate equipment at the premises to see whether evidential material is accessible by doing so, if the inspector believes on reasonable grounds that the operation of the equipment can be carried out without damage to the equipment.

(2) If the inspector, after operating the equipment, finds that evidential material is accessible by doing so, the inspector may:

(a) Seize the equipment and any disk, tape or other associated device; or

(b) if the material can, by using facilities at the premises, be put in documentary form operate the facilities to put the material in that form and seize the documents so produced; or

(c) If the material can be transferred to a disk, tape or other storage device that:

(i) Is brought to the premises.

(ii) Is at the premises and the use of which for the purpose has been agreed to in writing by the occupier of the premises; operate the equipment or other facilities to copy the material to the storage device and take the storage device from the premises.

(3) An inspector may seize equipment under paragraph (2) (a) only if:

(a) it is not practicable to put the material in documentary form as mentioned in paragraph (2) (b) or to copy the material as mentioned in paragraph (2) (c).

(b) Possession by the occupier of the equipment could constitute an offence.

(4) An inspector may seize equipment under paragraph (2) (a) or documents under paragraph (2) (b) only if the inspector entered the premises under a warrant.

Division 5. Expert Assistance

157. *Expert Assistance to Operate a Thing*

(1) If an inspector believes on reasonable grounds that:

(a) Information relevant to determining whether there has been compliance with this Act or the regulations, or evidential material, may be accessible by operating a thing at particular premises.

(b) Expert assistance is required to operate the thing.

(c) If he or she does not take action under this subsection, the information or material may be destroyed, altered or otherwise interfered with; he or she may do whatever is necessary to secure the thing, whether by locking it up, placing a guard or otherwise.

(2) The inspector must give notice to the occupier of the premises of his or her intention to secure the thing and of the fact that the thing may be secured for up to 24 hours.

(3) The thing may be secured:

(a) For a period not exceeding 24 hours.

(b) Until the thing has been operated by the expert; whichever happens first.

(4) If the inspector believes on reasonable grounds that the expert assistance will not be available within 24 hours, he or she may apply to the magistrate for an extension of that period.

(5) The inspector must give notice to the occupier of the premises of his or her intention to apply for an extension, and the occupier is entitled to be heard in relation to the application.

Division 6. Emergency Powers

158. *Powers Available to Inspectors for Dealing with Dangerous Situations*

(1) This section applies if:

(a) An inspector has reasonable grounds for suspecting that there may be on any premises a particular thing in respect of which this Act or the regulations have not been complied with; and

(b) The inspector considers that it is necessary to exercise powers under this section in order to avoid an imminent risk of death, serious illness, serious injury, or to protect the environment.

(2) The inspector may do any of the following:

(a) Enter the premises.

(b) Search the premises for the thing.

(c) Secure the thing, if the inspector finds it on the premises, until a warrant is obtained to seize the thing.

(d) If the inspector has reasonable grounds for suspecting that a person has not complied with this Act or the regulations in respect of the thing require the person to take such steps as the inspector considers necessary for the person to comply with this Act or the regulations.

(e) Take such steps, or arrange for such steps to be taken, in relation to the thing as the inspector considers appropriate.

(3) The inspector may exercise the powers in subsection (2) only to the extent that it is necessary for the purpose of avoiding an imminent risk of

death, serious illness, serious injury or serious damage to the environment.

(4) If the Regulator incurs costs because of steps reasonably taken or arranged to be taken by an inspector under paragraph (2)(e), the person is liable to pay to the Commonwealth an amount equal to the costs, and the amount may be recovered by the Commonwealth as a debt due to the Commonwealth in a court of competent jurisdiction.

Division 7. Obligations and Incidental Powers of Inspectors

159. *Inspector must Produce Identity Card on Request*

An inspector is not entitled to exercise any powers under this Part in relation to premises if:

(a) The occupier of the premises has required the inspector to produce his or her identity card for inspection by the occupier.

