

Gene Technology Bill 2001

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Western Australia

LEGISLATIVE ASSEMBLY

(As amended during consideration in detail)

Gene Technology Bill 2001

A Bill for

An Act to regulate activities involving gene technology and for other purposes.

The Parliament of Western Australia enacts as follows:

Part 1 — Preliminary

1. Purpose and short title

- (1) This Act may be cited as the *Gene Technology Act 2001*.
- (2) The purpose of this Act is to regulate activities involving gene technology.
- (3) Without limiting subsection (1) and section 26(1) of the *Interpretation Act 1984*, this Act may be referred to as the *Gene Technology Law of Western Australia* or simply as the *Gene Technology Law*.

Note: This section differs from section 1 of the Commonwealth Act.

2. Commencement

- (1) This Act comes into operation on a day fixed by proclamation.
- (2) Different days may be fixed under subsection (1) for different provisions.

Note: This section differs from section 2 of the Commonwealth Act.

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 genetically modified organisms.

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;

- 5
- (a) provides an efficient and effective system for the application of gene technologies; and
 - (b) operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GMO products.

10 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**

15 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 genetically modified organisms by the Commonwealth and the States.

6. **Act to bind the Crown**

- 20
- (1) This Act binds the Crown in right of Western Australia and, so far as the legislative power of the Parliament permits, the Crown in all its other capacities.
 - (2) Nothing in this Act renders the Crown liable to be prosecuted for an offence.

7. **External Territories**

25 Note: The Commonwealth Act includes a provision extending that Act to every external Territory other than Norfolk Island.

8. **Offences**

Note: The Commonwealth Act includes a provision applying Chapter 2 of *The Criminal Code* to offences against that Act and construing penalty provisions in that Act.

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8A. Numbering

(1) In order to maintain consistent numbering between this Act and the *Gene Technology Act 2000* of the Commonwealth —

5 (a) if the Commonwealth Act contains a section that is not required in this Act, the provision number and heading to the section appearing in the Commonwealth Act are included in this Act despite the omission of the body of the section; and

10 (b) if this Act contains a section that is not included in the Commonwealth Act, the section is numbered so as to maintain consistency in numbering between sections common to both Acts.

(2) A provision number and heading referred to in subsection (1)(a) form part of this Act.

15 Note 1: A note appears under each heading of a kind referred to in subsection (1)(a) describing the omitted section of the Commonwealth Act.

Note 2: A note appears under each section of a kind referred to in subsection (1)(b) highlighting the non-appearance of an equivalent section in the Commonwealth Act.

20 Note 3: This section does not appear in the Commonwealth Act.

8B. Notes

Notes do not form part of this Act.

Note: This section does not appear in the Commonwealth Act.

8C. Outlines

25 The provisions appearing at the beginning of Parts 2 to 12 outlining that Part (“**simplified outlines**”) are intended only as a guide to readers as to the general scheme and effect of that Part.

Note: This section does not appear in the Commonwealth Act.

Part 2 — Interpretation and operation of Act

Division 1 — Simplified outline

9. Simplified outline

In outline this Part —

- 5
- contains the definitions used in this Act;
 - contains provisions to facilitate a nationally consistent regulatory scheme;
 - enables the Ministerial Council to issue policy principles, policy guidelines and codes of practice.

10 Note: This section differs from section 9 of the Commonwealth Act.

Division 2 — Definitions

10. Definitions

(1) In this Act —

15 “**accredited organisation**” means an organisation accredited under Part 7 Division 3;

“**Administrative Appeals Tribunal**” means the Administrative Appeals Tribunal established by the *Administrative Appeals Tribunal Act 1975* of the Commonwealth;

“**aggravated offence**” has the meaning given by section 38;

20 “**Commonwealth Act**” means the *Gene Technology Act 2000* of the Commonwealth;

“**Commonwealth authority**” means the following —

- 25
- (a) a body corporate established for a public purpose by or under a Commonwealth Act; or
 - (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;

5 **“Commonwealth Environment Minister”** means the Minister of State for the Commonwealth responsible for environment and conservation;

“confidential commercial information” means information declared by the Regulator to be confidential commercial information under section 185;

10 **“Consultative Committee”** means the Gene Technology Community Consultative Committee established by section 106 of the Commonwealth Act;

“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;

“deal with”, in relation to a GMO, means the following —

- 20 (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;
- 25 (f) grow, raise or culture the GMO; or
- (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);

30 **“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;

5

“Ethics Committee” means the Gene Technology Ethics Committee established by section 111 of the Commonwealth Act;

“evidential material” means any of the following —

10

(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;

15

(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;

20

“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;

25

(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 —

30

(a) sexual reproduction;

(b) homologous recombination; or

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Part 2 Interpretation and operation of Act

Division 2 Definitions

s. 10

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

5 **“Gene Technology Account”** means the Gene Technology Account established by section 129 of the Commonwealth Act;

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

10 **“Gene Technology Technical Advisory Committee”** means the Gene Technology Technical Advisory Committee established by section 100 of the Commonwealth Act;

“genetically modified organism” means —

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

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

20 (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 —

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

30 (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 of the Commonwealth Act;

“**GM product**” means a thing (other than a GMO) derived or produced from a GMO;

5 “**Institutional Biosafety Committee**” means a committee established by an accredited organisation as an Institutional Biosafety Committee;

“**jurisdiction**” means the following —

- (a) a State; or
- 10 (b) the Commonwealth;

“**licence holder**” means the holder of a GMO licence;

“**Ministerial Council**” means the Ministerial Council within the meaning of the Gene Technology Agreement;

15 “**notifiable low risk dealing**” has the meaning given by section 74;

“**officer**”, in relation to the Commonwealth, includes the following —

- (a) a Minister of the Crown in right of the Commonwealth;
- 20 (b) a person who holds —
 - (i) an office established by or under a Commonwealth Act;
 - (ii) an appointment made under a Commonwealth Act; or
 - 25 (iii) an appointment made by the Governor-General or a Minister of the Crown in right of the Commonwealth but not under a Commonwealth Act;
- 30 (c) a person who is a member or officer of a Commonwealth authority;

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Part 2 Interpretation and operation of Act

Division 2 Definitions

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

“organism” means any biological entity that is —

- 5 (a) viable;
(b) capable of reproduction; or
(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;

10 **“premises”** includes the following —

- (a) a building;
(b) a place (including an area of land);
(c) a vehicle;
(d) a vessel;
15 (e) an aircraft;
(f) a facility;
(g) any part of premises (including premises referred to in paragraphs (a) to (f));

20 **“Record”** means the Record of GMO and GM Product Dealings mentioned in section 138 of the Commonwealth Act;

“Regulator” means the Gene Technology Regulator appointed under section 118 of the Commonwealth Act;

“reviewable decision” has the meaning given by section 179;

25 **“State”** includes the Australian Capital Territory and the Northern Territory;

“State agency” means —

- (a) the Crown in right of Western Australia;
30 (b) a Minister of the Crown in right of Western Australia;

- (c) an agency within the meaning of the *Public Sector Management Act 1994*;
- (d) an instrumentality of the State of Western Australia, including a body corporate established for a public purpose by or under a law of the State of Western Australia; or
- (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 Western Australia;
- (ii) a person or body covered by paragraph (b) or (d);
- (iii) a body covered by any 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

Note: The Commonwealth Act includes a provision defining “corresponding State law” for the purposes of that Act.

12A. Meaning of reckless

(1) For the purposes of this Act a person is reckless with respect to circumstances if —

- 5
- (a) the person is aware of a substantial risk that the circumstance exists or will exist; and
 - (b) having regard to the circumstances known to the person, it is unjustifiable to take the risk.

(2) For the purposes of this Act a person is reckless with respect to a result if —

- 10
- (a) the person is aware of a substantial risk that the result will occur; and
 - (b) having regard to the circumstances known to the person, it is unjustifiable to take the risk.