(b) The inspector fails to comply with the requirement.

160. *Consent*

(1) Before obtaining the consent of a person for the purposes of paragraph 152 (2) (a) or 154 (2) (a), the inspector must inform the person that he or she may refuse consent.

(2) An entry of an inspector by virtue of the consent of a person is not lawful unless the person voluntarily consented to the entry.

161. *Details of Warrant to be Given to Occupier, Etcetera*

(1) If a warrant in relation to premises is being executed and the occupier of the premises or another person who apparently represents the occupier is present at the premises, the inspector must make available to that person a copy of the warrant.

(2) The inspector must identify himself or herself to that person.

(3) The copy of the warrant referred to in subsection (1) need not include the signature of the magistrate who issued the warrant.

162. *Announcement Before Entry*

(1) An inspector must, before entering premises under a warrant:

(a) Announce that he or she is authorised to enter the premises.

(b) Give any person at the premises an opportunity to allow entry to the premises.

(2) An inspector is not required to comply with subsection (1) if he or she believes on reasonable grounds that immediate entry to the premises is required:

(a) To ensure the safety of a person; or

(b) To prevent serious damage to the environment.

(c) To ensure that the effective execution of the warrant is not frustrated.

163. *Compensation for Damage*

(1) The owner of a thing is entitled to compensation for damage to the thing if:

(a) The damage was caused to the thing as a result of it being operated as mentioned in this Part.

(b) The damage was caused as a result of:

(i) Insufficient care being exercised in selecting the person who was to operate the thing.

(ii) Insufficient care being exercised by the person operating the thing.

(2) Compensation is payable out of money appropriated by the Parliament.

(3) In determining the amount of com- pensation payable, regard is to be had to whether the occupier of the premises and his or her employees and agents, if they were available at the time, had provided any warning or guidance as to the operation of the thing that was appropriate in the circumstances.

Division 8. Power to Search Goods, Baggage Etcetera

164. *Power to Search Goods, Baggage Etcetera*

(1) This section applies to any goods that are to be, are being, or have been, taken off a ship that voyages, or an aircraft that flies, between:

(a) A place outside Australia and a place in Australia.

(b) A place outside an external territory and a place in that territory.

(2) If an inspector believes, on reasonable grounds, that goods are goods to which this section applies, and that the goods may be, or may contain, evidential material, the inspector may:

(a) Examine the goods.

(b) If the goods are baggage open and search the baggage.

(c) If the goods are in a container open and search the container.

(3) An inspector may ask a person who owns, is carrying or is otherwise associated with, or appears to the inspector to be associated with, goods to which this section applies, any question in respect of the goods.

(4) A person must not refuse or fail to answer a question put to the person under subsection (3).

Maximum penalty: 30 penalty units.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

165. *Seizure of Goods*

An inspector may seize goods mentioned in section 164 if the inspector has reasonable grounds to suspect that the goods are evidential material.

Division 9. General Provisions Relating to Search and Seizure

166. *Copies of Seized Things to be Provided*

(1) Subject to subsection (2), if an inspector seizes, under a warrant relating to premises:

(a) A document, film, computer file or other thing that can be readily copied.

(b) A storage device, the information in which can be readily copied; the inspector must, if requested to do so by the occupier of the premises, or another person who apparently represents the occupier and who is present when the warrant is executed, give a copy of the thing or the information to that person as soon as practicable after the seizure.

(2) Subsection (1) does not apply if:

(a) The thing that has been seized was seized under paragraph 156(2)(b) or (c).

(b) Possession by the occupier of the document, film, computer file, thing or information could constitute an offence.

167. *Occupier Entitled to be Present During Search*

(1) If a warrant in relation to premises is being executed and the occupier of the premises, or another person who apparently represents the occupier is present at the premises, the person is entitled to observe the search being conducted.

(2) The right to observe the search being conducted ceases if the person impedes the search.

(3) This section does not prevent 2 or more areas of the premises being searched at the same time.