(3) The question whether taking a risk is unjustifiable is one of fact.

15 Note: This section is not required in the Commonwealth Act.

Division 3 — Operation of Act

13. Operation of Act

Note: The Commonwealth Act includes a provision about the application of that Act.

20 **14. Wind-back of reach of Act**

Note: The Commonwealth Act includes a provision about the giving of wind-back notices to a State.

15. Relationship to other State laws

25 The provisions of this Act are in addition to, and not in substitution for, the requirements of any other law of Western Australia (whether passed or made before or after the commencement of this section).

Note: The equivalent section in the Commonwealth Act deals with the relationship of that Act to other Commonwealth laws.

**Division 4 — Provisions to facilitate a nationally
consistent scheme**

Subdivision A — General provisions

16. State laws may operate concurrently

5 Note: The Commonwealth Act includes a provision allowing State laws (apart from State laws prescribed for the purposes of the provision) to operate concurrently with that Act.

17. Conferral of functions on Commonwealth officers and bodies

10 Note: The Commonwealth Act includes a provision allowing corresponding State laws to confer functions, powers and duties on certain Commonwealth officers and bodies.

18. No doubling-up of liabilities

(1) If —

- 15 (a) an act or omission is an offence against this Act and is also an offence against the Commonwealth Act; and
- (b) the offender has been punished for the offence under the Commonwealth Act,

20 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 the Commonwealth Act, the person is not liable to a pecuniary penalty under this Act in respect of the same conduct.

19. Review of certain decisions

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

(2) A decision made by the Regulator in the performance of a function or the exercise of a power conferred by this Act is a **“reviewable decision”** for the purposes of this section if —

(a) this Act provides for review by the Administrative Appeals Tribunal; and

(b) the decision is declared by the regulations made under the Commonwealth Act to be a reviewable State decision for the purposes of section 19 of the Commonwealth Act.

(3) The *Administrative Appeals Tribunal Act 1975* of the Commonwealth (excluding Part IVA) and the regulations in force for the time being under that Act apply as laws of Western Australia in relation to reviewable decisions.

(4) For the purposes of this section, a reference in a provision of the *Administrative Appeals Tribunal Act 1975* of the Commonwealth (as that provision applies as a law of Western Australia) to the whole or any part of Part IVA of that Act is taken to be a reference to the whole or any part of that Part as it has effect as a law of the Commonwealth.

Note: This section differs from section 19 of the Commonwealth Act.

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 the Commonwealth Act.

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 a law of Western Australia for the purpose of preserving the identity of one or both of the following —

- 5
- (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.

10 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: Section 43 of the *Interpretation Act 1984* confers power to revoke or amend any subsidiary legislation.

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

(3) Regulations for the purposes of subsection (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.

20 Note: This section differs from section 21 of the Commonwealth Act.

22. Consultation on policy principles

Note: The Commonwealth Act includes a provision about how policy principles are to be developed.

23. Ministerial Council may issue policy guidelines

25 The Ministerial Council may issue policy guidelines in relation to matters relevant to the functions of the Regulator under this Act or the regulations.

30 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: Section 43 of the *Interpretation Act 1984* confers power to revoke or amend any subsidiary legislation.

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Part 2 Interpretation and operation of Act

Division 4 Provisions to facilitate a nationally consistent scheme

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24. Ministerial Council may issue codes of practice

The Ministerial Council may issue codes of practice, developed in accordance with section 24(2) of the Commonwealth Act, in relation to gene technology.

5

Note 1: Section 43 of the *Interpretation Act 1984* confers power to revoke or amend any subsidiary legislation.

Note 2: Section 24 of the Commonwealth Act includes provisions about how codes of practice are to be developed and making them disallowable instruments.

Part 3 — The Gene Technology Regulator

25. Simplified outline

In outline this Part specifies the functions and powers of the Gene Technology Regulator under this Act or the regulations.

5 Note: This section differs from section 25 of the Commonwealth Act.

26. The Gene Technology Regulator

Note: Section 26 of the Commonwealth Act creates the office of Gene Technology Regulator.

27. Functions of the Regulator

10 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;
- 15 (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;
- 20 (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
 - 25 (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;

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- (i) to promote the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies;
- 5 (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 places outside Western Australia;
- 10 (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 under this Act or the regulations.

29. Delegation

- (1) The Regulator may, by instrument in writing, delegate any of the Regulator's powers or functions under this Act or the regulations to any of the following —
 - (a) a public service officer;
 - (b) an officer of an organisation within the meaning of the *Public Sector Management Act 1994*, if the functions of the organisation relate, whether directly or indirectly, to GMOs or GM products;
 - 25 (c) an employee of a Commonwealth authority, if the functions of the Commonwealth authority relate, whether directly or indirectly, to GMOs or GM products.

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

Note: This section differs from section 29 of the Commonwealth Act.

5 **30. Independence of the Regulator**

Subject to this Act and to other laws of the State of Western Australia, the Regulator has discretion in the performance or exercise of his or her functions or powers under this Act or the regulations. In particular, the Regulator is not subject to
10 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

In outline this Part —

- 5
- deals with the regulation of dealings with GMOs;
 - prohibits dealings with GMOs unless —
 - (a) the person undertaking the dealing is authorised to do so by a GMO licence;
 - 10 (b) the dealing is a notifiable low risk dealing (see Part 6 Division 2);
 - (c) the dealing is an exempt dealing; or
 - (d) the dealing is included in the GMO Register (see Part 6 Division 3);
 - 15 • imposes heavier penalties on unlawful dealings that cause, or are likely to cause, significant damage to the health and safety of people or the environment.

Division 2 — Dealings with GMOs must be licensed

32. Person not to deal with a GMO without a licence

- 20
- (1) A person commits an offence if —
- (a) the person deals with a GMO, knowing that it is a GMO;
 - (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;
 - 25 (c) the person knows that the dealing with the GMO is not a notifiable low risk dealing or is reckless as to whether or not the dealing is a notifiable low risk dealing;

- (d) the person knows that the dealing with the GMO is not an exempt dealing or is reckless as to whether or not the dealing is an exempt dealing; and
- 5 (e) the person knows that the dealing with the GMO is not included in the GMO Register or is reckless as to whether or not the dealing is included on the GMO Register.
- (1a) The offence under subsection (1) is a crime if the offence is an aggravated offence.
- 10 Note: Section 38 defines “aggravated offence”.
- (2) A person who commits an offence under subsection (1) is liable —
- (a) if it is a simple offence, to imprisonment for 2 years or a fine of \$55 000; or
- 15 (b) if it is a crime, to imprisonment for 5 years or a fine of \$220 000.
- (2a) A person charged with an offence under subsection (1) may be convicted of an offence under section 33(1), if that offence is established by the evidence.
- 20 (3) In this section —
- “**exempt dealing**” means a dealing specified by the regulations to be an exempt dealing.
- (4) Regulations made under subsection (3) may be expressed to exempt —
- 25 (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; or
- 30 (c) one or more specified dealings with a GMO or with a specified class of GMOs.

Note: This section differs from section 32 of the Commonwealth Act.

33. Person not to deal with a GMO without a licence — strict liability offence

(1) A person commits an offence if —

- (a) the person deals with a GMO, knowing that it is a GMO;
- 5 (b) the dealing with the GMO by the person is not authorised by a GMO licence;
- (c) the dealing with the GMO is not a notifiable low risk dealing;
- (d) the dealing with the GMO is not an exempt dealing;
- 10 (e) the dealing with the GMO is not included on the GMO Register.

(2) Note: Section 33(2) of the Commonwealth Act provides that strict liability applies to subsection (1)(b), (c), (d) and (e).

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

- (a) in the case of an aggravated offence — \$22 000; or
- (b) in any other case — \$5 500.

Note: Section 38 defines “aggravated offence”.

(4) In this section —

20 **“exempt dealing”** has the same meaning as in section 32.

Note: This section differs from section 33 of the Commonwealth Act.

34. Person must not breach conditions of a GMO licence

(1) The holder of a GMO licence commits an offence if the holder —

- 25 (a) intentionally takes an action or omits to take an action; and
- (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.

(1a) The offence under subsection (1) is a crime if the offence is an aggravated offence.

Note: Section 38 defines "aggravated offence".

5 (1b) A person charged with an offence under subsection (1) may be convicted of an offence under section 35(1), if that offence is established by the evidence.

(2) A person covered by a GMO licence commits an offence if —

- 10 (a) the person intentionally takes an action or omits to take an action;
- (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.

15 (2a) The offence under subsection (2) is a crime if the offence is an aggravated offence.

Note: Section 38 defines "aggravated offence".

20 (2b) A person charged with an offence under subsection (2) may be convicted of an offence under section 35(2), if that offence is established by the evidence.

(3) A person who commits an offence under this section is liable —

- 25 (a) if it is a simple offence, to imprisonment for 2 years or a fine of \$55 000 and an additional fine not exceeding \$5 500 for every day during which the offence continues;
- (b) if it is a crime, to imprisonment for 5 years or a fine of \$220 000 and an additional fine not exceeding \$22 000 for every day during which the offence continues.

Note: This section differs from section 34 of the Commonwealth Act.

35. Person must not breach conditions of a GMO licence — strict liability offence

- (1) The holder of a GMO licence commits an offence if —
- (a) the holder takes an action or omits to take an action; and
 - (b) the action or omission contravenes the licence.

- (2) A person covered by a GMO licence commits an offence if —
- (a) the person takes an action or omits to take an action;
 - (b) the action or omission contravenes the licence; and
 - (c) the person has knowledge of the conditions of the licence.

- (3) Note: Section 35(3) of the Commonwealth Act provides that strict liability applies to paragraphs (1)(a) and (b) and (2)(a) and (b).

- (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 — \$22 000; or
- (b) in any other case — \$5 500.

Note 1: Section 38 defines “aggravated offence”.

Note 2: This section differs from section 35 of the Commonwealth Act.

36. Person must not breach conditions on GMO Register

A person commits an offence if —

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

Penalty: \$5 500.

Note: This section differs from section 36 of the Commonwealth Act.

37. Offence relating to notifiable low risk dealings

A person commits an offence if —

- (a) the person deals with a GMO, knowing that it is a GMO;
- (b) the dealing is a notifiable low risk dealing; and
- 5 (c) the dealing by the person was not undertaken in accordance with the regulations.

Penalty: \$5 500.

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

10 Note 2: This section differs from section 37 of the Commonwealth Act.

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

- 15 (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 —
 - 20 (a) intended their conduct to cause significant damage to the health and safety of people or to the environment; or
 - (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

In outline this Part —

- 5
- provides a licensing system under which a person can apply to the Regulator for a licence authorising dealings with GMOs;
 - sets out the processes to be followed by the Regulator in relation to applications involving 2 kinds of dealings —
10
 - (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;
 - provides that a licence can cover dealings by persons other than the licence holder and requires the licence holder to
15 inform such persons of any conditions of the licence that apply to them.

Division 2 — Licence applications

40. Person may apply for a licence

- 20
- (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 —
25
 - (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.
- 5 (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;
 - (b) a specified class of dealings with a GMO, or with a specified class of GMOs; or
 - 10 (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 —
- 15 (a) a specified person or persons;
 - (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

- 20 (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

- 25 (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.
- 5 (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;
 - 10 (b) the application does not satisfy section 40(3);
 - (c) the application is not accompanied by the application fee (if any) prescribed by the regulations;
 - (d) the applicant did not provide further information required by the Regulator by notice under section 42
15 within the period specified in the notice; or
 - (e) the Regulator is satisfied that to issue the licence would be inconsistent with a policy principle in force under section 21.
- 20 (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
25 application.

45. Regulator must not use certain information in considering licence application

- If —
- 30 (a) a person (the “**first person**”) applies for a GMO licence;

- (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,
- 5 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.

10 **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

15 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.
- 20 (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.
- 25 (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; and
 - (b) the environment.

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Part 5 Licensing system

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

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- (4) The Regulator may consult —
- (a) the States;
 - (b) the Gene Technology Technical Advisory Committee;
 - (c) relevant Commonwealth authorities or agencies;
 - 5 (d) any local government that the Regulator considers appropriate; and
 - (e) any other person the Regulator considers appropriate,
- on any aspect of the application.

**Division 4 — Initial consideration of licences for dealings
10 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
15 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
20 proposed to be authorised by the licence may pose significant risks to the health and safety of people or the environment, the Regulator must publish a notice in respect of the application —
- (a) in the *Gazette*;
 - (b) in a newspaper circulating generally in Western Australia; and
 - 25 (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 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;
 - 5 (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;
 - 10 (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;
 - 15 (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;
 - 20 (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 —
 - 25 (i) under section 51(1)(a) in preparing a risk assessment in relation to the dealings proposed to be authorised by the licence; and
 - (ii) under section 51(2)(a) in preparing a risk management plan in relation to those dealings;
 - and
 - 30 (d) specify the closing date for submissions, which must not be earlier than 30 days after the date on which the notice was published.

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Part 5 Licensing system

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

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50. Regulator must prepare risk assessment and risk management plan

- 5
- (1) Before issuing the licence, the Regulator must prepare a risk assessment and a risk management plan in relation to the dealing 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.
- 10 (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;
- 15 (c) each Commonwealth authority or agency prescribed by the regulations for the purposes of this paragraph;
- (d) the Commonwealth Environment Minister; and
- (e) any local government that the Regulator considers appropriate.

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

- 20
- (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 —
- 25 (a) the risks posed by those dealings, including any risks to the health and safety of people or risks to the environment having regard to the matters mentioned in section 49(2)(a) to (f);
- (b) any submission made under section 49(3)(c) in relation to such risks;

- (c) any advice in relation to the risk assessment provided by the State or a local government in response to a request under section 50(3);
- 5 (d) any advice in relation to the risk assessment provided by the Gene Technology Technical Advisory Committee in response to a request under section 50(3);
- (e) any advice in relation to the risk assessment provided by a Commonwealth authority or agency in response to a request under section 50(3);
- 10 (f) any advice in relation to the risk assessment provided by the Commonwealth Environment Minister in response to a request under section 50(3);
- (g) any other matter prescribed by the regulations for the purposes of this paragraph.
- 15 (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 —
- 20 (i) the health and safety of people; and
- (ii) the environment;
- (b) any submissions made under section 49(3)(c) in relation to the means of managing such risks;
- (c) any advice in relation to the risk management plan provided by the State or a local government in response to a request under section 50(3);
- 25 (d) any advice in relation to the risk management plan provided by the Gene Technology Technical Advisory Committee in response to a request under section 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 section 50(3);
- 30

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- 5
- (f) any advice in relation to the risk management plan provided by the Commonwealth Environment Minister in response to a request under section 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 subsection (2)(a), the Regulator —
- 10 (a) is not limited to considering submissions or advice mentioned in subsection (2)(b), (c), (d), (e) or (f); and
 - (b) subject to section 45, may take into account other information, including, but not limited to, relevant independent research.

15 **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 —
- 20 (a) in the *Gazette*;
 - (b) in a newspaper circulating generally in Western Australia; and
 - (c) on the Regulator's website (if any).
- (2) The notice must —
- 25 (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;
 - (b) state that a person may request further information about the risk assessment and the risk management plan under section 54;
 - 30 (c) invite written submissions in relation to the risk assessment and the risk management plan; and

- (d) specify the closing date for submissions, which must not be earlier than 30 days after the date on which the notice was published.
- 5 (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;
- 10 (d) the Commonwealth Environment Minister; and
- (e) any local government that the Regulator considers appropriate.

53. Regulator may take other actions

- 15 (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.
- 20 (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
- 25 documents produced, at a public hearing.
- (4) A person must not contravene a direction given under subsection (3).
Penalty: \$3 300.