168. *Receipts for Things Seized*

(1) If a thing is seized under this Part, the inspector must provide a receipt for the thing.

(2) If 2 or more things are seized, they may be covered in the one receipt.

169. *Retention of Seized Things*

(1) Subject to any contrary order of a court, if an inspector seizes a thing under this Part, the inspector must return it if:

(a) The reason for its seizure no longer exists or it is decided that it is not to be used in evidence.

(b) The period of 60 days after its seizure ends; whichever first occurs, unless the thing is forfeited or forfeitable to the Commonwealth.

(2) At the end of the 60 days specified in subsection (1), an inspector must take reasonable steps to return the thing to the person from whom it was seized, unless:

(a) Proceedings in respect of which the thing may afford evidence were instituted before the end of the 60 days and have not been completed (including an appeal to a court in relation to those proceedings).

(b) An inspector may retain the thing because of an order under section 170.

(c) To return the thing could cause an imminent risk of death, serious illness, serious injury or serious damage to the environment.

(d) An inspector is otherwise authorised (by a law, or an order of a court, of the Commonwealth or of a State) to retain, destroy or dispose of the thing.

(3) The thing may be returned under subsection (2) either unconditionally or on such terms and conditions as the Regulator sees fit.

170. *Magistrate may Permit a Thing to Be Retained*

(1) An inspector may apply to a magistrate for an order that he or she may retain the thing for a further period if:

(a) Before the end of 60 days after the seizure.

(b) Before the end of a period previously specified in an order of a magistrate under this section; proceedings in respect of which the thing may afford evidence have not commenced.

(2) If the magistrate is satisfied that it is necessary for an inspector to continue to retain the thing:

(a) For the purposes of an investigation as to whether an offence against this Act has been committed.

(b) To enable evidence of an offence against this Act to be secured for the purposes of a prosecution; the magistrate may order that an inspector may retain the thing for a period (not being a period exceeding 3 years) specified in the order.

(3) Before making the application, the inspector must:

(a) Take reasonable steps to discover who has an interest in the retention of the thing.

(b) If it is practicable to do so, notify each person whom the inspector believes to have such an interest of the proposed application.

171. *Disposal of Goods if there is No Owner or Owner Cannot Be Located*

If:

(a) A thing is seized under this Part.

(b) Apart from this section, the Commonwealth is required to return the thing to the owner.

(c) There is no owner or the Regulator cannot, despite making reasonable efforts, locate the owner; the Regulator may dispose of the thing in such manner as the Regulator thinks appropriate.

Division 10. Warrants

172. *Monitoring Warrants*

(1) An inspector may apply to a magistrate for a warrant under this section in relation to premises.

(2) Subject to subsection (3), the magistrate may issue the warrant if the magistrate is satisfied, by information on oath, that it is reasonably necessary that one or more inspectors should have access to the premises for the purposes of finding out whether this Act or the regulations have been complied with.

(3) The magistrate must not issue the warrant unless the inspector or some other person has given to the magistrate, either orally or by affidavit, such further information (if any) as the magistrate requires concerning the grounds on which the issue of the warrant is being sought.

(4) The warrant must:

(a) authorise one or more inspectors (whether or not named in the warrant), with such assistance and by such force as is necessary and reasonable:

(i) To enter the premises.

(ii) To exercise the powers set out in section 153 in relation to the premises.

(b) state whether the entry is authorised to be made at any time of the day or night or during specified hours of the day or night.

(c) Specify the day (not more than 6 months after the issue of the warrant) on which the warrant ceases to have effect.

(d) State the purpose for which the warrant is issued.

173. *Offence-related Warrants*

(1) An inspector may apply to a magistrate for a warrant under this section in relation to premises.

(2) Subject to subsection (3), the magistrate may issue the warrant if the magistrate is satisfied, by information on oath, that there are reasonable grounds for suspecting that the-

re is, or there may be within the next 72 hours, evidential material in or on the premises.