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;
- 5 (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 —

- 10 (a) any confidential commercial information contained in the documents; and
- (b) any information contained in the documents about relevant convictions (within the meaning of section 58) of the applicant for the licence.

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

Division 5 — Decision on licence etc.

55. Regulator must make a decision on licence and licence conditions

20 After taking any steps required by Division 3 or 4 in relation to an application for a GMO licence, the Regulator —

- (a) must decide whether to issue or refuse to issue the licence; and
- 25 (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; and
- (b) the environment.

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

- 10 (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;
- 15 (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; or
 - 20 (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

- 25 (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

- 5 (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 —
- 10 (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 Western Australia, the Commonwealth, another State or a foreign country, relating to the health and safety of people or the environment; and
 - (c) the capacity of the person to meet the conditions of the licence.
- 15 (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 —
- 20 (a) any relevant conviction of the body corporate;
 - (b) if there is a relevant conviction of the body corporate —
 - 25 (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; and
 - (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;
 - 30 (c) any revocation or suspension of a licence or permit (however described) held by the body corporate under a law of Western Australia, the Commonwealth, another State or a foreign country, relating to the health and safety of people or the environment; and

(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 Western Australia, the Commonwealth, another 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; and

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

Note: This section differs from section 58 of the Commonwealth Act.

15 **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

20 (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; or

(b) otherwise — until it is cancelled or surrendered.

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

25 **Division 6 — Conditions of licence**

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 derived 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;

- 5 (m) supervision by, and monitoring by, Institutional Biosafety Committees;
- (n) contingency planning in respect of unintended effects of the dealings authorised by the licence;
- 5 (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.
- 10

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 —
- 15 (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 —
- 20 (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.
- 25 (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; and

5 (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 purposes of auditing or monitoring the dealing.

10 (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**

15 (1) It is a condition of a licence that the licence holder inform the
Regulator if the licence holder —

(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;

20 (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.

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

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

30 (b) the licence holder is taken to have become aware of
contraventions, or unintended effects, of a kind
mentioned in subsection (1) if the licence holder 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 the person —

- 5
- (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
 - 10 (c) becomes aware of any unintended effects of the dealings authorised by the licence.

67. Protection of persons who give information

15 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 a licence if —

- 20
- (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;
 - 25 (c) any annual charge payable in respect of the licence remains unpaid after the due date;
 - (d) the licence was obtained improperly;
 - 30 (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; or

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

69. Surrender of licence

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

70. Transfer of licence

- 10 (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.
- (2) The application must be in writing, and must contain —
- 15 (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 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 —
- 20 (a) the health and safety of people; and
- (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.
- 25 (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; and
 - (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.

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; or
- (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 authorised 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

- 5 (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 —
- 10 (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; and
- 15 (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 —
- 20 (a) must give the information referred to in subsection (2)(b); and
- (b) may make a submission under subsection (2)(c).
- The period must not end earlier than 30 days after the day on which the notice was given.
- 25 (4) In considering whether to suspend, cancel or vary a licence, the Regulator must have regard to any submission made under subsection (2)(c).
- (5) The section does not apply to a suspension, cancellation or variation requested by the licence holder.
- 30 (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.

Division 8 — Annual charge

72A. GMO licence — annual charge

- 5 (1) A person who is the holder of a GMO licence at any time during a financial year is liable to pay a charge for the licence in respect of that year.
- (2) The amount of the charge for a financial year is such amount as is prescribed by the regulations.

10 Note 1: This section does not appear in the Commonwealth Act but charges are imposed under the *Gene Technology (Licence Charges) Act 2000* of the Commonwealth.

 Note 2: See also the *Gene Technology Amendment Act 2001*.

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

Division 1 — Simplified outline

73. Simplified outline

5 In outline this Part —

- establishes a mechanism for the regulations to regulate certain dealings with GMOs (“**notifiable low risk dealings**”) that do not involve the intentional release of GMOs into the environment (see Division 2);
- 10 • provides that the regulations may (among other things) require that the Regulator be notified of such dealings;
- enables the Regulator to determine that certain dealings previously authorised by a licence be included on the GMO Register;
- 15 • ensures that, if a dealing is included on the GMO Register, anyone may undertake the dealing, subject to specified conditions.

Note: This section differs from section 73 of the Commonwealth Act.

Division 2 — Notifiable low risk dealings

20 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 makes regulations declaring a dealing with a GMO to be a notifiable low risk dealing, the Regulator must
25 be satisfied that the dealing would not involve the intentional release of a GMO into the environment.

- (3) Before the Governor makes regulations declaring a dealing with a GMO to be a notifiable low risk dealing, the Regulator must consider the following matters —
- 5 (a) whether the GMO is biologically contained so that it is not able to survive or reproduce without human intervention;
 - 10 (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).
- 15 (4) Regulations under subsection (1) may be expressed to apply to —
- (a) all dealings with a GMO or with a specified class of GMOs;
 - 20 (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.

75. Regulation of notifiable low risk dealings

- (1) The regulations may regulate —
- 25 (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.

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GMO Register

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(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 —

- 5
- (a) the class of person 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;
 - 10 (d) the containment level of facilities in which notifiable
low risk dealings may be undertaken.

Division 3 — The GMO Register

76. The GMO Register

Note: Section 76 of the Commonwealth Act provides for the establishment
and maintenance of the GMO Register.

15 **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 —

- 20
- (a) a description of the dealing with the GMO; and
 - (b) any condition to which the dealing is subject.

**78. Regulator may include dealings with GMOs on GMO
Register**

- 25
- (1) The Regulator may, by writing, determine that the dealing with
the 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; or
 - (b) the GMO concerned —
 - (i) is a GM product; and

(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 —

- 5 (a) on application by the holder of a licence that authorises the dealing; or
(b) on the initiative of the Regulator.

10 (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.

Note: Section 78(4) of the Commonwealth Act provides for determinations to be disallowable instruments.

15 **79. Regulator not to make determination unless risks can be managed**

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

- 20 (a) that any risks posed by the dealing are minimal; and
(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.

25 (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;
30 (b) any other information as to risks associated with the dealing of which the Regulator is aware, including information provided by the Regulator by a licence holder under section 65 or by another person under section 66;

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- (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.
- 5 (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.
- 10 (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; or
 - (c) impose additional conditions to which a dealing on the
- 15 GMO Register is subject.

Note: Section 80(3) of the Commonwealth Act provides for determinations to be disallowable instruments.

81. Inspection of Register

- 20 Note: Section 81 of the Commonwealth Act requires the Regulator to permit any person to inspect the GMO Register.

Part 7 — Certification and accreditation

Division 1 — Simplified outline

82. Simplified outline

In outline this Part —

- 5
- 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 (see Division 2);
- 10
- 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 (see
- 15
- Division 3).

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.
- 20 (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.

- 25 (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

- 5 (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.

10 **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;
- 15 (b) any conditions imposed by the Regulator under section 87 after certification;
- (c) any conditions imposed by the regulations.

87. Variation of certification

- 20 (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.

25 **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

- 5 (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 —
- 10 (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; and
- 15 (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 —
- 20 (a) must give the information referred to in subsection (2)(b); and
- (b) may make a submission under subsection (2)(c).
- The period must not end earlier than 30 days after the day on which the notice was given.
- 25 (4) In considering whether to suspend, cancel or vary a certification, the Regulator must have regard to any submission made under subsection (2)(c).
- (5) This section does not apply to a suspension, cancellation or variation requested by the holder of the certification.
- 30 (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

- 5
- (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

10 **91. Application for accreditation**

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

15 Note: The conditions of a licence may require supervision of dealings by an Institutional Biosafety Committee established by an accredited organisation (see section 62(2)(m)), and the regulations may require such supervision of notifiable low risk dealings (see section 75(2)(c)).

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

92. Regulator may accredit organisations

- 20
- (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 —

- 25
- (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;
- 5 (c) whether the organisation has, or will have, appropriate indemnity arrangements for its Institutional Biosafety Committee members; and
- (d) any other matters specified in such guidelines.

93. Regulator may require applicant to give further information

- 10 (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.

15 **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;
- 20 (b) any conditions imposed by the Regulator under section 95 after accreditation;
- (c) any conditions prescribed by the regulations.

95. Variation of accreditation

- 25 (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

5 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

10 (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 —

- 15 (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; and
- 20 (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 —

- 25 (a) must give the information referred to in subsection (2)(b); and
- (b) may make a submission under subsection (2)(c).

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

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

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Part 8 The Gene Technology Technical Advisory Committee, the Gene Technology Community Consultative Group and the Gene Technology Ethics Committee

Division 1 Simplified outline

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Part 8 — The Gene Technology Technical Advisory Committee, the Gene Technology Community Consultative Group and the Gene Technology Ethics Committee

5

Division 1 — Simplified outline

99. Simplified outline

10 In outline this Part sets out the functions under this Act of the Gene Technology Technical Advisory Committee, the Gene Technology Community Consultative Committee and the Gene Technology Ethics Committee.

Note: This section differs from section 99 of the Commonwealth Act.

Division 2 — The Gene Technology Technical Advisory Committee

100. The Gene Technology Technical Advisory Committee

15

Note: Section 100 of the Commonwealth Act provides for the establishment and membership of the Gene Technology Technical Advisory Committee.

101. Function of the Gene Technology Technical Advisory Committee

20

The function of the Gene Technology Technical Advisory Committee under this Act is to provide scientific and technical advice, on the request of the Regulator or the Ministerial Council, on the following —

25

- (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

5 Note: Section 102 of the Commonwealth Act provides for the appointment of expert advisers to the Gene Technology Technical Advisory Committee.

103. Remuneration

Note: Section 103 of the Commonwealth Act provides for the payment of remuneration and allowances to members of, and expert advisers to, the Gene Technology Technical Advisory Committee.

10 **104. Members and procedures**

Note: Section 104 of the Commonwealth Act empowers the making of regulations relating to the membership and operation of the Gene Technology Technical Advisory Committee.

105. Subcommittees

15 Note: Section 105 of the Commonwealth Act deals with the establishment of subcommittees by the Gene Technology Technical Advisory Committee.

Division 3 — The Gene Technology Community Consultative Committee

106. The Gene Technology Community Consultative Committee

20 Note: Section 106 of the Commonwealth Act establishes the Gene Technology Community Consultative Committee.

107. Function of Consultative Committee

25 The function of the Consultative Committee under this Act 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;

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Division 4 The Gene Technology Ethics Committee

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- (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.

5 **108. Membership**

Note: Section 108 of the Commonwealth Act provides for the membership of the Consultative Committee.

109. Remuneration

10 Note: Section 109 of the Commonwealth Act provides for the payment of remuneration and allowances to members of the Consultative Committee.

110. Regulations

Note: Section 110 of the Commonwealth Act empowers the making of regulations relating to the membership and operation of the Consultative Committee.

15 **110A. Subcommittees**

Note: Section 110A of the Commonwealth Act deals with the establishment of subcommittees by the Consultative Committee.

Division 4 — The Gene Technology Ethics Committee

111. The Gene Technology Ethics Committee

20 Note: Section 111 of the Commonwealth Act provides for the establishment and membership of the Gene Technology Ethics Committee.

112. Function of the Gene Technology Ethics Committee

25 The function of the Gene Technology Ethics Committee under this Act 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

5 Note: Section 113 of the Commonwealth Act provides for the appointment of expert advisers to the Ethics Committee.

114. Remuneration

10 Note: Section 114 of the Commonwealth Act provides for the payment of remuneration and allowances to members of, and expert advisers to, the Ethics Committee.

115. Members and procedures

Note: Section 115 of the Commonwealth Act empowers the making of regulations relating to the membership and operation of the Ethics Committee.

15 **116. Subcommittees**

Note: Section 116 of the Commonwealth Act deals with the establishment of subcommittees by the Ethics Committee.

Part 9 — Administration

Division 1 — Simplified outline

117. Simplified outline

In outline this Part —

- 5 • provides for financial matters (see Division 3);
- sets out reporting requirements (see Division 5);
- requires the Regulator to ensure that certain information is entered on a record of GMOs and GM products (see Division 6);
- 10 • permits the Regulator to review notifiable low risk dealings and exemptions (see Division 7).

Note: This section differs from section 117 of the Commonwealth Act.

Division 2 — Appointment and conditions of Regulator

118. Appointment of the Regulator

15 Note: Section 118 of the Commonwealth Act provides for the appointment of the Regulator.

119. Termination of appointment

Note: Section 119 of the Commonwealth Act sets out the circumstances in which the Regulator's appointment may be terminated.

120. Disclosure of interests

20 Note: Section 120 of the Commonwealth Act requires the Regulator to disclose his or her interests to the Minister.

121. Acting appointment

25 Note: Section 121 of the Commonwealth Act deals with the appointment of a person to act as the Regulator.

122. Terms and conditions

Note: Section 122 of the Commonwealth Act deals with the terms and conditions of appointment of the Regulator.

123. Outside employment

5 Note: Section 123 of the Commonwealth Act prohibits the Regulator from engaging in paid outside employment without the approval of the Minister.

124. Remuneration

Note: Section 124 of the Commonwealth Act provides for the payment of remuneration and allowances to the Regulator.

10 **125. Leave of absence**

Note: Section 125 of the Commonwealth Act deals with the entitlement of the Regulator to leave of absence.

126. Resignation

15 Note: Section 126 of the Commonwealth Act deals with the procedure for resignation by the Regulator.

Division 3 — Money

127. Regulator may charge for services

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

128. Notional payments by the State

- (1) The purpose of this section is to ensure that fees and charges under this Act and the regulations are notionally payable by the State of Western Australia and bodies representing the State.
- 25 (2) The Minister responsible for administering the *Financial Administration and Audit Act 1985* may give written directions for the purpose of this section, including directions relating to the transfer of accounts within, or between, accounts operated by the State of Western Australia.

30 Note: This section differs from section 128 of the Commonwealth Act.

129. Gene Technology Account

Note: Section 129 of the Commonwealth Act provides for the establishment of the Gene Technology Account.

130. Credits to Gene Technology Account

- 5 (1) There must be paid to the Commonwealth for crediting to the Gene Technology Account the following —
- 10 (a) amounts equal to money from time to time received by the State of Western Australia under Part 5 Division 8;
 - (b) amounts equal to fees received by the State of Western Australia under sections 40(6) and 83(3);
 - 15 (c) amounts equal to amounts received by the State of Western Australia in connection with the performance of the Regulator's functions under this Act or the regulations;
 - (d) amounts equal to amounts recovered by the State of Western Australia under section 146(5) or 158(4) to the extent that they are referable to costs paid out of the Gene Technology Account.
- 20 (2) The Consolidated Fund is appropriated to the necessary extent to enable amounts to be paid to the Commonwealth in accordance with subsection (1).

Note: This section differs from section 130 of the Commonwealth Act.

131. Recovery of amounts

25 The following amounts may be recovered in a court of competent jurisdiction as debts due to the State of Western Australia —

- 30 (a) amounts payable to the State of Western Australia under Part 5 Division 8;
- (b) fees payable to the State of Western Australia under this Act or the regulations;

- (c) amounts payable to the State of Western Australia in connection with the performance of the Regulator's functions under this Act or the regulations.

132. Purposes of Account

5 Note: Section 132 of the Commonwealth Act sets out the purposes for which money in the Account may be expended.

Division 4 — Staffing

133. Staff assisting the Regulator

10 Note: Section 133 of the Commonwealth Act provides for staff to be made available to assist the Regulator.

134. Consultants

Note: Section 134 of the Commonwealth Act enables the Regulator to engage consultants.