(3) The magistrate must not issue the warrant unless the inspector or some other person has given to the magistrate, either orally or by affidavit, such further information (if any) as the magistrate requires concerning the grounds on which the issue of the warrant is being sought.

(4) The warrant must:

(a) Name one or more inspectors; and

(b) Authorise the inspectors so named, with such assistance and by such force as is necessary and reasonable:

(i) To enter the premises.

(ii) To exercise the powers set out in subsection 154(3) and section 155.

(iii) To seize the evidential material.

(c) State whether the entry is authorised to be made at any time of the day or night or during specified hours of the day or night.

(d) Specify the day (not more than one week after the issue of the warrant) on which the warrant ceases to have effect.

(e) State the purpose for which the warrant is issued.

174. *Offence-related Warrants by telephone, telex, fax, etcetera*

(1) If, in an urgent case, an inspector considers it necessary to do so, the inspector may apply to a magistrate by telephone, telex, fax or other electronic means for a warrant under section 173 in relation to premises.

(2) The magistrate may require communication by voice to the extent that it is practicable in the circumstances.

(3) Before applying for the warrant, the inspector must prepare an information of the kind mentioned in subsection 173(2) in relation to the premises that sets out the grounds on which the warrant is sought.

(4) If it is necessary to do so, the inspector may apply for the warrant before the information is sworn.

(5) If the magistrate is satisfied:

(a) After having considered the terms of the information.

(b) After having received such further information (if any) as the magistrate requires concerning the grounds on which the issue of the warrant is being sought; that there are reasonable grounds for issuing the warrant, the magistrate may complete and sign the same warrant that the magistrate would issue under section 173 if the application had been made under that section.

(6) If the magistrate completes and signs the warrant:

(a) The magistrate must:

(i) Tell the inspector what the terms of the warrant are.

(ii) Tell the inspector the day on which and the time at which the warrant was signed.

(iii) Tell the inspector the day (not more than one week after the magistrate completes and signs the warrant) on which the warrant ceases to have effect.

(iv) Record on the warrant the reasons for issuing the warrant.

(b) The inspector must:

(i) Complete a form of warrant in the same terms as the warrant completed and signed by the magistrate; and

(ii) Write on the form the name of the magistrate and the day on which

and the time at which the warrant was signed.

(7) The inspector must also, not later than the day after the day of expiry or execution of the warrant, whichever is the earlier, send to the magistrate:

(a) The form of warrant completed by the inspector.

(b) The information referred to in subsection (3), which must have been duly sworn.

(8) When the magistrate receives those documents, the magistrate must:

(a) Attach them to the warrant that the magistrate completed and signed.

(b) Deal with them in the way in which the magistrate would have dealt with the information if the application had been made under section 173.

(9) A form of warrant duly completed under subsection (6) is authority for any entry, search, seizure or other exercise of a power that the warrant signed by the magistrate authorises.

(10) If:

(a) It is material, in any proceedings, for a court to be satisfied that an exercise of a power was authorised by this section.

(b) The warrant signed by the magistrate authorising the exercise of the power is not produced in evidence; the court must assume, unless the contrary is proved, that the exercise of the power was not authorised by such a warrant.

(11) A reference in this Part to a warrant under section 173 includes a reference to a warrant signed by a magistrate under this section.

175. *Offences Relating to Warrants*

(1) An inspector must not make, in an application for a warrant, a statement that the inspector knows to be false or misleading in a material particular.

Maximum penalty: Imprisonment for 2 years or 120 penalty units.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

(2) An inspector must not:

(a) State in a document that purports to be a form of warrant under section 174 the name of a magistrate unless that magistrate issued the warrant.

(b) State on a form of warrant under that section a matter that, to the inspector's knowledge, departs in a material particular from the form authorised by the magistrate.

(c) Purport to execute, or present to another person, a document that purports to be a form of warrant under that section that the inspector knows:

(i) Has not been approved by a magistrate under that section.