135. Seconded officers

15 Note: Section 135 of the Commonwealth Act provides for staff to be seconded to the Regulator.

Division 5 — Reporting requirements

136. Annual report

20 (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 under this Act and the regulations during that year.

25 (2) The Minister must cause a copy of the report to be laid before each House of Parliament within 15 sitting days of that House after the Minister receives the report.

Note: Section 136(3) of the Commonwealth Act requires the Regulator to give a copy of his or her report under that section to each State.

136A. Quarterly reports

5 (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 under this Act and the regulations 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;
- 10 (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.

15 (3) The Minister must cause a copy of the report to be laid before each House of the Parliament within 15 sitting days of that House after the Minister receives the report.

(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.

20 **137. Reports to Parliament**

(1) The Regulator may at any time cause a report about matters relating to the Regulator’s functions under this Act or the regulations to be laid before each House of Parliament.

(2) The Regulator must give a copy of the report to the Minister.

25 Note: Section 137(2) of the Commonwealth Act requires the Regulator to give a copy of his or her report under that section to each State.

Division 6 — Record of GMO and GM product dealings

138. Record of GMO and GM product dealings

- 5 (1) 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;
 - 10 (d) any licence conditions;
 - (e) the date on which the licence was issued, and its expiry date (if any).
- 15 (2) 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.
- 20 (3) 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 any Act.
- (4) The Record must also contain —
- 25 (a) a description of each dealing on the GMO Register; and
 - (b) any condition to which the dealing is subject.
- (5) The Regulator must ensure that information mentioned in subsection (1), (2), (3) or (4) is entered on the Record as soon as reasonably practicable.

(6) In this section —

“designated notification” means a notification required to be given to the Regulator under an Act or any law applying as a law of the State of Western Australia by force of an Act.

5 Note: This section differs from section 138 of the Commonwealth Act.

139. Inspection of Record

Note: Section 139 of the Commonwealth Act requires the Regulator to permit any person to inspect the Record.

**Division 7 — Reviews of notifiable low risk dealings
and exemptions**

10

140. Regulator may review notifiable low risk dealings

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

- 15
- (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 —

- 20
- (a) the matters of which the Regulator must be satisfied under section 74(2); or
 - (b) the matters the Regulator must consider under section 74(3).

141. Regulator may review exemptions

25 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 section 32 should not be an exempt dealing;
- (b) whether a dealing should be an exempt dealing within the meaning of that section.

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 —
- 5 (a) specify the matters to which submissions are to relate; and
- (b) specify the closing date for submissions, which must not be earlier than 30 days after the date on which the notice was published.
- 10 (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;
- 15 and
- (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.

20 **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 section 74(2);
- 25 (c) the Regulator has considered the matters mentioned in section 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; and

5

(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 recommend to the Ministerial Council that the regulations be amended accordingly.

(3) If the matter relates to whether a dealing —

10

(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

15

Nothing in this Division requires the Regulator to consider a matter under section 140 or 141.

Part 10 — Enforcement

145. Simplified outline

In outline this Part —

- 5 • 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; and
 - (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;
- 10 • empowers the Supreme Court to issue injunctions, and contains a forfeiture provision.

Note: This section differs from section 145 of the Commonwealth Act.

146. Regulator may give directions

- 15 (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; and
 - (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,
- 20 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.
- 25 (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; and

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- (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,

5 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.

- 10 (3) A person must take the steps specified in a notice under subsection (1) or (2) within the time specified in the notice.

Penalty:

- (a) in the case of an aggravated offence — \$220 000;
(b) in any other case — \$55 000.

Note: Section 38 defines “aggravated offence”.

- 15 (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.

- 20 (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 State of Western Australia an amount equal to the cost, and the amount may be recovered by the State as a debt due to the State in a court of competent jurisdiction.

- 25 (6) A time specified in a notice under subsection (1) or (2) must be reasonable having regard to the circumstances.

Note: This section differs from section 146 of the Commonwealth Act.

147. Injunctions

- 30 (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 Supreme Court (“**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 —

- 5 (a) a person has refused or failed, is refusing or failing, or is
about to refuse or fail, to do a thing; and
(b) the refusal or failure is, or would be, an offence against
this Act or the regulations,

10 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 —

- 15 (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; and
(b) whether or not the person has previously engaged in
conduct of that kind.

20 (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.

25 Note: Section 147 of the Commonwealth Act confers a similar power to grant
injunctions on the Federal Court of Australia.

148. Forfeiture

- 30 (1) If a court finds a person guilty of an offence against this Act or
the regulations, the court may order forfeiture to the State of
Western Australia of any thing used or otherwise involved in
the commission of the offence.

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- (2) A thing ordered by a court to be forfeited under this section becomes the property of the State of Western Australia and may be sold or otherwise dealt with in accordance with the directions of the Regulator.
- 5 (3) Until the Regulator gives a direction, the thing must be kept in such custody as the Regulator directs.

Note: This section differs from section 148 of the Commonwealth Act.

Part 11 — Powers of inspection

Division 1 — Simplified outline

149. Simplified outline

In outline this Part —

- 5 • provides for powers of inspection in relation to monitoring and offences;
- provides for the appointment of inspectors (see Division 2);
- 10 • deals with the powers and obligations of inspectors and the rights and responsibilities of an occupier of premises when an inspector seeks to exercise powers (see Divisions 3 to 9);
- sets out procedures relating to monitoring warrants and offence-related warrants (see Division 10);
- 15 • 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

- 20 (1) The Regulator may, by instrument in writing, appoint any of the following persons as inspectors —
 - (a) any employee or class of employee employed under Part 3 of the *Public Sector Management Act 1994*; or
 - 25 (b) a person who is appointed or employed by the Commonwealth.

- (2) In exercising powers or performing functions as an inspector, an inspector must comply with any directions of the Regulator.

Note: This section differs from section 150 of the Commonwealth Act.

151. Identity card

- 5 (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; and
- (b) must contain a recent photograph of the inspector.
- 10 (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.
- Penalty: \$110.
- (4) An inspector must carry his or her identity card at all times when exercising powers or performing functions as an inspector.
- 15

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 —
- 20 (a) enter any premises; and
- (b) exercise the monitoring powers set out in section 153.
- (2) An inspector is not authorised to enter premises under subsection (1) unless —
- 25 (a) the occupier of the premises has consented to the entry;
- (b) the entry is made under a warrant under section 172; or
- (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 section 152(1)(b) are as follows —
- (a) to search the premises and any thing on the premises;
 - 5 (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;
 - 10 (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
 - 15 (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;
 - 20 (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 —
 - 25 (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
 - 30 (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; or
 - (b) a disk, tape or other storage device that —
 - (i) is at the premises; and
 - (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 this 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; or
 - (b) if the information can be transferred to a tape, disk or other storage device that —
 - (i) is brought to the premises; or
 - (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; and
- (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; and
- (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 section 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

- 5 (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 —
- 10 (a) seize the equipment and any disk, tape or other associated device;
- (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
- 15 (c) if the material can be transferred to a disk, tape or other storage device that —
- (i) is brought to the premises; or
- (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.
- 25 (3) An inspector may seize equipment under subsection (2)(a) only if —
- (a) it is not practicable to put the material in documentary form as mentioned in subsection (2)(b) or to copy the material as mentioned in subsection (2)(c); or
- 30 (b) possession by the occupier of the equipment could constitute an offence.

- (4) An inspector may seize equipment under subsection (2)(a) or documents under subsection (2)(b) only if the inspector entered the premises under a warrant.

Division 5 — Expert assistance

5 **157. Expert assistance to operate a thing**

- (1) If an inspector believes on reasonable grounds that —
- 10 (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; and
- (c) if the inspector does not take action under this subsection, the information or material may be destroyed, altered or otherwise interfered with,
- 15 the inspector 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.
- 20 (3) The thing may be secured —
- (a) for a period not exceeding 24 hours; or
- (b) until the equipment has been operated by the expert, whichever happens first.
- (4) If the inspector believes on reasonable grounds that the expert
- 25 assistance will not be available within 24 hours, the inspector may apply to a magistrate for an extension of that period.
- (5) The inspector must give notice to the occupier of the premises of the inspector's 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 —
- 5 (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 has not been complied with; and
- 10 (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 —
- 15 (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;
- 20 (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 that the inspector considers necessary for the person to comply with this Act or the regulations;
- 25 (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.
- 30 (4) If the Regulator incurs costs because of steps reasonably taken or arranged to be taken by an inspector under subsection (2)(e),

the person is liable to pay to the State of Western Australia an amount equal to the cost, and the amount may be recovered by the State as a debt due to the State in a court of competent jurisdiction.

5 **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 —

- 10 (a) the occupier of the premises has required the inspector to produce his or her identity card for inspection by the occupier; and
- (b) the inspector fails to comply with the requirement.

160. Consent

- 15 (1) Before obtaining the consent of a person for the purposes of section 152(2)(a) or 154(2)(a), the inspector must inform the person that the person 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 etc.

- 20 (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.
- 25 (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 the inspector is authorised to enter the premises; and
 - 5 (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 the inspector believes on reasonable grounds that immediate entry to the premises is required —
- 10 (a) to ensure the safety of a person;
 - (b) to prevent serious damage to the environment; or
 - (c) to ensure that the effective execution of the warrant is not frustrated.

163. Compensation for damage

- 15 (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; and
 - (b) the damage was caused as a result of —
- 20 (i) insufficient care being exercised in selecting the person who was to operate the thing; or
 - (ii) insufficient care being exercised by the person operating the thing.
- (2) Compensation is payable by the Regulator.
- 25 (3) In determining the amount of compensation payable, regard is to be had to whether the occupier of the premises and their 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.

30 Note: Section 163(2) of the Commonwealth Act provides for compensation to be payable out of money appropriated by Parliament.

Division 8 — Power to search goods, baggage etc.

164. Power to search goods, baggage etc.

- 5 (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 place outside Western Australia and a place in Western Australia.
- (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 —
- 10 (a) examine the goods;
- (b) if the goods are baggage — open and search the baggage; or
- (c) if the goods are in a container — open and search the container.
- 15 (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 a person under subsection (3).
- 20

Penalty: \$3 300.

Note: This section differs from section 164 of the Commonwealth Act.

165. Seizure of goods

25 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 —

- 5 (a) a document, film, computer file or other thing that can be readily copied; or
- (b) a storage device, the information on which can be readily copied,

10 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 —

- 15 (a) the thing that has been seized was seized under section 156(2)(b) or (c); or
- (b) possession by the occupier of the document, film, computer file, thing or information could constitute an offence.

20 **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.

25 (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; or
- (b) the period of 60 days after its seizure ends,

whichever first occurs, unless the thing is forfeited or forfeitable to the State of Western Australia.

- (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; or
- (d) an inspector is otherwise authorised (by a law, or an order of a court, of the State of Western Australia or the Commonwealth) 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

- 5 (1) An inspector may apply to a magistrate for an order that the inspector may retain the thing for a further period if —
- (a) before the end of 60 days after the seizure; or
 - (b) before the end of a period previously specified in an order by a magistrate under this section,
- 10 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 —
- 15 (a) for the purposes of an investigation as to whether an offence against this Act or the regulations has been committed; or
 - (b) to enable evidence of an offence against this Act or the regulations to be secured for the purposes of a prosecution,
- 20 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 —
- 25 (a) take reasonable steps to discover who has an interest in the retention of the thing; and
 - (b) if it is practicable to do so, notify each person whom the inspector believes to have such an interest of the proposed application.

Note: This section differs from section 170 of the Commonwealth Act.

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

If —

- (a) a thing is seized under this Part;
 - 5 (b) apart from this section, the State of Western Australia is required to return the thing to the owner; and
 - (c) there is no owner or the Regulator cannot, despite making reasonable efforts, locate the owner,
- 10 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.
- 15 (2) Subject to subsection (3), the magistrate may issue the warrant if the magistrate is satisfied, by evidence 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.
- 20 (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.
- 25 (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; and

- (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; and
- (d) state the purpose for which the warrant is issued.
- 10 **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 evidence on oath, that there are reasonable grounds for suspecting that there is, or there may be within the next 72 hours, evidential material in or on the premises.
- (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;
- (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 sections 154(3) and 155; and
- (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;
- 5 (d) specify the day (not more than one week after the issue of the warrant) on which the warrant ceases to have effect; and
- (e) state the purpose for which the warrant is issued.

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

- 10 (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.
- 15 (3) Before applying for the warrant, the inspector must prepare an affidavit 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 affidavit is sworn.
- 20 (5) If the magistrate is satisfied —
 - (a) after having considered the terms of the affidavit; and
 - (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,
- 25 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;
 - 5 (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; and
 - 10 (iv) record on the warrant the reasons for issuing the warrant;
 - and
 - (b) the inspector must —
 - 15 (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
 - 20 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 —
- 25 (a) the form of warrant completed by the inspector; and
 - (b) the affidavit referred to in subsection (3) which must have been duly sworn.
- (8) When the magistrate receives those documents, the magistrate must —
- 30 (a) attach them to the warrant that the magistrate completed and signed; and

- (b) deal with them in the way in which the magistrate would have dealt with the affidavit if the application had been made under section 173.
- 5 (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 —
- 10 (a) it is material, in any proceedings, for a court to be satisfied that an exercise of a power was authorised by this section; and
- (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.
- 15 (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

- 20 (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.
- Penalty: Imprisonment for 2 years or \$13 200.
- (2) An inspector must not —
- 25 (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;

- 5
- (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; or
- (ii) departs in a material particular from the terms authorised by a magistrate under that section;
- or
- 10 (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.

Penalty: Imprisonment for 2 years or \$13 200.

Division 11 — Other matters

- 15 **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 the person or make the person liable to a penalty.
- 20 **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

5 In outline this Part provides for miscellaneous matters,
including the following —

- review of decisions;
- provisions relating to confidential commercial information;
- the making of regulations;
- 10 • transitional provisions;
- review of the operation of the Act.

Division 2 — Review of decisions

179. Meaning of terms

15 The following Table sets out —

- (a) decisions that are “**reviewable decisions**”; and
- (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

Item	Decision	Provision under which decision made	Eligible person in relation to decision
6	To specify a condition of 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 —
- 5 (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.

5 **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.

10 (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.

15 (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; and

20 (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;

25 (b) the period is specified under this Act or the regulations for giving notice of the decision to the applicant; and

(c) the Regulator has not notified the applicant of the Regulator's decision within that period,

30 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* of the Commonwealth, an application may be made by an eligible person in relation to —

- 5 (a) a reviewable decision made by the Regulator personally;
or
(b) a decision made by the Regulator under section 181 (which provides for internal review).

(2) In this section —

10 **“decision”** has the same meaning as in the *Administrative Appeals Tribunal Act 1975* of the Commonwealth.

183A. Extended standing for judicial review

15 Note: Section 183A of the Commonwealth Act requires that a State be taken to be a person aggrieved for the purpose of the application of the *Administrative Decisions (Judicial Review) Act 1977* of the Commonwealth in relation to certain decisions, failures or conduct under the Commonwealth Act or regulations.