(ii) Departs in a material particular from the terms authorised by a magistrate under that section.

(d) Give to a magistrate a form of warrant under that section that is not the form of warrant that the inspector purported to execute.

Maximum penalty: Imprisonment for 2 years or 120 penalty units.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

Division 11. Other Matters

176. *Part Not to Abrogate Privilege against Self-incrimination*

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.

177. *Part does not Limit Power to Impose Licence Conditions*

This Part is not to be taken to limit the Regulator's power to impose licence conditions.

PART 12. MISCELLANEOUS

Division 1. Simplified Outline

178. *Simplified Outline*

The following is a simplified outline of this Part:

This Part provides for miscellaneous matters, including the following:

(a) Review of decisions.

(b) Provisions relating to confidential commercial information.

(c) The making of regulations.

(d) Transitional provisions.

(e) Review of the operation of the Act.

Division 2. Review of Decisions

179. *Meaning of Terms*

The following table sets out:

(a) Decisions that are reviewable decisions.

(b) Each eligible person in relation to a reviewable decision:

Reviewable Decisions and Eligible Persons

Item	*Decision*	*Provision under which decision made*	*Eligible person in relation to decision*
1	To refuse to issue a licence	Section 55	The applicant for the licence
2	To impose a licence condition	Section 55	The licence holder
3	To suspend or cancel a licence	Section 68	The licence holder
4	To vary a licence	Section 71	The licence holder
5	To refuse to certify a facility	Section 84	The applicant for certification
6	To specify a condition of a certification	Section 86	The holder of the certification
7	To vary a certification	Section 87	The holder of the certification
8	To suspend or cancel a certification	Section 88	The holder of the certification
9	To refuse to accredit an organisation	Section 92	The applicant for accreditation
10	To specify a condition of an accreditation	Section 94	The holder of the accreditation
11	To vary an accreditation	Section 95	The holder of the accreditation
12	To suspend or cancel an accreditation	Section 96	The holder of the accreditation
13	To refuse to declare information to be confidential commercial information	Section 185	The person who made an application under section 184 in relation to the information
14	To revoke a declaration that information is confidential commercial information	Section 186	The person who made an application under section 184 in relation to the information

180. *Notification of Decisions and Review Rights*

(1) The Regulator must, as soon as practicable after making a reviewable decision, cause a notice in writing to be given to each eligible person in relation to the decision, containing:

(a) The terms of the decision.

(b) The reasons for the decision; and

(c) A statement setting out particulars of the person's review rights.

(2) A failure to comply with the requirements of subsection (1) in relation to a decision does not affect the validity of the decision.

181. *Internal Review*

(1) An eligible person in relation to a reviewable decision (other than a decision made by the Regulator personally) may apply in writing to the Regulator for review (internal review) of the decision.

(2) An application for internal review must be made within 30 days after the day on which the decision first came to the notice of the applicant, or within such period (if any) as the Regulator, either before or after the end of that period, allows.

(3) The Regulator must, on receiving an application, review the reviewable decision personally.

(4) The Regulator may:

(a) Make a decision affirming, varying or revoking the reviewable decision.

(b) If the Regulator revokes the decision, make such other decision as the Regulator thinks appropriate.

182. *Deadlines for Making Reviewable Decisions*

If:

(a) This Act provides for a person to apply to the Regulator to make a reviewable decision.

(b) A period is specified under this Act or the regulations for giving notice of the decision to the applicant.

(c) The Regulator has not notified the applicant of the Regulator's decision within that period; the Regulator is taken, for the purposes of this Act, to have made a decision to reject the application.

183. *Review of Decisions by Administrative Appeals Tribunal*

(1) Subject to the Administrative Appeals Tribunal Act 1975, an application may be made by an eligible person in relation to:

(a) A reviewable decision made by the Regulator personally.

(b) A decision made by the Regulator under section 181 (which provides for internal review).

(2) In this section:

Decision has the same meaning as in the Administrative Appeals Tribunal Act 1975.

183.A *Extended Standing for Judicial Review*

(1) This section extends (and does not limit) the meaning of the term person aggrieved in the Administrative Decisions (Judicial Review) Act 1977 for the purposes of the application of that Act in relation to:

(a) A decision made under this Act or the regulations.

(b) A failure to make a decision under this Act or the regulations.

(c) Conduct engaged in for the purpose of making a decision under this Act or the regulations.

(2) A State is taken to be a person aggrieved by the decision, failure or conduct.

(3) A term (except person aggrieved) used in this section and in the Administrative Decisions (*Judicial Review*) Act 1977 has the same meaning in this section as it has in that Act.

Division 3. Confidential Commercial Information

184. *Application for Protection of Confidential Commercial Information*

(1) A person may apply to the Regulator for a declaration that specified information to which this Act relates is confidential commercial information for the purposes of this Act.

(2) An application under subsection (1) must be in writing in the form approved by the Regulator.

185. *Regulator May Declare that Information is Confidential Commercial Information*

(1) Subject to subsection (2), if the person satisfies the Regulator that the information specified in the application is:

(a) A trade secret.

(b) Any other information that has a commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed.

(c) Other information that:

(i) Concerns the lawful commercial or financial affairs of a person, organisation or undertaking.

(ii) If it were disclosed, could unreasonably affect the person, organisation or undertaking; the Regulator must declare that the information is confidential commercial information for the purposes of this Act.

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

(2A) The Regulator must 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.

Note: This means that, in general, information about sites where dealings with GMOs are occurring will be required to be disclosed under sections 54 and 138, unless the Regulator is satisfied that disclosure would involve significant risks to health and safety.

(3) The Regulator must give the applicant written notice of the Regulator's decision about the application.

(3A) If:

(a) The Regulator declares that particular information is confidential commercial information.

(b) The information relates to one or more locations at which field trials involving GMOs are occurring, or are proposed to occur; the Regulator must make publicly available a statement of reasons for the making of the declaration, including, but not limited to:

(c) The reasons why the Regulator was satisfied as mentioned in subsection (1).

(d) The reasons why the Regulator was not satisfied under subsection (2) that the public interest in disclosure of the information outweighed the prejudice that the disclosure would cause.

(e) The reasons why the Regulator was satisfied under subsection (2A) that significant damage to the health and safety of people, the environment or property would be likely to occur if the locations were disclosed.

(4) If the Regulator refuses an application under subsection 184(1) in relation to information, the information is to be treated as confidential commercial information until any review rights under section 181 or 183 in relation to the application are exhausted.

186. *Revocation of Declaration*

(1) The Regulator may, by written notice given to the applicant, revoke a declaration under section 185 if the Regulator is satisfied:

(a) That the information concerned no longer satisfies paragraph 185(1)(a), (b) or (c).

(b) That the public interest in disclosure of the information outweighs the prejudice that disclosure would cause to any person.

(2) A revocation by the Regulator under subsection (1) does not take effect until any review rights under section 181 or 183 in relation to the revocation are exhausted.

187. *Confidential Commercial Information Must Not Be Disclosed*

(1) A person who:

(a) Has confidential commercial information.

(b) Has it only because of performing duties or functions under this Act or under a corresponding State law.

(c) Knows that the information is confidential commercial information; must not disclose the information except:

(d) To any of the following in the course of carrying out duties or functions under this Act or under a corresponding State law:

(i) The Commonwealth or a Commonwealth authority.

(ii) A State agency.

(iii) the Gene Technology Technical Advisory Committee.

(e) By order of a court.

(f) With the consent of the person who applied to have the information treated as confidential commercial information.

Maximum penalty: Imprisonment for 2 years or 120 penalty units.

Note 1: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

Note 2: Information to which subsection (1) applies is information to which section 38 of the Freedom of Information Act 1982 applies, because subsection (1) is listed in Schedule 3 to that Act.