Division 3 — Confidential commercial information

20 **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.
- 25

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 —

- 30 (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; or
- 5 (c) other information that —
- (i) concerns the lawful commercial or financial affairs of a person, organisation or undertaking; and
- (ii) if it were disclosed, could unreasonably affect
- 10 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
- 15 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
- 20 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.
- 25 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
- 30 Regulator's decision about the application.
- (3A) If —
- (a) the Regulator declares that particular information is confidential commercial information; and

- (b) the information relates to one or more locations at which field trials involving GMOs are occurring, or are proposed to occur,

5 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);
- 10 (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; and
- (e) the reasons why the Regulator was satisfied under 15 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 section 184(1) in relation to information, the information is to be treated as 20 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, 25 revoke a declaration under section 185 if the Regulator is satisfied —

- (a) that the information concerned no longer satisfies section 185(1)(a), (b) or (c); or
- 30 (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

- 5 (1) A person who —
- (a) has confidential commercial information;
 - (b) has it only because of performing duties or functions under this Act or the regulations or under the Commonwealth Act or a corresponding State law within
10 the meaning of the Commonwealth Act; and
 - (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
15 duties or functions under this Act or the regulations or under the Commonwealth Act or a corresponding State law within the meaning of the Commonwealth Act —
 - (i) a State agency;
 - (ii) the Commonwealth or a Commonwealth
20 authority;
 - (iii) the Gene Technology Technical Advisory Committee;
 - (e) by order of a court; or
 - (f) with the consent of the person who applied to have the
25 information treated as confidential commercial information.

Penalty: Imprisonment for 2 years or \$13 200.

- (2) A person who —
- (a) has confidential commercial information;

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- (b) has it because of a disclosure under subsection (1) or this subsection; and
- (c) knows that the information is confidential commercial information,

5 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 the regulations or under the Commonwealth Act or a corresponding State law within the meaning of the Commonwealth Act —

- 10 (i) a State agency;
- (ii) the Commonwealth or a Commonwealth authority;
- (iii) the Gene Technology Technical Advisory Committee;

15 (e) by order of the court; or

- (f) with the consent of the person who applied to have the information treated as confidential commercial information.

Penalty: Imprisonment for 2 years or \$13 200.

20 Note: See also Schedule 1 item 14(4) of the *Freedom of Information Act 1992*.

(3) In this section —

25 “**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.

Note: This section differs from section 187 of the Commonwealth Act.

Division 4 — Conduct by directors, employees and agents

188. Conduct by directors, employees and agents

- 5 (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 —
- 10 (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; and
- (b) that the director, employee or agent had the state of mind.
- 15 (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,
- 20 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.
- 25 (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 —
- 30 (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; and
- (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; or
- (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 section 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; and
- (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 State of Western Australia, the Commonwealth or another State.

- (3) A reference in section 188 to engaging in conduct includes a reference to failing or a 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, or that may be dealt with and punished under an ancillary criminal law within the meaning of section 192E 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; and
- (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; and
- (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) providing correct information to that person, if the person producing the document is in possession of, or can reasonably acquire, the correct information.

5 Penalty: Imprisonment for one year or \$6 600.

192A. Interference with dealings with GMOs

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

(a) the person engages in conduct; and

(b) the conduct —

10 (i) results in damage to, destruction of, or interference with, premises at which dealings with GMOs are being undertaken; or

 (ii) involves damaging, destroying, or interfering with, a thing at, or removing a thing from, such premises;

15 (c) the owner or occupier of the premises, or the owner of the thing (as the case requires), has not consented to the conduct;

20 (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; and

(e) the person knows, or is reckless as to, the matters mentioned in paragraphs (b) and (c).

Penalty: Imprisonment for 2 years or \$13 200.

25 (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 —

30 (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; or
- (d) that are included on the GMO Register.

Note: This section differs from section 192A of the Commonwealth Act.

192B. Cloning of human beings is prohibited

5 Note 1: Section 192B of the Commonwealth Act prohibits the cloning of whole human beings.

Note 2: Section 7 of the *Human Reproductive Technology Act 1991* prohibits procedures directed at human cloning.

192C. Certain experiments involving animal eggs prohibited

10 Note 1: Section 192C of the Commonwealth Act prohibits experiments or research involving putting human cells, or a combination of human cells and animals cells, into animal eggs.

Note 2: Section 7 of the *Human Reproductive Technology Act 1991* prohibits procedures directed at the production of a chimaera etc.

15 **192D. Certain experiments involving putting human and animal cells into a human uterus prohibited**

Note 1: Section 192D of the Commonwealth Act prohibits experiments or research involving putting a combination of human cells, or a combination of human cells and animal cells, into a human uterus.

20 Note 2: Section 7 of the *Human Reproductive Technology Act 1991* prohibits the placing of animal eggs or embryos in the body of a woman.

192E. Ancillary offences (parties to offences, attempts, incitement or conspiracy)

(1) In this section —

25 “**ancillary criminal laws**” means section 4, Chapters II, LVII and LVIII and section 562 of *The Criminal Code*.

(2) The ancillary criminal laws apply in relation to an offence against this Act or the regulations and —

30 (a) section 555A of *The Criminal Code* so applies as if the words “under this Code” in subsections (1) and (2) were deleted; and

(b) section 562 of *The Criminal Code* so applies as if the following subsection were inserted after subsection (2) —

“

5 (3) Any person who becomes an accessory after the fact to a simple offence is guilty of a simple offence and is liable to the penalty to which a person convicted of the first-mentioned offence is liable.

”.

10 (3) In this Act or the regulations, a reference to an offence against this Act or those regulations includes a reference to a related offence under the ancillary criminal laws.

Note: This section is not required in the Commonwealth Act.

193. Regulations: general

15 (1) The Governor may make regulations prescribing matters —
(a) required or permitted by this Act to be prescribed; or
(b) necessary or convenient to be prescribed for carrying out or giving effect to this Act.

20 (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

25 (1) The Minister must cause an independent review of the operation of this Act 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 Minister a written report of the review.

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(3) The Minister must cause a copy of the report of the review to be laid before each House of Parliament within 12 months after the fourth anniversary of the commencement of this Act.

(4) In this section —

5 **“independent review”** means a review undertaken by persons who —

(a) in the opinion of the Minister possess appropriate qualifications to undertake the review; and

10 (b) include one or more persons who are not employed by the State of Western Australia, a State agency, the Commonwealth or a Commonwealth authority.

Note: This section differs from section 194 of the Commonwealth Act.

Part 13 — Consequential amendments

195. *Agriculture and Related Resources Protection Act 1976* amended

5 After section 106A of the *Agriculture and Related Resources Protection Act 1976** the following section is inserted —

“

106B. Regulations — designated area

10 Without limiting the generality of section 103 the Governor may make regulations designating areas of the State for the purposes of section 21(1)(aa) of the *Gene Technology Act 2001* and section 21(1)(aa) of the *Gene Technology Act 2000* of the Commonwealth.

”.

[Reprinted as at 15 October 1999.

15 For subsequent amendments see 2000 Index to Legislation of Western Australia, Table 1, p. 13.]

196. *Agricultural and Veterinary Chemicals (Western Australia) Act 1995* amended

20 After section 23 of the *Agricultural and Veterinary Chemicals (Western Australia) Act 1995** the following section is inserted —

“

23A. Consultation with Gene Technology Regulator

25 (1) A duty imposed or a function or power conferred on the NRA under section 8A of the *Agricultural and Veterinary Chemicals (Administration) Act* in respect of any matter arising in relation to the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act* extends to any corresponding matter arising in relation to the applicable provisions of
30 this jurisdiction, and this section applies accordingly.

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- 5 (2) If the NRA gives the Regulator within the meaning of the *Gene Technology Act 2001* a notice under section 8A(3) of the Agricultural and Veterinary Chemicals (Administration) Act (as that section applies by force of subsection (1) of this section), the Regulator may give written advice to the NRA about the application, reconsideration or issue.
- 10 (3) The advice is to be given within the period specified in the notice.
- 15 (4) A reference in the Agvet Code of this jurisdiction to a provision of section 8A of the Agricultural and Veterinary Chemicals (Administration) Act has effect as if it were a reference in that provision as applying by force of subsection (1) of this section.

”.

[Act No. 3 of 1995.

For subsequent amendments see 2000 Index to Legislation of Western Australia, Table 1, p. 9.]

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