(2) A person who:

(a) Has confidential commercial information.

(b) Has it because of a disclosure under subsection (1) or under this subsection.

(c) Knows that the information is confidential commercial information; must not disclose the information except:

(d) To any of the following in the course of carrying out duties or functions under this Act or under a corresponding State law:

(i) The Commonwealth or a Commonwealth authority.

(ii) A State agency.

(iii) The Gene Technology Technical Advisory Committee.

(e) By order of a court.

(f) With the consent of the person who applied to have the information treated as confidential commercial information.

Maximum penalty: Imprisonment for 2 years or 120 penalty units.

Note 1: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

Note 2: Information to which subsection (2) applies is information to which section 38 of the Freedom of Information Act 1982 applies, because subsection (2) is listed in Schedule 3 to that Act.

(3) In this section:

Court includes a tribunal, authority or person having power to require the production of documents or the answering of questions.

Disclose, in relation to information, means give or communicate in any way.

Division 4. Conduct by Directors, Employees and Agents

188. *Conduct by Directors, Employees and Agents*

(1) If, in proceedings for an offence against this Act or the regulations, or an ancillary offence in relation to this Act or the regulations, it is necessary to establish the state of mind of a body corporate in relation to particular conduct, it is sufficient to show:

(a) That the conduct was engaged in by a director, employee or agent of the body corporate within the scope of his or her actual or apparent authority.

(b) That the director, employee or agent had the state of mind.

(2) Any conduct engaged in on behalf of a body corporate by a director, employee or agent of the body corporate within the scope of his or her actual or apparent authority is taken, for the purposes of a prosecution for:

(a) An offence against this Act or the regulations; or

(b) An ancillary offence relating to this Act or the regulations; to have been engaged in also by the body corporate, unless the body corporate establishes that the body corporate took reasonable precautions and exercised due diligence to avoid the conduct.

(3) If, in proceedings for an ancillary offence relating to this Act or the regulations, it is necessary to establish the state of mind of a person other than a body corporate in relation to particular conduct, it is sufficient to show:

(a) That the conduct was engaged in by an employee or agent of the person within the scope of his or her actual or apparent authority.

(b) That the employee or agent had the state of mind.

(4) Any conduct engaged in on behalf of a person (the first person), other than a body corporate, by an employee or agent of the first person, within the scope of the actual or apparent authority of the employee or agent is taken, for the purposes of a prosecution for:

(a) An offence against this Act or the regulations.

(b) An ancillary offence relating to this Act or the regulations; to have been engaged in also by the first person unless the first person establishes that he or she took reasonable precautions and exercised due diligence to avoid the conduct.

(5)If:

(a) A person other than a body corporate is convicted of an offence; and

(b) The person would not have been convicted of the offence if subsections (3) and (4) had not been enacted; the person is not liable to be punished by imprisonment for that offence.

189. *Meaning of Terms*

(1) A reference in subsection 188(1) or (3) to the state of mind of a person includes a reference to:

(a) The knowledge, intention, opinion, belief or purpose of the person.

(b) The person's reasons for the intention, opinion, belief or purpose.

(2) A reference in section 188 to a director of a body corporate includes a reference to a constituent member of a body corporate incorporated for a public purpose by a law of the Commonwealth or a State.

(3) A reference in section 188 to engaging in conduct includes a reference to failing or refusing to engage in conduct.

(4) A reference in section 188 to an ancillary offence relating to this Act or the regulations is a reference to an offence created by section 5, 6, 7 or 7A or subsection 86 (1) of the Crimes Act 1914 that relates to this Act or the regulations.

Division 5. Transitional Provisions

190. *Transitional Provision-dealings covered by Genetic Manipulation Advisory Committee advice to Proceed*

(1) The prohibitions in this Act apply to a dealing with a GMO by a person at a particular time during the transition period (the dealing time) with the modifications set out in subsection (2), if:

(a) Immediately before the commencement of Part 4 of this Act, an advice to proceed was in force in relation to the dealing with the GMO by the person.

(b) The advice to proceed is in force at the dealing time.

(c) The dealing is in accordance with the advice to proceed.

(2) Unless the dealing is a notifiable low risk dealing, an exempt dealing or a dealing on the GMO Register:

(a) The advice to proceed is taken for the purposes of this Act to be a GMO licence.

(b) The holder of the advice to proceed is taken to be the licence holder.

(c) The licence is taken to be subject to any conditions to which the advice to proceed is subject.

(d) The licence is taken to remain in force for the period ending at the earliest of the following times:

(i) The time when the advice to proceed expires.

(ii) The end of the transition period.

(iii) When the licence is cancelled under section 68 or surrendered under section 69.

(3) In this section:

Advice to proceed means an advice to proceed issued by the Genetic Manipulation Advisory Committee, in accordance with Guidelines issued by that Committee.

Transition period means the period of 2 years beginning at the commencement of Part 4 of this Act.

191. *Regulations May Relate to Transitional Matters*

Regulations may be made in relation to transitional matters arising from the enactment of this Act.

Division 6. Other

192. *False or Misleading Information or Document*

A person must not:

(a) In connection with an application made to the Regulator under this Act or the regulations.

(b) In compliance or purported compliance with this Act or the regulations; do either of the following:

(c) Give information (whether orally or in writing) that the person knows to be false or misleading in a material particular.

(d) Produce a document that the person knows to be false or misleading in a material particular without:

(i) Indicating to the person to whom the document is produced that it is false or misleading, and the respect in which it is false or misleading.

(ii) Providing correct information to that person, if the person producing the document is in possession of, or can reasonably acquire, the correct information.

Maximum penalty: Imprisonment for 1 year or 60 penalty units.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

192. *A Interference with Dealings with GMOs*

(1) A person is guilty of an offence if:

(a) The person engages in conduct; and

(b) The conduct:

(i) Results in damage to, destruction of, or interference with, premises at which dealings with GMOs are being undertaken.

(ii) Involves damaging, destroying, or interfering with, a thing at, or removing a thing from, such premises.

(c) The owner or occupier of the premises, or the owner of the thing (as the case requires), has not consented to the conduct.

(d) In engaging in the conduct, the person intends to prevent or hinder

authorised GMO dealings that are being undertaken at the premises or facility.

(e) The person knows, or is reckless as to, the matters mentioned in paragraphs (b) and (c).

Maximum penalty: Imprisonment for 2 years or 120 penalty units.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

(2) In this section:

Authorised GMO dealings, in relation to premises or a facility, means dealings with GMOs being undertaken at the premises or facility:

(a) That are authorised to be undertaken at the premises or facility by a GMO licence.

(b) That are notifiable low risk dealings.

(c) That are exempt dealings.

(d) That are deregulated GMO dealings.

193. *Regulations*

(1) The governor-general may make regulations prescribing matters:

(a) Required or permitted by this Act to be prescribed.

(b) Necessary or convenient to be prescribed for carrying out or giving effect to this Act.

(2) Without limiting subsection (1), the regulations may require a person to comply with codes of practice or guidelines issued under this Act as in force at a particular time or from time to time.

194. *Review of operation of Act*

(1) The Ministerial Council must cause an independent review of the operation of this Act, including the structure of the Office of the Gene Technology Regulator, to be undertaken as soon as possible after the fourth anniversary of the commencement of this Act.

(2) A person who undertakes such a review must give the Ministerial Council a written report of the review.

(3) The minister, on behalf of the Ministerial Council, must cause a copy of the report of the review to be tabled in each House of the Parliament within 12 months after the fourth anniversary of the commencement of this Act.

(4) In this section:

Independent review means a review undertaken by persons who:

(a) In the opinion of a majority of the Ministerial Council possess appropriate qualifications to undertake the review.

(b) Include one or more persons who are not employed by the Commonwealth or a Commonwealth authority.